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Assessment in Physical Medicine and Rehabilitation

Views and Perspectives

Michel Barat
Franco Franchignoni
Editors

PI-ME Press

ADVANCES IN Rehabilitation

AGGIORNAMENTI IN MEDICINA RIABILITATIVA

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Views and Perspectives

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Advances in Rehabilitation

AGGIORNAMENTI IN MEDICINA RIABILITATIVA

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Académie Européenne de Médecine de Réadaptation

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ADVANCES IN REHABILITATION
AGGIORNAMENTI IN MEDICINA RIABILITATIVA
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ASSESSMENT IN PHYSICAL MEDICINE AND REHABILITATION
VIEWS AND PERSPECTIVES
Michel Barat, Franco Franchignoni
Editors

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PREFACE

It gives us great pleasure to write the preface to this book, the third in a series of monographs produced by members of the European Academy of Rehabilitation Medicine and the first published by the Foundation "Salvatore Maugeri". We have great pleasure in thanking the Foundation for its generous support.

Whilst it is increasingly accepted that rehabilitation is effective much remains to be done to enlarge the evidence base for practice. Evidence can be no better than the measurement tools used in its production. The whole process of rehabilitation rests on these and accurate assessments. Assessment is not easy; similarly measures may not be sufficiently sensitive for the proper evaluation of interventions, or they may not be robust enough for clinical practice. A decision often has to be made as to whether one should use a generic or a specific measure. We therefore need to be sure that established measures have good psychometric properties; where they do not – and only then – we need to produce new ones. Both are included in this text by authorities in their fields whose experience has been used in the selection of appropriate assessment schedules and methods. This accessible state of the art monograph will inform new research and practice; we anticipate that it will be useful to established practitioners as well as those in training and to the researchers who work with them.

The European Academy of Rehabilitation Medicine consists of senior doctors in the field, distinguished in their profession, noted for their major clinical and often, also, research contributions. They are doctors who are particularly concerned with the human dimension of the specialty and with doing all in their power, in terms mainly of teaching, ethics and research, to improve services for people with disabilities. The Academy meets regularly and discussion on contemporary matters is lively. It is currently supporting an annual training course for all European trainees, in the University of Marseille, as well as other courses. Believing that Rehabilitation is better understood and practised if there is access to the best information it has launched a series of monographs. Two books have already been published:

– La plasticité de la fonction motrice, ed. J.P. Didier. Springer, 2004.
– Vocational Rehabilitation, eds. C. Gobelet & F. Franchignoni. Springer, 2004.

and further are in preparation:

– Les fonctions des sphincters, eds. G. Amarenco & A. Chantraine. Springer, 2005.
– Cancer and Rehabilitation, ed. H. Delbrück. Springer, 2005.

We have no doubt that these will provide the most up to date evidence for practice and will find their place in University libraries as well as on the bookshelves of all persons interested in the problems they discuss.

M. Anne Chamberlain
President

Alex Chantraine
Hon. Secretary

Académie Européenne de Médecine de Réadaptation
/ European Academy of Rehabilitation Medicine

INTRODUCTION

Assessment is fundamental in medical sciences – as in any other science – by virtue of the need to replace an empirical approach to the sick person with a scientific methodology, and thereby improve the effectiveness of clinical practice. The validation of progress in all health fields is strictly linked to the accuracy of the assessment process. Rehabilitation Medicine needs to follow the same line, for its present and future standing and for its accountability as health service provider.

Further, Rehabilitation Medicine holds a distinctive place. It is a disciplinary crossroads which deals with many diseases and impairments and aims to alleviate the consequences of illness for the individual, minimizing disablement and improving the patient's ability to fulfil functions and obligations. In this view, assessment is often – as Wade states: *"the process whereby the health care professional (or team) collects and analyses data to identify the problems a patient has, to determine all factors relevant to the resolution of those difficulties, and to set goals for action"*. Thus, assessment in our discipline must rely on the tools of each medical discipline in question (orthopaedics, rheumatology, neurology...), but also on specific outcome measures analyzing the personal, psychological and social repercussions of health-related states (i.e. paying attention – according to the International Classification of Functioning, Disability and Health, ICF – not only to body functions and structures, and impairments, but also to activity and participation).

The assessment process has many targets. First of all it indicates a rigorous and objective analysis and a comparison within considerable homogeneous groups, so helping the clinical decision-making process. Then, standards for measurements and evaluation procedures improve evidence-based medicine and quality of practice, define shared working methods, unify professional perspectives, and enhance the rigour of research.

The quality of a measurement instrument is based on the quality of its development process. Confusion or inconsistency in conceptual models, theoretical assumptions or working definitions related to assessment procedures (due to poor methodology) generate questionable results leading to mistakes in interpretation and unsuitable extrapolations.

The wide number of assessment tools (rating scales and questionnaires) for a given medical situation often complicates judgements and choices, and hinders reliable comparisons. A critical starting point is to exactly define what is to be measured for what purpose (and at what cost). A number of papers present guidelines for the criteria that should be considered in selecting, using and evaluating assessment tools and out-

come measures. The most important issue is to evaluate the appropriateness of an instrument, i.e. how well its content matches the purposes and questions which the specific clinical trial is intended to address (objectives, patient population, intervention, etc). Furthermore, it is crucial to ascertain acceptable levels of reliability, validity and responsiveness for the aims of a particular trial, and it is increasingly recognized that some pragmatic issues have also to be considered, such as the acceptability of an instrument (respondent burden) and its ease of administering and processing (administrative burden). As a result, the users have to choose a specific measure on the basis of the structure, the properties required for the intended purpose, previous use of the measure in similar situations, and practicality (i.e. an appropriate balance between the detail and accuracy required, and the effort required for collecting data).

Whatever the reason behind the assessment (diagnostic/prognostic; legal/administrative; research, etc.), the assessment procedure should not overlook the basic clinical target which is the care and attention paid by all members of the therapeutic team to the individual person. Hence assessment cannot be reduced to a "score" of disability or handicap scales, but should always aim to improve the global clinical approach and therapeutic management. For this reason, the inclusion of patient perspectives (the so-called "patient-based measures", such as perceived health, quality of life, well-being, patient satisfaction, and so on) within the assessment framework is imperative. Taking into account the patient's opinion gives insights into individual perceptions of disease and treatment, and expectations, so capitalizing on patient's strengths in a positive manner.

This book is organized into ten chapters. In chapter 1, Van Djik presents a theoretical framework that might help us in the practice of rehabilitation to select relevant variables for measurement, and subsequently make interpretations of the measurement outcomes that are relevant for this practice. Chapter 2 deals with the principles and practice of measuring outcome in P&RM, including issues about: how do we identify appropriate outcomes? how do we judge the quality of an outcome measure? and how should we use such measures? Chapter 3 examines generic and specific measures for outcome assessment in the rehabilitation of orthopaedic and rheumatologic diseases, including health-related quality of life measures and utility measures, as well as disease-specific and region- or site-specific instruments. Chapter 4 and 5 are devoted to the assessment of rehabilitation of neurological diseases, and examine the consequences of spinal cord injury (chapter 4) and chronic disabilities of patients suffering from stroke, multiple sclerosis, severe traumatic brain injury, Parkinson's disease, and so on (chapter 5). The following two chapters describe the recent advances in neurophysiological basis of posture and gait (chapter 6), in order to introduce the issues related to the assessment of postural control and balance in ageing and neurological diseases (chapter 7), with sections illustrating clinical tests of balance, multi-item balance scales, fear of falling and fall-efficacy scales, and instrumentation

for kinetic and kinematic measures. The methodological issues of cognitive impairment are considered in chapter 8 that provides important cues for assessing cognition in brain-damaged adults. Chapter 9 examines the specific protocols for the evaluation of assistive technology devices in their particular context of use. The book's last chapter provides a detailed description of instruments for assessing mobility, in particular for long-term activity monitoring, an area of increasing interest in Rehabilitation Medicine in the light of the World Health Organisation ICF framework.

The list of contents for this book is not intended to be comprehensive. The field of outcome assessment in Physical and Rehabilitation Medicine is considerable and undergoing continual evolution. We have selected topics of pivotal interest that focus on paradigmatic themes. We hope that this book will be a valuable contribution to enable better understanding of the assessment process in Rehabilitation Medicine and its pivotal importance for clinical governance, audit, and research.

Michel Barat
Franco Franchignoni

A.J. VAN DIJK

CHAPTER 1
ASSESSMENT IN REHABILITATION: BUT WHICH CONCEPTUAL FRAMEWORK OF FUNCTIONING?

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1. WHY IS A CONCEPTUAL FRAMEWORK RELEVANT FOR ASSESSMENT?

Rehabilitation professionals focus on changes in people's daily living. They try to find out how disturbances of daily living come about, and to find ways to assist the people concerned in their efforts to restore daily living. Assessment in individual patient care is meant to help them to find these ways.

What is assessment? Wade (1) (p 16) describes *assessment* as the process of determining the meaning of the outcome of measurement. *Measurement* is the quantification of an observation by comparison with a standard. One could measure for example the *quality* or *strength* of a particular function. Assessment would then be determining the meaning of this quality or strength. This meaning could be expressed in terms of diagnosis, prognosis, indication for interventions or effect of interventions. In brief: measurement serves assessment, and assessment serves clinical decision-making.

The quality of measurement and hence assessment has *methodological* aspects:

– The measurement on which the assessment is based should meet certain methodological criteria in order to be

sufficiently *reliable*. With the term 'reliable' is meant how close successive measurements fall to each other.
– The measurement often reflects only a part of what the assessment applies to. The term 'valid' indicates how close, on average, the measurements represent what they are meant to represent. Measurement should be sufficiently *valid* in order to allow relevant assessment.

In the field of rehabilitation, the quality of assessment, i.e., the quality of statements about the meaning of an outcome, also has other, more *theoretical* aspects.
– To what extent can outcome of measurement of a situation be explained from intervention and to what extent from processes occurring without intervention? I.e., what is the outcome of measurement *attributed to*?
– What makes an outcome *desirable*? Does the desirability of an outcome also *justify* measures to reach this outcome? And can the justification itself be assessed?
– *What is functioning*? And what is it that functions, i.e., what is its *subject*?
– What is *individual experience*? What is the use of this concept? What is the meaning of its measurement? Is there a relation with desirable outcomes?
– How can we analyse *change in functioning*, reckoning with all these issues, and subsequently decide on intervention?

These questions reflect our desire to know how things work. We want to know how things work as it helps us in assisting people. To put it differently, a theoretical framework might help us in the practice of rehabilitation to select relevant variables for measurement, and subsequently make interpretations of the measurement outcomes that are relevant for this practice.

In this chapter I propose such a framework. To that effect, I start with conceptual issues in section 2, such as the meaning of the term 'rehabilitation', the role of adaptation, the nature of justification of rehabilitation measures, and assumptions regarding functioning and individual experience. In section 3 I elaborate on this framework using these conceptual issues. In section 4 I suggest ways to analyse change in functioning, individual experience and adaptation that are based on this framework.

2. CONCEPTUAL ISSUES

2.1 What is the meaning of the term 'rehabilitation'?

Consider this example:

A polio infection at the age of 6 resulting in irreversible neurological damage left Mr M with deformities of the left leg. In the past, treatment was provided to prevent contractures, but was only partially effective. The hip shows limited extension, with slight over-extension of the knee in standing and walking, and the foot shows fixed equinovarus position. He has since achieved to walk fast and safe though being asymmetrical. The skin tissue of the lateral side of his foot has changed considerably being exposed to weight bearing. Though the walking is fast and safe, he is not good at sports. He chose different ways of leisure activities. He earns a living as a car mechanic.

What made Mr M achieve fast and safe walking? What made his skin change? What made him choose certain leisure activities? Walking and skin have both changed for the better, but have never been object of intervention. Would training with professional help have made a difference? Can we differentiate *recovery without intervention* from the *effects of interventions*? And is it self-evident to reserve the term 'rehabilitation' for intervention only? I attempt to answer these questions, by exploring the meaning of the term 'rehabilitation'.

2.1.1 TWO CONNOTATIONS: PROCESS OF ADAPTATION AND ASSISTANCE TOWARDS THAT PROCESS

The meaning of the term 'rehabilitation' has been subject of discussion for many decades. Bloom (2) (p 114) summarises the range of conceptions as follows:

> Rehabilitation has been conceived of as what is *done* to bring about the patient's recovery, as the *process* by which the patient recovers, as the *goal of services* rendered (the recovery of the patient) and as *one phase* of the treatment given.

Assuming that what is *done* to a patient is intrinsically accompanied by *goal* and *phases*, I reduce the number of conceptions to two, namely *process* and *assistance towards that process*. Below I work out these two conceptions.

Rehabilitation *as a process* can be associated with *getting better*, either in the eyes of the patient or in the eyes of the professional or both. Several processes can be distinguished within a person, such as tissue changes, recovery of skills, accepting a loss, using cognitive strategies, and finding again meaningful activities. Such processes could be referred to as *adaptation*. Insight in such processes by professionals is relevant for estimating prognosis, and prognosis is relevant for deciding on interventions.

Rehabilitation *as assistance towards the process*, i.e., that what is done to bring about the patient's recovery, can be associated with *making better*. It is represented by actions from outside the person concerned. I take the *target group* to consist of people with disturbed or lost functioning or the risk thereof, in association with disease, physical trauma, congenital disorder, somatoform disorder and ageing (3) (p 65-68).

Rivière (4) gives a definition of rehabilitation (p 2) that contains both connotations:

> Rehabilitation is both the concept of a disabled or handicapped individual's optimal achievement of his potential for self-realisation and his assistance therein by the community through organised services directed towards that end.

The 'achievement of potential for self-realisation' reflects the *process*, and 'organised services' reflect *assistance towards that process*. In the description by Fugl-Meyer and others (5) the conception of rehabilitation as a process is implied in 'to mobilise the resources':

> The aim of rehabilitation [is] to mobilise the resources of individuals with impairment(s) so that, by having realistic goals, they may achieve optimal life satisfaction.

In the following sections I elaborate the connotation of process of adaptation.

2.1.2 Rehabilitation as a process of adaptation

What are the 'resources' that are mobilised in the process of rehabilitation? Rivière (4) (p 72) refers to 'rehabilitation potential' and states:

> The definition of rehabilitation potential . . . is the interplay of all the assets and liabilities . . . and their implications for an individual's total adjustment to impairment, disability, and handicap, and the demands of his living environment, towards the achievement of his fullest development and use of his assets.

This implies that rehabilitation itself can be considered a *process of an individual's total adjustment*. What is the nature of this adjustment? In the *medical* world, the term 'getting better' is usually associated with recovery of an individual from disease or injury. In *rehabilitation* the term 'getting better' is usually associated with *functional* recovery. This not necessarily implies repair of tissue or organs but rather a more effective and/or efficient use of capacities, i.e., personal resources. Also *psychological* adjustment can be associated with 'getting better'. But this distinction between medical, functional and psychological is somewhat artificial.

Let us take a closer look at adaptation. Adaptation is conceived of as the individual's response to changes both inside and outside the body (6) (p 6). This conception implies that the individual is considered an 'open system' in interaction with its environment (7) (p 15). The term 'open system' implies a body of theory that explains the concept of adaptation. What sort of adaptation processes can we distinguish?

Kidd (8) (p 57), in explaining 'return of control', brings together the concept of adaptation and the concept of damage, when he states:

> . . . the neuromuscular system develops and changes due to the activity of the individual and in order to adapt to the environment. Once it has reached maturity it does not become static but continues to change in response to the environment and its own induced activity, particularly after damage.

Is recovery from damage very different from adaptation? Tissue *healing* may not in itself represent a clear response to challenge. However, the *quality* of healing of tissue certainly is, e.g., by load or endurance. But also without damage, tissue adapts to changes in its environment. For example heart muscle, skeletal muscle, bones, ligaments, or blood vessels adapt to what is 'requested' from them. Their function changes, mediated by changes in structure, in response to the forces and strains applied to them on the one hand, and according to their intrinsic characteristics on the other. The process Kidd refers to regards *systems* of organs. And changes in neuromuscular or psyschoneurophysiological systems are associated with learning. Learning can designate a largely unconscious process, but it can also be a deliberate attempt to change one's repertoire of behaviour.

Tentatively, for the purpose of clarifying the idea of adaptation, I distinguish four levels of adaptation: *intrinsic recovery*: repair at the level of cells and tissues; *intrinsic adaptation*: adaptation of tissues, organs and or-

gan systems; *implicit learning*: unconscious learning by an organism, and *explicit learning*: deliberate choices of an individual. Table 1 summarises these four levels.

TABLE 1. Four terms to indicate different levels of adaptation.

Different levels of adaptation	Description
Intrinsic recovery: (cells and tissues)	Repair of tissue structure and of potential tissue function, after damage.
Intrinsic adaptation: (tissues, organs & system of organs)	Change in function of tissue, organ or system of organs based on intrinsic characteristics of the tissues, organs or system of organs, in response to changes in the internal environment
Implicit learning: (organism)	A usually automatic and unconscious process of reinforcement of behaviour of the organism based on intrinsic characteristics of the organism, in response to changes in the external environment
Explicit learning: (person)	A usually voluntary and conscious process of change of behaviour of the person based on characteristics of that person, in response to changes in the external environment, in order to change oneself or the environment

In the example of Mr M, *intrinsic recovery* applies to the repair of tissues in the nervous system after his disease. It involves cellular processes. *Intrinsic adaptation* applies to the process of change in the nervous system and to the process of change in the skin of the foot. *Implicit learning* applies to the automatic learning to walk in a different way. *Explicit learning* applies to, for example, his way of deciding how to earn a living.

Why so much emphasis on adaptation? This is because adaptation, being (part of) a process of getting better (i.e. without assistance), determines prognosis. Prognosis in its turn determines the need for intervention. That makes adaptation a core concept in clinical decision-making in the field of rehabilitation.

But what is the *desirable situation* that is associated with adaptation? In the next section, I explore this issue.

2.2 Health, and justification for rehabilitation measures

Fuhrer (9) states:

> In attempting to specify the desired outcomes of rehabilitation practice, we are considering the very justification for this form of human services.

But people may have very different ideas about the desired outcome of rehabilitation services (3). In a pre-arranged discussion between Fugl-Meyer from Sweden and Hai from Vietnam, Fugl-Meyer stated that the aim of rehabilitation is to mobilise the resources of individuals so that they may achieve optimal life satisfaction (10). Hai defended that the aim of rehabilitation for adults is to create income, and for children to receive schooling (11). Would such different aims as life satisfaction and income

generation represent two different justifications? Or could there be one justification in the sense of a unifying concept, within which two different desired outcomes (two aims) would make sense?

I argue that the two different ultimate aims of rehabilitation can be reconciled with the concept of health as described by Whitbeck (12) (p 617). She states:

> Health is the capacity for a high level of integrated psychophysiological functioning, which enables the agent to act or respond to situations in a way that promotes the agent's projects and goals (and that promotes the availability of a wide range of responses in the future).

The psychophysiological capacity to act or respond can be equated with adaptation potential. She further states (12) (p 616) that health connotes wholeness of the person. This sense of wholeness of a person implies

> … the ability to engage in distinctively human activities.

To assess people's health, one must therefore take into account their *abilities to engage in such activities*. These abilities are based not only on the people's biological capacities such as the function of a system of organs, organs or cells (12) (p 616). They are also based on whether such abilities and capacities are exercised in ways that serve the interests of the person concerned. In other words, for assessing a person's abilities to engage in human activities, one needs insight in not only recovery of tissue and adaptation of tissue and organs, but also in learning capacities and in processes such as making choices.

Rehabilitation as a process reflects a person's effort to regain this capacity for integrated psychophysiological functioning. If this effort is successful, health might be regained (health in Whitbeck's interpretation). If not or only insufficiently so, assistance could be of use. To achieve health in this sense could therefore be considered a *justification for rehabilitation as assistance*.

This view implies that, in the rehabilitation practice, analysis of not only functioning but also adaptation is relevant (13). In section 2.3, I elaborate some conceptual issues regarding functioning and adaptation. In section 3, I propose an operationalisation of these concepts, and in section 4 I illustrate how this operationalisation can be used for explaining change in functioning, individual experience and adaptation.

2.3 Assumptions regarding functioning

Keith (14) (p 263) considers the functional orientation in rehabilitation basic to an understanding of aims, processes and outcomes. But he signals that the meaning of the term 'functional' is vague. He states that:

> . . . emphasis [on functional orientation] is a defining characteristic of the field of rehabilitation. Restoration of function has been contrasted with the medical model, which has the aim of alleviating disease and injury (Granger 1984). Even though function is a fundamental concept in rehabilitation, it is a remarkably elusive term. When referring to physical, emotional, or social functioning, it includes most of life's activities.

Why is functioning such an elusive term? I think that is because the term 'functioning' is essentially empty, unless a syntactic subject is speci-

fied. This subject in its turn could specify the nature of 'functioning' if this subject is a system with an *intrinsic* way of functioning. In rehabilitation not all systems of functioning (e.g., "the shoulder") indicate an intrinsic way of functioning.

For assessment of functioning it is important to know what we mean with the term. Therefore, in the subsections below, I attempt to specify functioning in terms of *interaction, subject* and *purpose*, in terms of *systems* and *hierarchy*, and in terms of *individual experience* and *adaptation*.

2.3.1 FUNCTIONING: INTERACTION, SUBJECT AND PURPOSE

Functioning is a particular type of interaction. It is interaction by a specified *subject* with its *environment*, geared towards a *particular purpose*.

Interaction implies relations between two or more systems (Figure 1A). Interaction is a fairly abstract concept. Yet function and functioning are considered a concrete thing in the field of rehabilitation. Indeed, functioning is regarded as *an object in itself*. This is represented (Figure 1B) by reciprocal influence between functioning on the one hand and person and environment on the other.

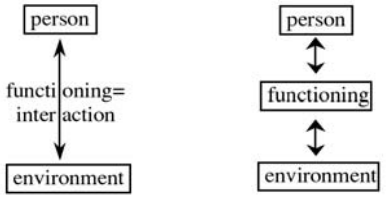


FIGURE 1A *FIGURE 1B*

FIGURE 1. Representation of functioning. Figure 1A represents functioning as interaction between a person and his environment. The two-pointed arrow represents the interaction. Figure 1B represents functioning as a phenomenon in itself, influenced by characteristics of the person and the environment. Reciprocal influence between person and environment is through functioning.

The term 'interaction' suggests symmetry between the factor *person* and the factor *environment*. The term 'functioning' however implies *asymmetry* as the term applies to a *subject*, a *bearer* of the function, i.e., the person and not the environment.

The notion of 'interaction' is essential for assessment. An example: analysis of gait implies a role of *reaction forces*. Gait cannot be implemented without a surface to walk on, and itself is clearly influenced by the type of surface (= environment).

In the next section I propose a more detailed notion of subject and purpose, by referring to *systems* of functioning, and to a *hierarchy of systems*.

2.3.2 FUNCTIONING: SYSTEMS AND HIERARCHY

How could we specify the syntactic subject of the verb 'to function'? For example, what part of the body shows a *body function*? And what is

the subject that shows an *activity*? And which characteristics go with a person functioning *over time*?

I consider all things that function to be 'systems'. Some systems have an *intrinsic* way of functioning, i.e., their own way of interaction with their environment. The interaction may change in a predictable way if the characteristics of the person or the environment change. But as I noted before, in the field of rehabilitation not all identified systems have an intrinsic way of functioning.

What are systems? Brody (15) described a hierarchical organisation of natural systems: subatomic particles – atoms – molecules – cells – tissues – organs – systems [of organs] – person – family – community – subculture – culture – society – homo sapiens – biosphere. There are some essential properties of systems. The relevant one in this context is that natural systems maintain themselves in a changing environment.

Wilkerson and Johnston (16) refer to Wilkerson who distinguishes levels of functioning using a hierarchy of complexity (17(cited in 16)):

> A complementary way of conceiving rehabilitation outcomes is in terms of a hierarchy or levels of functions (Wilkerson, 1992) – micro, meso, and macro – in which the basic building block functions must be assembled to achieve higher-order function. Micro-level functions (e.g., endurance, range of motion, strength) are packaged into meso-level functions (e.g., dressing, communicating, ambulation), and those in turn into macro-level functions (e.g., homemaking, working, leisure activity) …

The difference between Brody and Wilkerson e.a. is that some of the functions of Wilkerson, e.g., range of motion, do not reflect an intrinsic or characteristic way of functioning. Take "the shoulder" again. If the term 'functioning' refers to the different joints of the shoulder girdle, then "the shoulder" does not function intrinsically, but *is driven* by other systems. In the field of rehabilitation it may therefore be useful to make a distinction between a *structural* system and a *dynamic* system. Both types of system function, but the first type of system functions by 'being driven', and the second type functions as an intrinsic process. Change in functioning can probably be better predicted if the system at hand is functioning as an intrinsic process.

From Brody's hierarchy, the systems from "cells" up to and including "person" seem relevant in rehabilitation. Why not systems higher than "person"? Because, in terms of functioning, a family or a community constitutes *environment* for a particular person. A family or a community could itself be the *subject* of functioning in a different context, e.g., in family therapy.

What is the use of such a hierarchy in the practice of rehabilitation? The hierarchy implies that lower-level systems are part of higher-level systems, and could be considered *conditions* for these higher-level systems. Higher-level systems consist of lower-level systems, and could be considered a *purpose* for lower-level systems. This notion of condition and purpose is useful for explaining changes in functioning, but also for understanding of individual experience and adaptation. In the next section, I propose assumptions regarding individual experience and adaptation that are based on these assumptions.

2.3.3 FUNCTIONING: INDIVIDUAL EXPERIENCE AND ADAPTATION

Why is *individual experience* relevant in rehabilitation? By taking individual experience into account, rehabilitation professionals respect a person's autonomy. Furthermore, individual experience may help understand what a person regards important, significant or of value. Finally, and most relevant for my argument, individual experience has explanatory power as regards adaptation.

In order to operationalise individual experience, I equate individual experience with appraisal of (change in) functioning. Lazarus considers appraisal the evaluation of the *significance* of what is happening in the person-environment relationship for personal well-being (18).

How could appraisal be measured? And how could the meaning of this outcome be determined? Measuring appraisal would require a standard. What could be a standard for appraisal? In other words, what could be a standard for the evaluation of the significance of functioning or rather the significance of *change* in functioning? If a hierarchy of functioning is assumed, then the significance of a particular functioning is its contribution to achieving a *higher-order* functioning. This implies that the standard is that level of goodness that enables the actual achievement of this higher-order functioning.

Adaptation is a term that in its turn specifies *functioning* by adding the connotation of the particular purpose of *maintaining integrity*, or *getting better*. As regards adaptation in the field of rehabilitation, there is a paradox. One would expect that a change for the worse in daily living would lead to a negative appraisal of daily living, as the person concerned can no longer achieve what he or she aspires. Michalos (19) refers to this as the aspiration-achievement gap. However, studies have shown that even an irreversible change of functioning does not necessarily lead to an infinite negative appraisal (20). How can an aspiration-achievement gap in a situation of irreversible loss of functioning, be reconciled with negative appraisal turning positive again? And if this 'turning positive' reflects adaptation, can this process of adaptation be explained in terms of functioning, and the paradox be eliminated? I will answer this in section 4.2. But to do so, I first operationalise functioning and individual experience, in section 3.

3. A FRAMEWORK OF FUNCTIONING AND INDIVIDUAL EXPERIENCE

The most relevant level of functioning in rehabilitation seems to be *intentional activity* (12, 21). It comes close to what the International Classification of Functioning, Disability and Health (ICF) refers to as activity (22), and which if disturbed, is referred to as disability. Examples are to eat, to play a game, to dress. Examples of lower-order functioning are standing, balancing, grasping, holding, and chewing. These could be termed *basic activities*. Again a lower-order functioning is muscle contraction, vision, proprioception, for example. These could be referred to as *basic functions*. Intentional activities are *observable*. Observable functioning is *momentary*.

Yet, an intentional activity, lasting for a moment, is usually performed in a context of a *pursuit*. A pursuit is *performed over time*. Pursuits reflect *ongoing* functioning. Pursuits can be conceived of as consecutive (sets of) inten-

tional activities chosen to realise an aspiration. Pursuits are *not observable* except for the present intentional activity that forms part of it. An aspiration, i.e. a purpose of a pursuit, can be thought to give direction to that pursuit, just as an intention gives direction to an intentional activity. For the practice of rehabilitation, short-term pursuits might be usefully distinguished from long-term pursuits. The concept of pursuit could help operationalise another concept of the ICF, namely 'participation' (22) (see below, section 3.2). The highest-order pursuit could be considered *meaningful daily living*.

Daily living is an overall term to indicate human functioning. My description of daily living is to some extent similar to Whitbeck's definition of health (12), but daily living does not automatically imply health. *Daily living is the engagement in distinctively human activities that is directed towards (but not necessarily effectively supportive of) the person's goals and aspirations*.

Figure 2 represents the hierarchical notion of different levels of functioning. Both the component aspect and the hierarchical aspect are demonstrated.

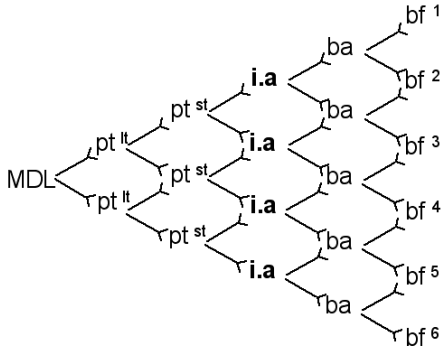


FIGURE 2. A way of representing levels of functioning based on the notion of a hierarchy of complexity. Intentional activity i.a is the central level of functioning. It is composed of several lower-level basic activities ba, each of which in its turn is composed of several basic functions bf. Several intentional activities form a short-term pursuit pt^{st} and several short-term pursuits form a long-term pursuit pt^{lt}. Meaningful daily living MDL (in terms of functioning) consists of several pursuits. The symbol –< indicates from left to right 'has as components'; from right to left 'are component of'.

In the following sections, I will operationalise the different levels of functioning. Individual experience will be operationalised using Lazarus' description of appraisal (18).

3.1 Momentary functioning

Momentary functioning is functioning that takes place in a small, indefinite period of time. It is observable. Relevant levels of functioning are intentional activity, basic activity and basic function. In Figure 3 the component aspect is reflected not by using branching but using a symbol for a set of components.

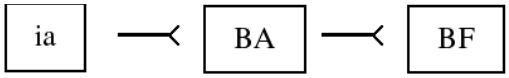


FIGURE 3. Schematic representation of an intentional activity (ia) consisting of a set of basic activities (BA) which in its turn consists of a set of basic functions (BF). The symbol –< indicates from left to right 'has as components'; from right to left 'are component of'.

3.1.1 INTENTIONAL ACTIVITIES, BASIC ACTIVITIES AND BASIC FUNCTIONS

Intentional activities represent the meaningful units in which the daily living, i.e., the engagement in activities supportive of a person's goals and aspirations, can be described. I propose the following description:

An activity can be designated an intentional activity for a particular person

– if an instant and single aim, or intention, pertains to that activity, and
– if in relation to that activity a pursuit or aspiration can be identified that renders the attainment of the intention of that activity meaningful or valuable for that person.

The *intention* is often implied in the verb naming the activity, e.g., to eat, to dress, to work. Examples of intentional activities are given in Table 2.

TABLE 2. Examples of Intentional Activities[1].

Communication	***Personal care***	***Relationships***
• to inform	• to sleep	• to share objects
• to explain	• to eat and to drink	• to take turns
• to understand	• to wash and to groom	• to co-operate
• to sympathise	• to dress or undress	• to join in
• to comfort	• to maintain continence	• to greet
		• to cuddle
Mobility	***Occupation***	• to make love
• to use different forms of transport	• to provide for meals	
• to go around walking	• to carry out household activities	
	• to carry out professional activities	
	• to carry out leisure activities	

[1] Adapted from the Rehabilitation Activities Profile developed by Bennekom and Jelles (23).

Intentional activities can be *abstract*, i.e., referred to only in one's imagination, or *concrete*, i.e., real. The term 'ability' could be used to refer to such an abstract, i.e., not realised but possible intentional activity.

Outcomes of measurement of intentional activities can be related to *performance* as well as to *reaching the intention*. Also the *attainment of an aspiration* could serve as an outcome of measurement of intentional activity, but such an outcome represents a *distal* outcome, relating less directly to the intentional activity. Outcomes relating to *performance* of an activity can be described in terms of action characteristics, e.g., speed, organisation or tidiness, or pattern of components. Grading of these results could be on a spectrum e.g., respectively between slow and fast, between efficient and inefficient, between orderly and chaotic. For example, out-

comes relating to eating, dressing and playing darts, could be *proper* use of knife and fork; getting the buttons *right*; *properly* throwing the darts, respectively. Outcomes in terms of *reaching the intention* of an activity can be described in terms of intention or direct purpose such as: to get food inside the body (to eat), to get covered or kept warm (to dress), to get darts in the right field (to play).

In order to *assess* intentional activities (i.e. determine the meaning of their measurement), one should know the context, e.g. the pursuit of which the intentional activity is a component, The intention (or very short-term aspiration) guiding the intentional activity *to eat* could be for example *enjoying holiday.* Similarly, the intention guiding the intentional activity *to dress* could be for example: *earning one's living as a mannequin*. The intention directing the intentional activity *to play darts* could be for example *to become the regional champion.* But also the *relevance* of activity and pursuit for the person concerned should be known (21).

Basic activities form the next category of observable functioning. They can be considered the neutral equivalent of Nagi's functional limitation (24,25). The distinction of basic activities is useful in clinical practice for a number of reasons. They relate more directly to biomedical conditions than intentional activities. Thus they may clarify the relations between biomedical conditions on the one hand, and intentional activities on the other. Furthermore, in the practice of rehabilitation this level of functioning is very much the focus of the different disciplines. Examples are *gross motor function*, *balance*, *reaching*, *grasping*, and *oral motor skills*. These terms are used, among others, in physiotherapy, occupational therapy and speech therapy. Lastly they often form points of impact for interventions.

I propose the following description: *A function can be designated a basic activity*

– if it forms a component of an intentional activity, and
– if an identifiable receptive and executive aspect is interwoven in the function, and
– if it can be performed consciously but usually is performed with a high degree of automaticity, and
– if it is composed of body functions.

Examples are given in Table 3. Basic activities can be *abstract*, i.e., referred to only in one's imagination, or *concrete*, i.e., real. The term 'capacity' could be used to refer to such an abstract, i.e., not realised but possible, basic activity.

Outcomes of measurement of basic activities will usually be in terms of *performance*, which can be expressed in pattern, sustenance, efficiency, range, and speed, for example.

As regards *assessment* of basic activities, the meaning of the outcome of measurement often regards the underlying mechanism and, in case of disturbance, a certain diagnosis. The relevance of determining the meaning of the outcome also appears from the setting of measurement. In practice it may seem feasible to measure basic activities in their own right,

TABLE 3. Examples of Basic Activities.

Focusing	***Expressing***	***Moving***
• directing attention	• speaking	• walking
• sustaining attention	• gesticulating	• swaying leg
• dividing attention		
• remembering	***Digesting***	***Manipulating***
	• swallowing	• throwing
Manifesting emotions	• chewing	• using scissors
• showing empathy		• kicking a ball
• showing anger	***Positioning***	
• showing joy	• sustaining position	
	• changing position	
Perceiving	• keeping balance	
• looking	• standing	
• listening	• bending	
• tasting	• kneeling	
• touching		

e.g., balancing, reaching, grasping. However, performance of such a basic activity on request will come very close to performing an intentional activity. The intention of such an activity is for example 'showing the professional a certain movement or act'. This is in accordance with the observation that the performance of a basic activity as part of an intentional activity will be different from the performance in its own right and on request.

Basic functions form the third category of observable functioning. Although basic functions are considered by many authors to be intrinsic characteristics of the person, whether impaired or not, functioning at this level still can be conceived of as interaction. For example, strong or weak muscle strength is called strong or weak in relation to counterforces from the environment. Such counterforces could for example be the professional's muscle strength in testing. The distinction of this level of functioning is useful for a number of reasons. First, basic functions are of diagnostic value. They can help in assessing the condition of the body in terms of confirming or rejecting disease, injury, congenital or other disorder, or ageing. Furthermore, they can provide information as to what extent organs or organ systems function well. Lastly, they can form points of impact for interventions. I therefore propose the following description:
a function is a basic function
– if it is a component of a basic activity, and
– if this function cannot be performed voluntarily in isolation, and
– if a decrease can be directly related to disease, injury, congenital or other disorder, or ageing.

Table 4 gives examples of basic functions. Just as the other levels of functioning, basic functions can be *abstract*, i.e. referred to only in one's imagination, or *concrete*, i.e., real. The term 'faculty' could be used to refer to such an abstract, i.e., not realised but possible basic function.

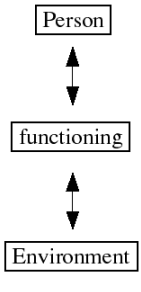
TABLE 4. Examples of Basic Functions.

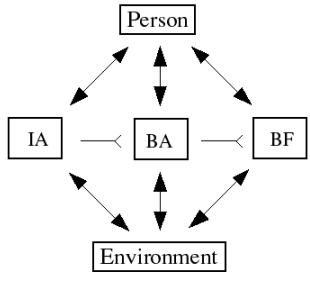
Functions regarding movement, including peripheral nerves: • muscle contraction • proprioception • range of motion	***Visceral functions***: • heart-lung function • bowel function • bladder function ***Sexual functions***: • orgasm • vaginal lubrication • erection • ejaculation	***Functions regarding exteroception***: • hearing • seeing • feeling • smelling • tasting

Outcome of measurement of basic functions can be related to the purpose of measurement. *Assessment*, i.e. the relevance of measurement of basic functions, regards for example diagnosis. In that case certain threshold values may be relevant. For assessing a quality of a basic function, grading along a continuum could be preferable.

3.1.2 Person and environment characteristics corresponding with momentary functioning

I have argued that functioning is influenced by person and environment characteristics. The person is the syntactic subject of this functioning (Figure 4A). Thereafter I suggested three different categories of momentary functioning: intentional activity, basic activity and basic function (Figure 4B). The figure suggests that 'the person' is the subject of each cat-





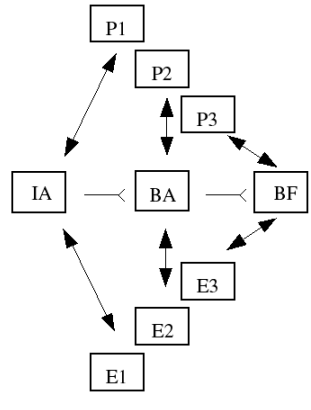


FIGURE 4A ***FIGURE 4B*** ***FIGURE 4C***

FIGURE 4. Different representations of functioning. Figure 4A represents person P being the subject of functioning. Figure 4B represents P being the subject and E being the environment of three different categories of functioning. Figure 4C represents three different categories of person and environment characteristics. The symbol –< indicates from left to right 'has as components'; from right to left 'are component of'. The two-pointed arrows indicate 'reciprocal influence'.

egory of functioning. However, I argued above that functioning could be better specified if the subject is more precisely identified. So in correspondence with distinguishing three different categories of functioning, three different categories of person characteristics can be identified in accordance with the functioning with which they seem to have their main relation (Figure 4C). Similarly three categories of environment characteristics can be identified.

In Figure 5, the three groups of person characteristics and environment characteristics are *named*. In addition it shows arrows in the right upper corner that represent *intra-personal relations*, i.e., between supposed characteristics within the person.

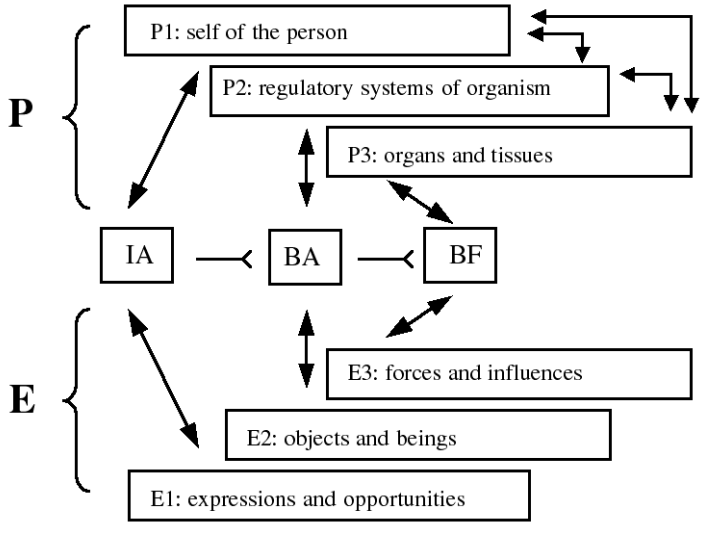


FIGURE 5. Three categories of functioning, each with its own 'subject' and environment. P = categories of person characteristics. E = categories of environment characteristics. The large two-pointed arrows indicate 'reciprocal influence'. The small two-pointed arrows indicate intra-personal relations. IA = a set of intentional activities. BA = a set of basic activities. BF = a set of basic functions. The symbol –< indicates from left to right 'has as components'; from right to left 'are component of'.

In table 5, examples are given of characteristics of person and environment, grouped according to the three levels of functioning. The method of *measurement* of these characteristics will depend on the nature of the characteristic. *Assessment* will usually regard the influence by these characteristics on functioning or rather on the change in functioning. But equally relevant is the influence of the change in functioning on person and environment.

TABLE 5. Examples of characteristics of person and environment, corresponding with three levels of momentary functioning.

	At level of intentional functioning	**At level of basic activities**	**At level of basic functions**
Person characteristics	– Ability to intentional activity – Ability to explicit learning – Sense of meaningfulness of living – Long-term aspirations – Short-term aspirations – Intentions – Self-esteem – Ideas, beliefs, moral values – Previous experiences – Emotions and mood	– Capacity for basic activities – Capacity for implicit learning – Physical condition – Psychoneurophysiological systems – Shape and structure of the body	– Faculties for basic functions – Faculties for intrinsic adaptation and for intrinsic recovery – Metabolic processes – Physiological processes – Immunological processes – Cerebral dominance – Anatomical structure of tissues and organs
Person characteristics	***Human*** – Showing feelings – Having momentary expectations – Giving mental support – Providing basic security – Presenting requests, demands, pressure – Giving information – Having long-term expectations – Presenting challenges – Loss important other ***Living non-human*** – Life stock – Pets – Crops – Vegetation – Garden – 'Nature' ***Material*** – Providing opportunity for shelter, for housing, for transport – Presenting obstacles – Loss of shelter, housing ***Socio-economic*** – Providing social opportunity – Providing job opportunities – Providing health services, welfare services – Providing opportunity for education	***Human beings*** – Human body characteristics such as mass, size, warmth – Gestures – Touch – Facial expression – Intonation ***Other living beings*** – Plant characteristics such as mass, size, shape, surface, smell – Animal characteristics such as mass, size, shape, skin surface, skin temperature, smell, movement ***Objects*** – Object characteristics such as mass, size, shape, surface – Aids and appliances – Passage, walking surface – Sitting and lying surfaces – clothes	***Biological influences*** – Bacteria – Viruses – Fungi – Allergens ***Physical forces and influences*** – Reaction forces – Shearing forces – Heat, cold – Noise, light ***Chemical forces and influences*** – Substances – Medicines ***Climatic influences*** – Humidity – Temperature – Wind

3.2 Ongoing functioning

Ongoing functioning is functioning that extends from the present or a past moment in time, to a later moment in time. It is associated with roles and with pursuits of particular goals or aspirations (26,27). For the practice of rehabilitation, one could for example distinguish *short-term pursuits* (of short-term aspirations), *long-term pursuits* (of long-term aspirations), and, ultimately, *meaningful living* (in pursuit of a sense of meaningfulness). Figure 6 represents the different levels of functioning.

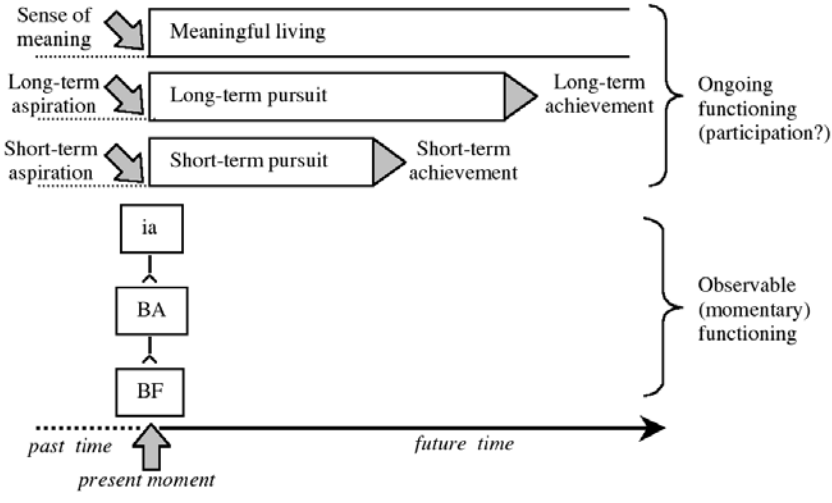


FIGURE 6. Graphical representation of momentary and ongoing functioning. Ongoing functioning regards functioning over time. Within ongoing functioning, pursuits can be distinguished. Ongoing functioning can not be observed as it largely takes place in future or past. However, at a given moment in time (grey arrow pointing upwards), an intentional activity that forms part of a pursuit can be observed, together with the aspirations corresponding with the pursuit (grey arrows pointing down). Pursuits may result in achieving the aspiration.

3.2.1 SHORT-TERM AND LONG-TERM PURSUITS

Pursuits can be considered a consecutive (set of) intentional activities over time serving a particular *aspiration*. Aspirations can be conceived of as person characteristics. Such aspirations can apply throughout time (e.g., always being polite), as well as to a specified period in time (e.g. completing secondary school). In real life usually several aspirations are pursued at any given moment. This conception of pursuit might give an alternative meaning to the term 'participation' as used in the International Classification of Functioning, Disability and Health (ICF)[1] (22), by considering 'participation' to designate *functioning over time* (28).

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[1] As regards the concept of participation, the ICF (22) advices its readers to differentiate activities and participation in their own operational ways. The ICF offers four possible ways: (a) to designate some domains as activities and others as participation, not allowing overlap; (b) same as (a) above, but allowing overlap; (c) to designate all detailed domains as activities and the broad category headings as participation; (d) to use all domains as both activities and p articipation.

Just like the categories of momentary functioning, pursuits can be abstract, i.e. referred to only in one's imagination, or concrete, i.e. real. But as the greatest part of a pursuit is in the future or in the past, the term 'real' does not indicate that pursuits are observable, but just that they are realistic or feasible.

I propose the following description: *A function can be designated a pursuit*

- if it is composed of consecutive (sets of) intentional activities, and
- if this series of intentional activities has a common purpose or aspiration, and
- if the purposes of such series of intentional activities, i.e. aspirations, form meaningful components of that person's daily living, and
- if short series of such intentional activities can form components of long series of such intentional activities.

Table 6 presents examples of pursuits.

TABLE 6. Examples of pursuits.

Domains	*Long-term pursuits*[1]	*Short-term pursuits*[1]
Vocation	Earning a living …	by building a house
		by making and selling cloths
	Becoming an expert or experienced worker …	by gaining experience as a psychologist
		by being a dedicated policeman
	Showing commitment to a job Serving an interest of people or company …	by supplying furniture, other goods
Education	Schooling …	by attending primary education
	Studying a subject …	by attending a course
	Learning to become an skilled craftsman …	by gaining experience in shoemaking
House keeping	Keeping a household running	by routine cleaning activities
		by regularly providing meals
		by regular maintenance
Leisure	Maintaining friendship …	by an understanding attitude
	Become expert / skilled …	by weekly training in sports such as soccer
	Mastering a subject / skill …	by attending a course in painting
Partnership	Maintaining partner relation …	by regularly sharing experiences and emotions
		by keeping social contacts together
		by sharing leisure activities
		by enjoying and maintaining a sexual relationship
Parenthood	Raising children …	by providing an example in something
		by guiding a child's interest

[1] The terms for the pursuits imply the corresponding aspirations.

A short series of intentional activities corresponds with a short-term pursuit and a long series with a long-term pursuit. Pursuits relevant within rehabilitation are for example: following education; earning a living; maintaining a relationship; raising children. Indeed, the pursuits can usually be named after the aspiration they serve.

Outcomes of *measurement* of pursuits could regard the attainment of the corresponding aspiration. *Assessment*, i.e. the meaning of the outcome, could for example be related to the aspirations *being realistic* as regards a person's real potential and developmental potential, but also as regards this person's environment. Even if a person has real potential to pursue a particular aspiration, there still could be incompatibility with aspirations of other persons. Assessment of *pursuits* could also be related to the *choices* a person makes with regard to *means and ways* of pursuing.

3.2.2 PERSON AND ENVIRONMENT CHARACTERISTICS CORRESPONDING WITH ONGOING FUNCTIONING

Pursuits of aspirations often go together with changing of person characteristics. Some changes may reflect aspirations themselves, such as improving physical condition, or getting better from an illness. Other changes are conditions for achieving an aspiration, for example development, growth, and learning. Characteristics of the environment may also change over time, for example, the socio-economic situation, the political situation, developments in the family or in the community. For assessment of pursuits, estimates may be needed of these changes of person and environment. Characteristics that correspond with pursuits are mentioned in table 7.

TABLE 7. Examples of person and environment characteristics corresponding with ongoing functioning.

	At level of ongoing functioning (or pursuits)	
Person characteristics	– Sense of meaningful living – Long-term aspirations – Short-term aspirations – Ability to explicit learning – Self-esteem – Ideas, beliefs, moral values	– Ability to make choices – Short- and long-term planning – Short- and long-term expectations – Previous experiences
Environment characteristics	***Human*** – Having long-term expectations – Providing support system – Basic security – Presenting requests, demands, pressure – Giving information – Having long-term expectations – Presenting challenges ***Material*** – Providing opportunity for shelter, for housing	***Socio-economic*** – Providing social opportunity – Providing job opportunities – Providing health services, welfare services – Providing opportunity for education ***Living non-human*** – Life stock – Crops – Vegetation

Aspirations are essentially ideas of the person at the present moment. Therefore they can be considered person characteristics. Aspirations can be divided in short-term aspirations, long-term aspirations, and sense of meaningful living. Figure 7 represents the aspirations as person characteristics.

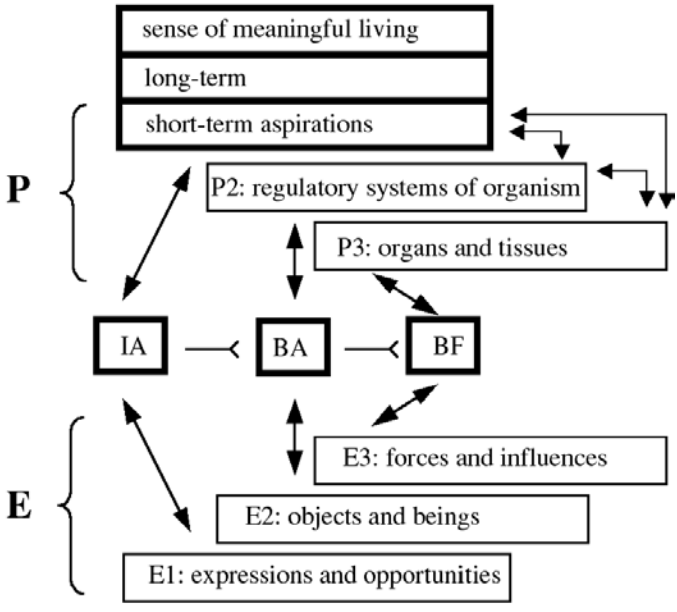

FIGURE 7. Graphical representation of aspirations as person characteristics, and of a hierarchy of functioning they are part of. The lower purposes in the hierarchy are the *observable* functions and activities. From 'low' to 'high': basic functioning (BF), basic activities (BA), intentional activities (IA), in bold frames. The aspirations reflect pursuits. Short-term aspirations reflect short-term pursuits. Long-term aspirations reflect long-term pursuits. Sense of meaningful daily living reflects meaningful daily living. The large two-pointed arrows indicate 'reciprocal influence'. The small two-pointed arrows indicate intra-personal processes. The symbol –< indicates reading from left to right 'has as components'; from right to left 'are component of'. P = person; E = environment.

3.3 Individual experience

Individual experience is conceived of as appraisal of functioning. It is relevant, as it may help understand functioning as *adaptation*. Adaptation is a process of getting better; the process of getting better determines prognosis; prognosis determines the need for assistance. Thus, understanding individual experience helps with clinical decision taking.

3.3.1 Appraisal

Appraisal according to Lazarus (18) is an evaluation of the significance of what is happening in the *person-environment relationship* between this individual and his environment for personal well-being. This

person-environment relationship reflects functioning. A particular instance of the person-environment relationship is the specific *person-environment encounter* (18), or in other words, a particular functioning. Both environmental and personal variables influence appraisal (18) (p 87), but the person is the one who appraises. How can appraisal be described using terms that correspond with the framework?

In his description Lazarus distinguishes six components of appraisal. Each of these aspects can be represented by a question. In the question the relation with a person characteristic becomes clear.

- *Does a particular encounter touch on personal goals*? This represents the appraisal component *goal relevance*. It relates to a person characteristic[1] *goal hierarchy*, that provides the individual with a basis for what is considered most or least harmful or beneficial (18) (p 94).
- *Is the encounter consistent or inconsistent with what the person wants*? This represents the appraisal component *goal congruence or incongruence*. It relates to a person characteristic *goal commitment*, i.e., the importance the person attaches to a certain goal (18) (p 95).
- *Which types of the Self is at stake*? This represents the appraisal component *ego-identity*. It relates to person characteristics *beliefs about self and the world* (i.e: self-esteem and social esteem; moral values; ego-ideals; essential meanings and ideas; other persons and their well-being; and life goals) (18) (p 101).

These appraisal components relate to person characteristics *that were already there* before the specific person-environment encounter. These characteristics could be *at risk* in the encounter.

The other three person characteristics *emerge* in a particular situation. The corresponding appraisal components can again be clarified with questions.

- *Who is to blame or credit for this situation*? The corresponding person characteristic is *knowledge about who or what is accountable*.
- *What is the person's perception of his or her coping potential in this situation*? The corresponding person characteristic is *evaluation of the prospects of being able to change the situation*.
- *What is the person's future expectancy following this situation*? This corresponds with the person characteristic *expectation of a change for the better or for the worse*.

These last three characteristics correspond to some extent with the explanatory model (EM) of Kleinman (29). The explanatory model is a way to map the ideas and beliefs of a person about a particular episode of sickness and of other persons involved in this episode. There are five major questions that EMs seek to explain for illness episodes. These are questions about:

- the cause;
- time and mode of onset of symptoms;

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[1] Lazarus uses the term "personal characteristic". To prevent confusion I use the term "person characteristic" instead.

– processes and mechanisms underlying the symptoms;
– the expected course of events, including the expected impact; and
– interventions.

Explanatory models can be applied to disability as well (30). They apply to *particular* episodes. They could be considered *situational* beliefs as distinguished from *general* beliefs about health, disease, sickness and illness, even though they draw upon these general beliefs (29). Explanatory models also apply to people in the environment of the person concerned.

The components of appraisal as well as the characteristics *at risk* and the characteristics that *emerge* are summarised in table 8.

TABLE 8. Correspondence between person characteristics and appraisal components.

Characteristics of the person		**Components of appraisal**
Characteristics, *at risk in* person-environment encounter:	Goal hierarchy	Goal relevance: Does the encounter touch on my goals?
	Goal commitment	Goal congruence or incongruence: Is the encounter consistent or inconsistent with what I want?
	Beliefs about self and the world	Ego-involvement: Which types of the Self is at stake?
Characteristics, *emerging at* person-environment encounter: (corresponding terms: situational knowledge; explanatory model)	Knowledge about who or what is accountable	Blame or credit?
	Evaluation of prospects of being able to change the situation	Perceived coping potential?
	Expectancy of psychological change for the better or worse	Future expectancy?

How do these person characteristics that explain appraisal, fit into the framework of functioning described above? In Figure 8, these factors are given a place in the framework, as person characteristics.

4. ANALYSIS OF CHANGE IN FUNCTIONING, OF INDIVIDUAL EXPERIENCE AND ADAPTATION

The *analysis* of change in functioning, individual experience and adaptation that I present in this section is based on the conceptual issues that I discussed in section 2, and on their operationalisation presented in section 3.

4.1 Change in functioning

In this section, I take a look at some aspects of functioning that can be used to analyse and explain *change* in functioning. I elaborate on functioning at one particular moment, on functioning as a possibility, on functioning as condition and as purpose, and on ongoing functioning.

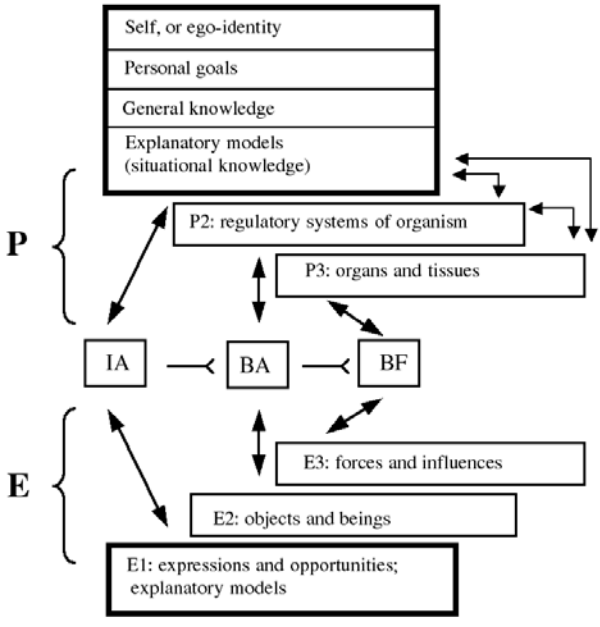

FIGURE 8. Main factors influencing appraisal of functioning in bold frames. Some are categorised as person characteristics: ego-identity, personal goals, general knowledge and explanatory model. Explanatory models is also an environment characteristic. IA = a set of intentional functioning. BA = a set of basic activities. BF = a set of basic functions. The large two-pointed arrows indicate 'reciprocal influence'. The small two-pointed arrows indicate intra-personal processes. The symbol –< indicates reading from left to right 'has as components'; from right to left 'are component of'. P = person; E = environment.

4.1.1 FUNCTIONING AT ONE PARTICULAR MOMENT

Functioning *at one particular moment* regards intentional activity. Analysing functioning *at one particular moment*, the relation between intentional activity and its components could be considered a *partitive relation*. A partitive relation implies that certain functions are a part, a component, of a higher-order function. These lower level functions *can* only exist in the quality of part or component (31) (p 38). They are observable *aspects* in the performance of the intentional activity. Which lower level units, or components, are distinguished, rests on the relevance of the components for the observer. The partitive relation is represented in Figure 9A. A slightly different representation (Figure 9B; see also Figure 3) is used in the subsequent figures.

Change in functioning of one particular person can be explained by comparison of functioning at two different moments. Also differences in functioning *between* persons can be made visible. For example how does functioning of a particular person compares with what is 'usual', i.e., common for a group of persons (21).

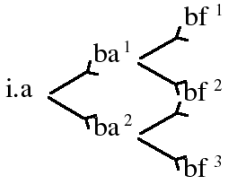

FIGURE 9A

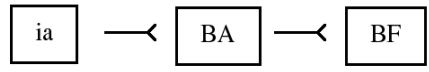

FIGURE 9B

FIGURE 9. Two ways to represent the composition of an intentional activity. Figure 9A: representation of a partitive relation. ia = intentional activity. ba = basic activity. bf = basic function. Figure 9B: representation of components of an intentional activity. The symbol –< indicates reading from left to right 'has as a component'; from right to left 'is a component of'. BA = a set of basic activities. BF = a set of basic functions.

4.1.2 Functioning as a possibility

We never carry out all the intentional activities that we can carry out. This has consequences for assessment. We need a term for indicating those intentional activities that can or may come into existence if one asks for it. One could use the term 'possible'. This term seems to have two connotations, one of opportunity, and one of skill. In the context of this chapter the connotation 'skill' is relevant. Terms for possible functioning in parallel with the three concepts of intentional activity, basic activity, and basic function could be ability, capacity and faculty.

Nordenfelt uses the terms 'first-order ability' for an ability, which can or may come into existence at any moment, given the appropriate circumstances. A 'second-order ability' is a possibility, a potential, which still needs to be developed (32) (p 49). It is an ability which cannot come into existence at present, but which may come into existence through training or development. It is assumed that following a training program is then a first-order ability of the individual concerned (32).

4.1.3 Functioning as condition and as purpose

Whereas the noun 'possibility' seems to refer to that level of functioning that is at stake, the noun 'condition' refers to a *prerequisite* for such a functioning. For example, intact nerve conduction forms a condition for muscle function and this in its turn a condition for basic activities such as grasping, holding and walking. These in their turn form conditions for intentional activities such as preparing a meal and shopping.

If one function is conditional to another, this may be expressed in terms of necessary condition, contributory condition, or sufficient condition (33). The term 'necessary function' however, does not imply that if it is lost, there is no other (second-order) faculty, capacity or ability that could take the place of the lost one.

The terms 'possibility' and 'condition' are both relevant to the practice. For example, assessing functioning by history taking or question-

naires implies that the functioning is *not realised*. The risk is that someone's report about functioning may not fully correlate with the reality (1) (p 73). Observation of the functioning concerned is often not possible in a rehabilitation centre. An estimate could then be made. One method is to see whether the function concerned can be observed in *artificial environment*, like 'preparing a meal' in the department of occupational therapy, or 'going around in the house' in the gym. This has drawbacks (34). The second way is to observe the *conditions for* that intentional activity (basic activities and basic functions), as a type of substitute assessment. Better maybe would be to find a second, different, intentional activity that includes the relevant conditions but which could be realised and observed in a natural way.

The meanings of the terms 'possibility' and 'condition' are illustrated in Figure 10. It contains both the concept of a possible intentional activity, and the *conditions* for both the possible and the realised intentional activity.

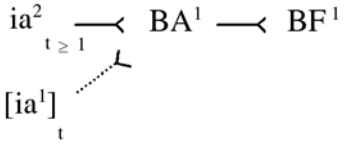

FIGURE 10. Representation of *conditions* for functioning and *possibility* to function. If circumstances provide no opportunity for intentional activity ia^2 to be carried out, it can be indirectly observed through observation of another intentional activity ia^1 which is composed of a set of similar basic activities BA^1 and for which both skills and opportunity are present. BA^1 in its turn is composed of a set of basic functions BF^1. The symbol –< indicates from left to right 'has as a component'; from right to left 'is a component of'. The dotted symbol indicates: 'forms a condition for'. The square brackets indicate not carried out, i.e. 'not possible', in this case because of lack of opportunity, not because of lack of skills.

There is also a relation the other way around. Functioning at a particular level could be purpose for functioning at a lower level. If the higher-order functioning changes, the conditional functioning may change. For example, if somebody stops sports training, i.e., changes purpose, the lower levels will change. This of course will take time, but after some time the changes of lower-order functioning may be observed, e.g., decreased running speed or decreased dexterity. Similar relations exist between pursuits and intentional activities.

4.1.4 CHANGE IN ONGOING FUNCTIONING

All rehabilitation professionals reckon with future aspects of the people concerned. The emergence of the term 'participation' is a reflection of just that. But about the future little can be made explicit. Only the functioning at the present moment is observable. How can we obtain a picture of one's future functioning, i.e., of pursuits?

Analysing pursuits regards mainly the relation between the corresponding aspirations on the one hand and the future potential functioning on the other. As regards aspirations, these can be realistic or too ambitious or too resigned. This is not easily measured, but common sense in individual patient care may be a guide to compensate for this. Possible functioning in future, i.e., abilities, capacities and faculties, can be predicted to some extent. But in rehabilitation practice one is more interested in predicting *changes* therein, both for the better and for the worse. In terms of the framework of functioning, this means to try and predict changes in characteristics of person and environment. Person characteristics may change over time in association with disease, development, growth, ageing, adaptation processes and learning, but also (through functioning) following changes in environment. Environment characteristics may change over time in association with socio-economical and political circumstances, with developments in the community or, more nearby, in association within the family.

It is difficult to imagine measuring something that still isn't there. But the operationalisation of ongoing functioning could help one identify variables for meaningful measurement.

4.2 Individual experience and appraisal

Assuming that appraisal reflects individual experience, how can it be used to analyse adaptation?

In this section I propose *standards* for appraisal of functioning based on the *hierarchy of functioning*. Next I explain adaptation of functioning using these standards of appraisal and resolve the paradox that irreversible decrease of functioning can be associated with positive appraisal.

In section 4.3, I present the case of Mr R to illustrate how a professional could estimate the process of adaptation, not only by using standards of appraisal of functioning, but also by observing person characteristics that influence this appraisal. As said before, this estimate of the process of adaptation serves clinical decision-making.

4.2.1 Standards for appraisal

Assessment of appraisal requires measurement. Measurement requires a standard. What could be a standard for appraisal of functioning? Let us look again at the description of appraisal by Lazarus (18): appraisal is the evaluation of the significance of what is happening in the person-environment relationship, in particular an instance of this: a person-environment encounter. In other words: an evaluation of the *significance of functioning*. Now what could be a standard for the *significance* of functioning?

Let us now take a look at the meaning of 'standard'. Standard according to Webster's dictionary (35) is *a degree of quality (or goodness), or a level of achievement, regarded as desirable and necessary for some purpose*. When this definition is applied to the standard for appraisal of functioning, the definition reads: the standard for *appraisal of functioning* is

that degree of goodness of the appraised functioning, that is regarded as desirable and necessary for a purpose.

Taking the descriptions of appraisal and standard together, it is tempting to equate *significance* to *desirable and necessary for a purpose*. Now what could the purpose be? I use the hierarchy of functioning to suggest that *the purpose of a particular functioning is a higher-order functioning*. Hence, functioning meeting the standard can be expressed as 'the functioning has a sufficient degree of goodness for realising a particular higher-order functioning'. This implies by the way that the standard is a personal one.

In Table 9 different levels of functioning are arranged in a hierarchical order, demonstrating that this *hierarchy of functioning* follows the same order as the *hierarchy of purposes implied in the standard* (36). In other words, each level of functioning can be appraised, whereby a higher-order functioning could be regarded the purpose. This purpose forms the significance of the appraised functioning.

TABLE 9. Standards of appraisal.

Appraised functioning		**Functioning implied in the standards for appraisal**
Long-term pursuits	→[1]	Meaningful daily living
Short-term pursuits	→	Long-term pursuits
Intentional activities	→	Short-term pursuits
Basic activities	→	Intentional activities
Basic functions	→	Basic activities
Physiological functions	→	Basic functions

[1] The symbol → indicates correspondence between the level of appraised functioning and the level of functioning implied in the standard of that appraisal.

4.2.2 DECREASED FUNCTIONING AND POSITIVE APPRAISAL: RESOLVING THE PARADOX

In rehabilitation, physical changes for the worse are associated with negative changes in functioning. Yet after such a change for the worse, people can take up their life, and appreciate it, even if the physical changes are irreversible. What makes the appraisal positive again?

To explain this phenomenon, I use the standard of appraisal described above. It is in particular the *aspect of purpose* of the standard that I use for the explanation of adaptation (Figure 11).

Suppose function F^1 or activity A^1 or pursuit G^1 serves purpose P^1. The standard for the appraisal of this function, activity or pursuit is: *sufficiently good for attaining a higher level purpose* P^1. Purpose P^1 serves purpose PP^1. Now if F^1, A^1 or G^1 is disturbed, the appraisal will be: *not sufficiently good for* P^1. In other words, F^1, A^1 or G^1 insufficiently contributes to the interests of the person concerned. Hence adaptation will come into being. In first instance adaptation does not imply that P^1 is reduced somehow or abandoned. On the contrary, adaptation involves mobilising resources or developing alternative resources in order to attain P^1. These

newly identified resources could be indicated as function F^2, activity A^2 or pursuit G^2. Once developed or trained, they serve the higher level purpose P^1. Purpose PP^1 remains realistic.

However, it could be that function F^2 or activity A^2 cannot be realised or that pursuit G^2 cannot be considered realistic. If F^2, A^2 can not be realised or G^2 can not be considered realistic, then appraisal of P^1 will reflect that P^1 is *permanently not sufficiently good for attaining the higher purpose* PP^1. Subsequently a *choice* for P^2 can be made, in which P^2 is considered to serve PP^1. This appraisal jumping to a higher order purpose is accompanied with a higher order standard, i.e., the standard no longer applies to F^1, A^1 or G^1 (and to F^2, A^2 or G^2), but to P^1 (and P^2).

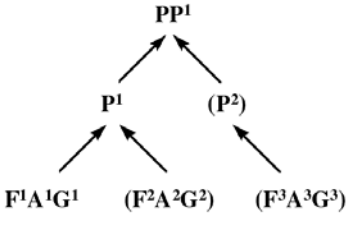

FIGURE 11A

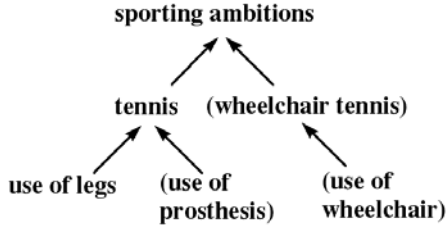

FIGURE 11B

FIGURE 11. Representation of a hierarchy of functioning to illustrate shifts in appraisal from one level of purpose to a higher-order level. (Figure 11A). If Function F^1 or activity A^1 or pursuit G^1 ($F^1A^1G^{1)}$ is decreased and *not sufficiently good* for the purpose P^1, other conditional skills for P^1 ($F^2A^2G^{2)}$ may be developed. However, re-appraisal may find that there are no alternatives for $F^1A^1G^1$. P^1 may then be appraised as *permanently not sufficiently good* for PP^1. P^2 could be another sufficient condition to PP^1, but requires $F^3A^3G^3$. By developing ($F^3A^3G^3$), (P^2) may be developed until it is *sufficiently good* for PP^1. Figure 11B provides an example.

The consequence of this approach is that an aspiration-achievement gap can be conceived of as a *gap between achievement at one level of functioning, and aspiration at a higher-order level of functioning*, and not a gap between achievement and aspiration at the same level of functioning. In other words, a gap between functioning as a purpose and functioning that forms a condition for this purpose. F^1, A^1 or G^1 can be considered *achievement*, and P^1 the corresponding *aspiration*. Other resources are mobilised or developed in the form of other conditional functioning F^2, A^2 or G^2. This new resource may close the gap between achievement F^2, A^2 or G^2 and aspiration P^1. Purpose PP^1 can then be maintained.

But if F^1, A^1 or G^1 and F^2, A^2 or G^2 are not possible any longer, and P1 is no longer realistic, the achievement-aspiration gap *between these two particular levels* is permanent. Now by jumping to higher levels, the aspiration-achievement gap is between PP^1 and P^1. Now instead of P^1 an alternative P^2 may be mobilised or developed, so as to form a sufficient condition to PP^1, requiring lower-order functioning F^3, A^3 or G^3. If F^3 or A^3 can be realised, or if G^3 is realistic, then P^2 becomes realisable, and the person

can stick to his pursuit PP^1. In other words, the aspiration-achievement gap between these two levels can be closed, even if F^1, A^1 or G^1 are still not possible. This is how the paradox can be resolved.

4.3 Functioning, individual experience and adaptation: the case of Mr R

I have argued that insight in someone's adaptation helps decide on interventions. Such an insight requires an answer on three questions: (1) What are the changes in functioning the person concerned probably needs to adapt to? (2) How to get an impression of this person's appraisal of these changes in functioning? (3) How to estimate whether this appraisal is adequate?

First, what are the expected changes in functioning the person needs to adapt to? The key word is *prognosis*. Using his expertise a professional can determine the prognosis of the *medical condition* (disease, trauma, congenital disorder, somatoform disorder, ageing), as well as the prognosis of the *direct consequences* in terms of basic activities. To know the prognosis of the more *indirect consequences* i.e. intentional activities and pursuits, requires knowledge about the intentional activities and pursuits that are *usual for the individual concerned* (21) (p 10) rather than usual for a group the individual belongs to. Yet often professionals will refer to intentional activities and pursuits *usual for a group*.

Second, how to get an impression of the individual's appraisal, i.e., of the individual's evaluation of the significance of the changes in functioning? As regards *medical conditions* and *basic activities*, their conditional role is rather universal. Estimating the significance of its changes in general requires little advance knowledge about this person. Also an estimate of the significance of the more *indirect consequences* in terms of intentional activities and pursuits often rests on a *population norm*. But an *individualised estimate* of the significance of these more indirect consequences requires knowledge about (in Lazarus' terms) that person's own *goal hierarchy*, *goal commitment*, and *beliefs about self and the world*.

Third, how to estimate whether the appraisal is adequate? 'Adequate' designates leading to optimal health (health as described by Whitbeck (12)), given the circumstances and life expectancy of the person concerned. In my experience, ego-identity and the short-term person characteristics seem to be major determinants. Though these can be measured, the outcomes are not always easy to interpret as regards the influence on appraisal.

Let me illustrate these issues with the case of Mr R.

Mr R met with a motor accident and sustained a fracture of the right lower leg. The fracture was both compound (with an open wound leading to the site of the fracture) and comminuted (more than two bone fragments). At the emergency department it was explained to him that complete recovery could not be warranted as contamination of the wound and the number of fragments of bone increase the risk of infection and mal-union. In addition there was considerable soft-tissue damage. During the first couple of days he seemed to be quite distraught. When he became more composed, his main worry was about playing football. Indeed football was his passion, and he had high sporting ambitions.

The *general knowledge* of Mr R concerning his condition influences his appraisal. If Mr R supposes that the prognosis is uncomplicated cure, he appraises the situation as *not incongruent with his long-term pursuits*. There may be *blame*, to himself or somebody else, but the idea of a favourable prognosis may alleviate the weight of the anger. He needs to cope with a situation of inactivity, of being admitted and not being at home, of pain, of dependency, but all these he considers temporary.

Now imagine that the surgeon after some days takes away uncertainty. He informs Mr R that the loss of tissue by the impact of the accident and by infection causes permanent loss of strength of the extensors of the knee, and of knee mobility. Both he and Mr R agree about the direct consequences: a relative but small shortage of the right leg, less capacity for fast running and for kicking a ball with his foot. It would be hard to play football, let alone football at professional level.

As regards appraisal, both men estimate (prognosis) that the remaining strength and mobility of the leg (basic functions) are *not sufficiently good for kicking a ball with his foot*. In other words, basic activity is implied in the standard for appraisal of basic functions. They also know that kicking a ball with his foot (basic activity) is *not sufficiently good for playing football*. In other words, intentional activity is implied in the standard for appraisal of basic activities. From his meetings with Mr R, the surgeon is familiar with Mr R's hobby, playing football, and his aspiration to become a good football player, aspiring to win the competition this season with his team. This gives the surgeon an indication of the relevant *goal hierarchy* and the *goal commitment*. In other words, as he knows the importance Mr R attaches to his pursuits, he can estimate the significance for Mr R of the change in these pursuits.

However, the surgeon may suspect, for example by observing the nature and intensity of emotions, that certain aspects of *ego-identity* play a role. Imagine, for example, a very strong emotional reaction that Mr R says relates to his belief that he would *no longer be able to become a world class football player*. This of course justifies strong emotions. Yet, if the professional sees nothing in the individual's daily living suggesting that he would ever have become such a player, this belief would seem to be unrealistic and hence the appraisal would not be adequate. Another example of an unrealistic appraisal would be that life is no longer worth living anymore (the appraisal regards too high a level of functioning), or that healing of tissues is all-important (appraisal regards too low a level of functioning).

Not only *ego-identity*, but also Lazarus' *person characteristics emerging at the encounter* (18) (or Kleinman's explanatory model (29)) may be required to explain inadequacy of appraisal. Person characteristics that influence appraisal may themselves become a reason for intervention.

It seems reasonable to think that the higher the level of a purpose in the hierarchy of purposes, the less chance that an alternative pursuit is

FIGURE 12. Representation of Mr R, his observable functioning (*playing football, kicking ball with foot, and stabilising ankle joints*), his personal characteristics *at risk* after the fracture (A), including his pursuits or personal goals (B) and those characteristics *emerging* after the fracture (C). The levels of observable functioning together with his pursuits form the hierarchy of functioning. See text for further explanation.

easily found. For example, if Mr R indeed wanted to become a world class football player, it would not be easy to replace it. But even then, he might choose an entirely different course of life, *sufficiently good to achieve a sense of meaningful daily living*.

5. EPILOGUE

In this contribution I propose a theoretical framework for analysis in the practice of rehabilitation. What is the connection with *assessment*? Assessment is defined as the process of determining the meaning of the outcome of measurement. This meaning can more readily be determined if theoretical relations between variables are established. A framework such as presented here, could assist in providing an overview of such relations between variables. In other words, it represents a summary of theoretical insights that are relevant in the practice. The framework may be new, but the knowledge it arranges is not. Moreover, if new theoretical insights would suggest that relations between concepts are different from what is assumed for this framework, the framework needs to be adapted.

The framework is meant to support rehabilitation professionals in analysing change in functioning, individual experience and adaptation. But this is not to say that each professional might use it in the same way. For example, experienced professionals may have their long-standing way

of working based on a lot of clinical experience. They usually have less need for explicit analysis than their younger colleagues do (37).

What then *are* reasons for explicit analysis? Why should one be able to make an explicit analysis?

– The first reason is to get experience from repeated explicit analysis. It applies in particular to post-graduate trainees. Such experience equals a measure of efficiency and efficacy of clinical decision-making. My assumption here is that repeated *analysis* forms a much stronger basis for efficiency and efficacy than only repeated *observation of phenomena*.
– A second reason is to be able to tackle patients' problems that are exceptionally difficult. A theoretical framework would guide one's thinking where experienced-based associations appear to be not sufficient for that. This reason applies to experienced rehabilitation professionals.
– Another reason is to manage *unusual* problems, for example problems experienced by people with a cultural background different from one's own.
– And finally, this framework may be drawn upon when *shaping scientific arguments* and *research questions*.

Even though the framework represents known theoretical insights, in its design there is a subjective element. This is my own view on what brings different fields of theory together. The core concept in my view is *adaptation*. The value implied in the concept of adaptation justifies *assistance towards processes of adaptation* in case these adaptation processes are not efficient or not sufficiently effective. The indication for assistance (i.e. rehabilitation measures) is related to the outcome of adaptation processes. If someone is able to generate adequate adaptation, there is no indication for assistance. Individual experience can be used as a means to estimate the course of the adaptation process, rather than as an aim of assistance. That is not to say that we do not value our clients' subjective well-being, or a good quality of life. But it does mean that assistance towards processes of adaptation implies providing the person concerned with tools to achieve this well-being, this quality of life, by himself or herself.

This point of view may not as a matter of fact appeal to all colleagues in rehabilitation medicine. Yet I do hope that the ideas contained in the framework will elicit discussion among rehabilitation physicians for the benefit of those we attend.

ACKNOWLEDGEMENT. I wish to thank prof. dr Annemarie Mol and prof. dr Axel Fugl-Meyer who supervised my PhD thesis from which this contribution evolved; Kees Pons, Jos Dekker and other members of the Study Group Curriculum Development who greatly supported the use of the theory-oriented framework into the Dutch post-graduate PRM-curriculum; and the Roessingh Centre for Rehabilitation for granting me time for writing.

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CHAPTER 2
PRINCIPALS AND PRACTICE OF MEASURING OUTCOME

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During the last two decades there has been an increasing focus on the non-fatal consequence of disease and injury. A variety of factors have contributed to this development, including a better understanding of the consequences of disease, facilitated by the World Health Organisations International Classification Of Functioning, Disability and Health [ICF] (1), and the emergence, within Europe and North America, of clinical audit, and 'evidence-based' medicine. In the former, consequences at the organ, person and societal level are documented, as well as the influence of environment. In the latter, emphasis is placed on outcome and quality of life as an integral aspect to clinical audit, along with the increased importance of contracting for health care where there is clear evidence of the efficacy of such care (2). In both cases 'outcome' plays a crucial role and consequently the measurement of outcome has become central to health care policy and practice.

The Shorter Oxford Dictionary defines outcome as 'that which comes out of something; visible or practical result, effect or product' (3). Within Physical Medicine and Rehabilitation [PM&R] a broad range of valid outcomes exist. For a newly diagnosed patient with rheumatoid arthritis, reduction of inflammation and pain may be

an important short-term goal. Helping the patient to retain their job may be important in the medium term. Maintenance of an adequate level of quality of life may be a valid goal for the long term. For the patient admitted to hospital after stroke, after overcoming any initial risk to survival, recovery in cognition, speech and physical function may be important short-term goals. In the medium term, independent living may be a valid goal, or, for younger patients, return to work. All are valid goal-orientated outcomes within their chosen context, and all require measurement. Consequently a broad range of 'outcome measures' have been developed, some of which involve a clinician or therapist assigning values to specified tasks undertaken by a patient, some where the patient, carer or a proxy fill in a questionnaire. The Barthel Index (4) is a classic example of the former, the Arthritis Impact Measurement Scale [AIMS] (5), the latter.

This chapter asks how do we identify appropriate outcomes? How do we judge the quality of an outcome measure? How should we use such measures? In short, what are the principals and practice of measuring outcome?

HOW DO WE IDENTIFY APPROPRIATE OUTCOMES?

In 1980 the World Health Organisation published the original version of the ICIDH (6). This provides a conceptual framework for looking at the consequences of disease. In the original, disease may give rise to impairment, defined as 'any loss or abnormality of psychological, physiological, or anatomical structure or function'. This may give rise to disability, defined as 'any restriction or lack of ability to perform an activity in the manner or within the range considered normal for a human being'. Impairments directly, or through disability, by interacting with the physical and social environment can lead to handicap, defined as a 'disadvantage for the given individual... that limits or prevents the fulfilment of a role that is normal'. It has been suggested that handicap reflects the circumstances that people find themselves in as a result of the interaction between impairment and disability, and the broader physical and cultural environment within which people live (7). Recently, Bent et al. have incorporated the notion of moderators and mediators into the model, showing how, for example, psychosocial or environmental factors may mediate between impairment/disability and handicap (8). The importance of extrinsic factors has been given further emphasis in the most recent revision – ICF, where the nomenclature has changed to 'impairment, activities and participation'. Virtually all published work to-date uses the original nomenclature.

In the ICF impairments are subdivided into structural and functional domains In Figure 1, functional impairments are illustrated [the two are very similar in nomenclature], along with activities [disability in ICIDH-1 terms] divided into various sub-categories such as Daily Life Activities. This is then, for example, further subdivided into *Keeping Self Clean, Washing, Dressing, Activities related to excretion, and so on.* Participation (handicap) emphasises the limiting factors placed on the individ-

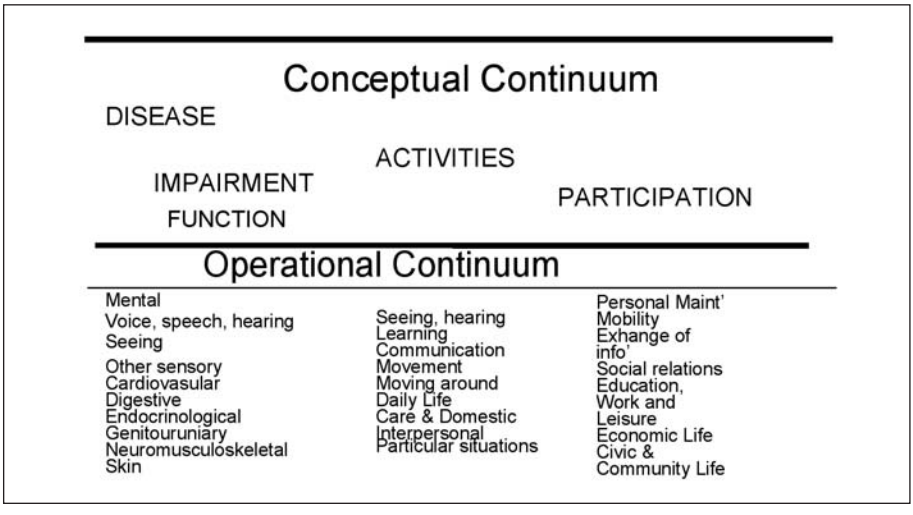

FIGURE 1. The International Classification of Functioning, Disability and Health: Impairment, Activities and Participation.

ual by the environment, and society's failure to respond to the needs of the individual.

Quality of Life [QoL] is not covered by the classification. Measures that address impairment and disability have traditionally been referred to as measures of health status (5, 9). More recently it has become usual to describe these same dimensions as 'health related quality of life' [HRQoL] (10). However, there is a tradition of measuring quality of life, grounded in the notions of life satisfaction and well being, that demonstrates that health status [or HRQoL as it is now called] contributes relatively little to life satisfaction or well-being (11). In this way it is quite possible to have a patient who, despite high levels of impairment and disability, reports a good QoL, or vice versa. Thus it is important to note that there may be a fundamental difference between a subjective patient-perceived QoL, and the more 'objective' measurement of health status.

With over a thousand impairments listed in the ICIDH and hundreds of limitations in activities, choosing relevant outcomes is a complex task. The critical issue is to ask what aspect of the outcome continuum is any intervention expected to affect? It is possible that many facets may be affected, for example, pain, fatigue, physical function and work. This may require a choice between different outcome measures, opting for a so-called 'generic' questionnaire that has a profile of these facets, or a recognition that time and resources need to be committed to the measurement process in order to capture all relevant outcomes. In this context, ceteris paribus, more time can be given to measuring outcome within a research programme than in routine clinical practice, usually because there is additional funding for the former.

The importance of the conceptual basis, including an understanding of potential mediators, cannot be understated in the context of measuring

outcome. Unless there is a precise understanding of the domain [s] to be measured, closely targeted at where the intervention is expected to impact, then the choice of measure may be inappropriate, and the measurement may be unreliable and off-target, so resulting in all the consequences of imprecise measurement.

HOW DO WE JUDGE THE QUALITY OF AN OUTCOME MEASURE?

Given a clear notion of what needs to be measured, the next task will be to identify [or if absolutely necessary develop] an appropriate outcome measure. What are the characteristics of a good outcome measure?

There are two sets of complementary information which help us decide about the quality of an outcome measure. Traditional Test Theory provides all the quality parameters that are familiar under the label psychometric theory. Psychometrics is concerned with the precision of measurement, and expresses this in terms such as reliability and validity (12). Reliability refers to the dispersion of the theoretical distribution of measurements while validity refers to its central tendency (13). There are many books that describe these attributes in detail (14). At a simple level we would expect to see evidence of test-retest reliability of an instrument, demonstrating stability in the instrument over repeated measures. Where appropriate, we would also expect to see evidence of agreement between different professionals when grading patients, and we would look for appropriate Kappa statistics to support this.

Traditionally, we would also expect to see an appropriate level for Cronbach's Alpha (15). This indicates the degree of connectiveness of a scale. We often see Cronbach's Alpha as a measure of internal consistency, and a figure of .85 or above has become the accepted level of internal consistency. Sometimes *split-half reliability* is presented which is another way of looking at internal consistency. Usually the items are randomly allocated to two scales, and we would expect to have a high correlation between the two halves. Recent work has shown that while coefficient α (Cronbach's Alpha) can be used as an indication of the connectedness of items within a scale, it does not confirm unidimensionality (16). It is quite possible to have two or more dimensions in a large item set which nevertheless give a high α.

There are many aspects of validity. Early in the development of a new instrument concern may be focussed on *face validity* - whether the items that comprise the new measure are credible. This is one aspect of *content validity*, which seeks to make sure that the items selected cover the concept to be measured. A panel of experts may have been recruited or, as is more appropriate for self-completed instruments, qualitative interviews may have been undertaken with patients who have the condition under scrutiny, in order to find out what is considered to be the most important consequences of that condition.

Having ensured credible content, the *criterion-related validity* could be assessed. Generally this is undertaken by comparing the results against some gold standard. Perhaps the new measure is shorter and easier to

work with than another, which is nevertheless recognised to do the job well. Comparing the two [usually by correlation] would give us the *concurrent validity* of our new measure. Another way to provide criterion-related validity is to demonstrate that it accurately predicts some future event; this would be *predictive validity*. As it requires monitoring for the future event, this is rarely done.

Usually no gold standard exists and a *construct validation* is undertaken. This involves gathering evidence using other types of validity such as *convergent* or *discriminant validity*. Here the new scale should correlate positively with other instruments measuring the same construct [converge] or not at all with those which measure different construct [discriminate]. Known groups validity offers a similar approach where the scale should clearly discriminate between those, for example, with and without the condition. Whichever approach is adopted, construct validation is seen as an ongoing process (14), where evidence accumulates over time to support the validity of the instrument.

Finally, in Tradition Test Theory, recent emphasis has been given to the ability of the instrument to detect change [responsiveness] (17). This may become to be seen as an essential part of validity, for it is saying that the instrument should be able to show change over time – a form of known groups validity. Recently the "effect size" (18) has been introduced to show how sensitive a measure is to change. Instead of looking at the crude difference between measures, as was often the case in the past, the mean score at time 2 is subtracted from the mean score at time 1, and the answer is divided by the standard deviation of the score at time 1. An effect size of .2 is considered small, .5 medium and .8 large, so the greater the effect size, the more sensitive the instrument is in picking up change. A positive or negative effect size simply reflects the direction of change, and this will vary between measures.

In contrast to Traditional Test Theory, Modern Test Theory emphasises characteristics of internal construct validity, item bias and the scaling properties of the instrument. The Rasch unidimensional measurement model is central to this approach (19). It is a measurement model that defines the requirements of fundamental measurement for manifest data. Many measures of outcome in use in PM&R focus on attributes that are not directly measurable, rather a latent trait such as pain, self esteem or dependency. Such measures give a 'manifest score' of the construct being measured. Consequently most outcomes are expressed as ordinal manifest scores, indicating some rank on a perceived underlying latent trait. In contrast, a few measures, mostly of impairment such as grip strength, or range of motion, deliver interval level measurement of the kind commonly associated with the physical sciences. This latter kind of measurement has been described as fundamental measurement (20). As the Rasch model offers this quality of measurement for manifest variables, outcome measures are increasingly being subjected to scrutiny by fit of their data to the Rasch model (21-24). Where data fit the Rasch model, and local independence of items is confirmed [that is there are no as-

sociations left in the residuals after the 'Rasch' factor has been extracted] then data that fit the Rasch model are deemed to be unidimensional. Unidimensionality is fundamental to measurement. This is the rationale behind the summation procedure in Likert scaling. Here, items are considered to be parallel instruments and through combining item scores targeted at a single dimension, random error that occurs with respect to individual items will be partly averaged away (25).

Another important aspect of quality of outcome measures that can be investigated through Rasch analysis is Differential Item Functioning [DIF]. Originally called 'item bias', an item is biased if equally able individuals, from different groups, do not have equal probabilities of doing the task (26). Figure 2 illustrates how a question on an outcome scale may differ between countries. At any given level of the trait being measured [in this case it is physical disability] the probability of response to the item differs significantly across countries. In health outcome measurement DIF may occur in several ways, for example by gender and age, by clinical subgroup or by culture. If DIF is present, then scores cannot be compared across groups. Thus, international clinical trial data should not be pooled where DIF exits for culture.

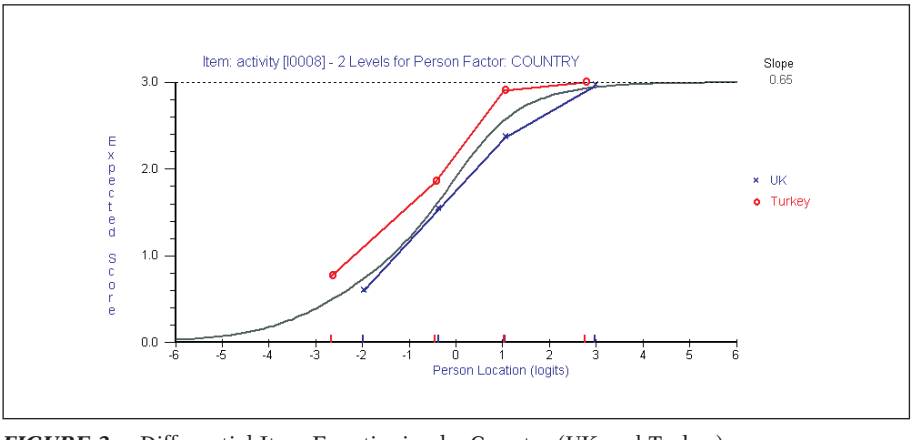

FIGURE 2. Differential Item Functioning by Country (UK and Turkey).

Finally, in Modern Test Theory, the true scaling properties of the outcome measure can be revealed. Consider a scale with eight items, each scored 0-3. In measurement terms, those points that mark the transition between one category and the next – thresholds – are critical to the process. Thus eight items with four categories have 24 thresholds, eight of each marking the transition between 0 and 1; 1 and 2, and 2 and 3. Figure 3 shows how these thresholds are placed on the underlying metric scale (the lower part of the graph – the upper being the distribution of patients). There are gaps in the thresholds along the continuum, and clusters. One patient may have to move only a small metric distance to gain, say, 5 points, another a considerable distance. Although one advantage of

data that fit the Rasch model is that much of the ordinal distortion is smoothed away in the middle of the scale, it is clear why the calculations of change scores are invalid for ordinal scales.

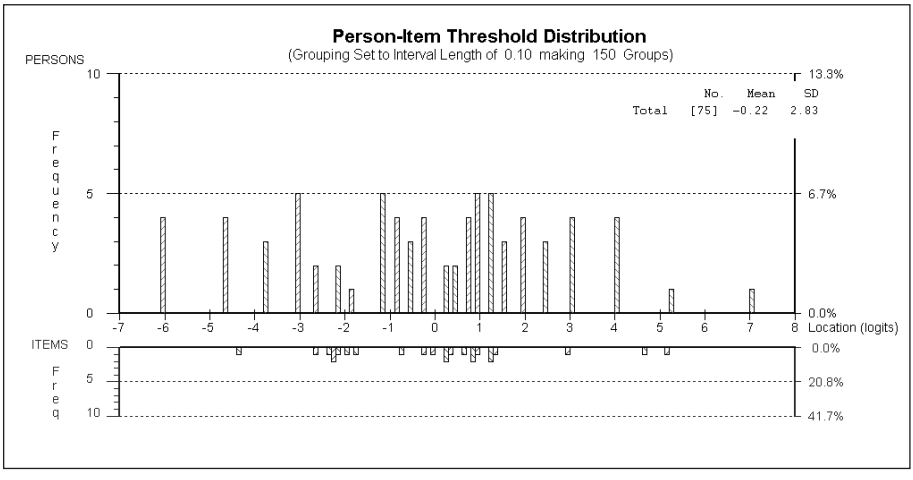

FIGURE 3. Person and item distribution of ordinal scale after fitting data to the Rasch model.

HOW SHOULD WE USE SUCH MEASURES?

It becomes clear that both Traditional and Modern Test Theory bring together a set of parameters for judging the quality of outcome measures. Given the reliability and validity of an instrument, knowing the level of measurement of the scale is crucial to making proper use of the instrument. Some measures of impairment and function such as grip strength, range of motion or walking are at the interval level and, after consideration of distribution, can be used with parametric statistics such as t-test, ANOVA or regression. However, it is important to recognise that most of the current questionnaire-based outcome measures used in PM&R preclude arithmetic operations and the calculation of attributes such as change scores or effect sizes are not valid under these conditions.

One way of overcoming this limitation it that, where data fit the Rasch model, ordinal scores are transformed to interval level logits. Else non-parametric statistics should be used at all times. Ordinal data 'are seldom in practice, and never in principle, sufficiently interval to justify arithmetical calculations employed by means, variance, regressions and factor analysis' (27).

Another important aspect of using outcome measures is what to do with missing values. These may be a particular problem for self-completed questionnaires, but may also arise in professional administered instruments (e.g. where patients become fatigued and cannot answer all the questions, or all the tasks). Missing data may also arise through poorly managed quality control procedures at the data entry stage.

Data imputation techniques are becoming increasingly popular, with the emergence of easy to use software (28). However, once again, when data fit the Rasch model, estimates of person ability are obtained which are not affected by missing values [except by loss of precision in the estimate].

SUMMARY

Measuring outcome requires a clear understanding of the measurement task a hand. This conceptualisation of the appropriate outcome space enables a choice of relevant instruments. All such instruments should meet the classical psychometric requirements of reliability, validity and responsiveness. Increasingly, such instruments should also demonstrate adequate internal construct validity [unidimensionality] and freedom from item bias. Once the data have been collected, appropriate analytical techniques should ensue that the findings are not compromised through the inappropriate use of arithmetic operations and choice of the wrong statistical procedures (29).

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CHAPTER 3
GENERIC AND SPECIFIC MEASURES FOR OUTCOME ASSESSMENT IN ORTHOPAEDIC AND RHEUMATOLOGIC REHABILITATION

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In recent years, with the growing demand for outcome data to verify quality of care, the development of effective outcome measures has become a major thrust of health research and has contributed to a better understanding of the relationship between outcomes and specific elements of health care (1-3). An outcome measure is essentially an assessment of change which judges how the patient is now as compared with previously, in order to study the effect of the health care process on the patient's health and well-being (4). This assessment often involves the determination of the meaning of a measurement, defined as the process of assigning numerals (or categorical names) to variables to represent quantities of characteristics according to certain rules (5).

Many measures have been used in orthopaedics and rheumatology to assess outcome in all forms of intervention (1, 3). As in other fields, they mainly focus on: a) clinical signs and symptoms (physiological and biological); b) physical and/or cognitive functioning; c) well-being and emotional status; d) social functioning; e) satisfaction with care and other personal con-

structs (stigma, life satisfaction, spirituality, etc.); f) health-related quality of life (HRQOL).

This paper reviews the literature and discusses, in particular, the major issues regarding measures of physical function (e.g. mobility or daily activities) and health status, including some so-called HRQOL instruments. Over the past 20 years there has been a growing recognition of the patient's point of view as an important component in the assessment of health care outcomes, and increasing interest in HRQOL as a consequence of the growing burden of chronic diseases, longer life expectation, the increasing number of health intervention alternatives, and greater emphasis on humanising health care (6). In addition, decision-making on issues of cost-effectiveness across health inputs and resource allocation across health programs is likely to be more sound if informed by HRQOL evidence.

The most common formats (1-4) used for measurement (alone or in combination) are: a) observation/examination – when health professionals (or others) make a judgement and rate some parameters on the basis of subjective evidence and with minimal input from the patient; b) patient report – in the form of a structured interview or, more often, of a self-completion questionnaire in which the client is asked to report, with minimal influence from other persons, experienced phenomena (such as pain, distress, fatigue and so on), or give a relativistic evaluation correlated to his/her perspectives/expectations (e.g. patient satisfaction). Sometimes, a proxy/caregiver account is collected when the client cannot self-report or when the examiner is interested also in alternative information.

The concept of interest can be measured by a single question, rating or item (summary item) or – more often – by a series of them. The response format is generally in the form of category rating scales with labelled tick boxes for choice of response (multiple-choice items, Likert-type items, dichotomous responses), but other formats are also used, such as visual analogue scales (VASs), semantic differential scales or other (7).

When the component ratings are presented separately for each dimension, a "profile" is formed. Contributions from the component scores may be combined to create a new single expression (an arithmetical overall score), termed "index", only when the items measure a single underlying construct (a construct, such as functional status or health-related quality of life, is a complex phenomenon containing multiple intangible attributes that cannot be easily isolated) (2-4). How items are combined to determine the overall score (sum, frequency count, etc.), and how they can be statistically processed, depends on the type (nominal, ordinal, interval, or ratio) and distribution of the data.

In choosing measurement instruments of physical function and health status, a common distinction is drawn between generic and specific measures (1): the first provide a broad picture of health status across a range of conditions, whereas the latter are more sensitive to the disorder under consideration and are therefore more likely to reflect clinically important changes. Furthermore, a widely used taxonomy subdivides "qual-

ity of life" measures into two supplementary categories: preference-based/utility measures (an approach assessing the value or desirability of a state of health against an external metric), and individualised measures (in which respondents are encouraged to identify and weight the most important aspects of their own life). Where necessary, these scales can be supplemented with specialised domain-specific scales (for the assessment of psychological well-being, social role functioning, etc.). Even if it is generally recognised that in this field the outcome of treatment is multidimensional, it is important in clinical practice to avoid using a long sequence of instruments with many overlapping items, as this is tiresome to respondents and expensive to administer and analyse.

GENERIC MEASURES

Many medical, surgical and rehabilitation interventions are designed to improve the quality rather than extend the duration of the patient's life. A direct measure of quality of life (QOL) is required to assess the benefit of such interventions. Acknowledgement that QOL is a valid outcome measure in clinical trials is hampered by a number of facts, including the conceptual vagueness of QOL, the use of assessment tools of dubious validity and reliability, inappropriateness of the methods used and weakness of the statistical analyses applied. While there is general agreement on the potential value of QOL measures as key evaluation variables, there is no clear agreement on a definition of QOL. As noted by Deyo and Patrick (8), conceptions relevant to health and QOL are various, scattered across many disciplines, and use many different labels (e.g. health status, functional status, health-related quality of life, quality of life). Generally, notions of quality of life are not specified but are considered to be implicit in the measure used, i.e. they are more inferred than explained. Nonetheless there seems to be acceptance that health-related quality of life is "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad-ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their relationship to salient features of their environment" (9). There is less agreement on which precise dimensions to include (10, 11).

Health status measures over the last two decades have gradually broadened their sphere of interest to embrace a wide spectrum of concepts including "quality of life". Generic health-status measures purport to be broadly applicable across different types and severities of disease, medical treatments or health interventions, and in a wide range of demographic and cultural sub-groups. They should also be able to measure the burden of illness of populations suffering from chronic conditions as compared with normals (11). There has been an increasing use of generic measures of HRQOL (12). Their use permits the comparison of different impairments, illnesses, populations, and programs, one of the most important objectives for policy analysis and decision making. As many

people with musculoskeletal disorders also have comorbidities, there is a case for using a generic measure in these patients to obtain a more holistic view of health-related quality of life,.

These generic measures (commonly developed for descriptive epidemiological or social science research applications) may provide a profile of scores for different components of health status and HRQOL, or operational definitions of several constructs summarised by a single index value. A concern with generic instruments is that they are sensitive to any changes in health. So, if the primary interest is of a specific nature, other changes in general health will potentially act as interference obscuring the particular outcome of interest. Moreover, in a generic measure a number of questions may be inappropriate or irrelevant for a particular problem while, on the contrary, there may be too few items tapping a specific area (this, to ensure a reasonable length of the generic questionnaire).

The most popular generic measures in rheumatology are: the Medical Outcomes Study 36-Item Short-Form Health Survey, the Sickness Impact Profile, and the Nottingham Health Profile (Table 1).

TABLE 1. Measurement specifications of selected generic instruments.

*Instrument**	*Item number*	*No. of levels*	*Administration method °*	*Scoring options §*	*Completion time (min)*
SF-36	36	3-6	S, I, P	Pr, SS	10-15
SIP	136	2 (y/n)	S, I, P	Pr, SS, SI	20-30
NHP	38	2 (y/n)	S, I	Pr	10-15
EuroQol	6	3	S, I	SI	7-10

* SF-36 = Medical Outcomes Study 36-Item Short-Form Health Survey; SIP = Sickness Impact Profile; NPH = Nottingham Health Profile; EuroQol = European Quality of Life Questionnaire.
° S = self-administered; I = interviewer; P = proxy.
§ Pr = profile; SS = summary scores; SI = single index.

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) (13) is a generic instrument with scores based on 36 responses to individual questions, which are subdivided into 8 scales, each of which measures a health concept. These scales include function domains and aspects of well-being, as follows: 1. Physical functioning (10 items) – extent to which health limits activities such as self-care, walking, climbing stairs, bending, lifting, and other moderate and vigorous activities; 2. Social functioning (2 items) – extent to which physical health or emotional problems interfere with normal social activities; 3. Physical role functioning (4 items) – extent to which physical health interferes with work or other daily activities (patients accomplish less than they wanted, are limited in kinds of activities they can do, etc.); 4. Emotional role functioning (3 items) – extent to which emotional problems interfere with work or other daily activities (including decreased time spent, accomplishing less than wanted, not working as carefully as usual); 5. Mental well-being (5 items)

– general mental health, including depression, anxiety, behavioural-emotional control, and general positive affect; 6. Vitality (4 items) – feeling energetic and full of pep versus tired and worn out; 7. Bodily pain (5 items) – intensity of pain and effect of pain on normal work, both inside and outside the house; 8. General health perceptions (5 items) – personal evaluation of health, including current health, health outlook, and resistance to illness. The SF-36 survey also includes a single-item measure of health transition, which is not used to score any multi-item scales. These eight scales, weighted according to normative algorithm, are scored from 0 to 100, with higher scores reflecting better quality of life (13). Recently, algorithms have been developed also to calculate two psychometrically based summary measures: the Physical Component Summary Scale Score (PCS) and the Mental Component Summary Scale Score (MCS) (14, 15). The PCS and MCS provide greater precision, reduce the number of statistical comparisons needed, and eliminate the floor and ceiling effects noted in several of the sub-scales (14, 16, 17). The SF-36 takes about 5 minutes to complete, when self-administered. Unfortunately, many older adults and patients describe difficulty in doing so and prefer the standard interview. With the possible exception of the summary scales, the instrument seems more relevant to groups with lower impairment because of the potential "floor" effect.

The Sickness Impact Profile (SIP) (18) contains 136 items grouped into 12 dimensions of daily activity: ambulation, body care and movement, mobility, social interaction, emotional behaviour, alertness, communication, home management, recreation and pastime, sleep and rest, eating, and work. Respondents check those items that apply to them at the time of the interview. Each item is weighted depending on the relative severity of dysfunction implied by each statement. For each dimension, the scores are summed and expressed as a percentage of the maximum score possible. Three summary scores are also calculated: total score (includes all domains), a physical score (ambulation, body care and movement, and mobility), and a psychosocial score (social interaction, emotional behaviour, alertness, and communication) (19). Higher scores represent greater dysfunction. The SIP can be administered by an interviewer or self-administered. Although it is easy to administer and score, the SIP is relatively time-consuming, taking approximately 30 minutes to complete (20).

The Nottingham Health Profile (NHP) (21) is intended for primary health care to provide a brief indication of a patient's perceived emotional, social and physical health problems. The questionnaire consisted of two parts, but only part I is now used: it contains 38 yes/no items that can be grouped into 6 domains (physical mobility, pain, sleep, social isolation, emotional reactions, and energy level) with each question weighted for severity. The sum of all weighted values in a given domain represents a continuum between 0 (best health) and 100 (worst health) (22). There is no summary score. The NHP has been used in both self-administered and

interview modes; its profile has been demonstrated to be a valid measure of disease activity and outcome in rheumatoid arthritis (23).

A second major category of generic measurements is represented by the functional disability indicators. Presentation of the generic instruments devoted to quantification of basic activities of daily living (ADL) (1), such as eating, washing self, using the toilet, dressing and so on (e.g. the Barthel Index, or the Functional Independence Measure, and other scales), is beyond the scope of this paper. However, in rheumatology the ability to perform a wider range of activities covering both ADL and "Instrumental ADL" (IADL) (activities needed for continued community residence, such as preparing meals, shopping, housework, etc.) is often evaluated. An interesting generic instrument measuring ADL and IADL in less severely disabled people is the Groningen Activity Restriction Scale. In addition, a significant disease-specific measure for the field of rheumatoid arthritis is the Stanford Health Assessment Questionnaire (HAQ) in its modified version (see next paragraph).

The Groningen Activity Restriction Scale (GARS) (24, 25) was developed as an instrument to quantify the degree of functional capacity in performing self-care and household activities independently. Like the HAQ the GARS concentrates on ADL (i.e. self-care activities) but, contrary to the HAQ, it also measures problems in the performance of IADL. The GARS has 18 items divided across 2 sub-scales: an ADL sub-scale (dressing, washing oneself, etc.) and an IADL sub-scale (mainly household activities). The response categories of the GARS range from 1 = fully independent without any difficulty; 2 = fully independent but with some difficulty; 3 = fully independent but with great difficulty; 4 = not fully independent, need someone's help; to 5 = completely dependent on help. The GARS has been found to be sensitive to change in patients with rheumatoid arthritis (26).

All the above generic disease measures do not capture the individual value that a given respondent may assign to a particular health state, and two individuals may rate differently the same health state depending on the value they assign to a symptom or impairment and their willingness to accept trade-offs between benefits and risks. In the context of health-related quality of life evaluation, preference-based (or utility) measures are specifically designed to assess the value or desirability of a particular health status/outcome. They provide a final score on a 0-1 scale where 0 is the worst possible imaginable state (or death) and 1 is perfect health. Rating can be elicited from different groups of individuals such as patients, health professionals, or the general public. These ratings can hence be used as quality of life adjustment weights to calculate, for example, quality-adjusted life years and similar measures, which can then be used in economic evaluations (27). A substantial criticism is that different weighting methods (e.g., those based on the general population vs. on

people with disabilities) may provide very different answers, and that persons with no direct knowledge of a condition are not in a good position to suggest preferences (the so-called "disability paradox"). There are two approaches to utility measurement of HRQOL. The first is to classify patients into categories based on their responses to questions about their functional status (preference-classification systems). Combining these categories or dimensions results in descriptions of patients' overall health states. The European Quality of Life Measure (EuroQol) and the Health Utility Index are based on this approach.

The European Quality of Life Questionnaire (EuroQol) (28) is a standardised, self-administered questionnaire that classifies the patient into one of 243 health states. It consists of a 5-part questionnaire (probing deficits in mobility, self-care, main working activity, social relationships, pain and mood), and a VAS on which patients rate their own health status (0-100). EuroQol was specifically designed to complement other quality of life measures such as the SF-36, NHP, SIP or disease-specific measures (28, 29). EuroQol is self-completed by respondents and ideally suited for use in postal surveys, clinics and face to face interviews (Table 1). It is cognitively simple, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire.

The Health Utilities Index (HUI) systems were developed as means to provide a comprehensive description of health status and obtain utility scores reflecting health-related quality of life (10). The system measures 8 attributes: vision, hearing, speech, physical mobility, dexterity, cognition, pain and discomfort, and emotion. The index is self-administered and provides a single, overall summary score. It has been administered by face to face interview and also by telephone. The use of HUI in clinical studies in reference to a wide variety of conditions and in numerous countries has been reported (30, 31). HUI provides a comprehensive description of the health status of subjects in clinical studies.

The second approach to utility measurement is to ask patients directly to assign a value to their overall health. The most widely used techniques are the rating scale (RS), the time trade-off (TTO) and the standard gamble (SG). The RS typically asks respondents to place health states on a line with clearly defined end-points (10). The TTO presents the respondent with the task of determining what amount of time they would be willing to give up to obtain a better as opposed to poorer state of health (10, 31). With the SG, the respondent is asked to make a choice between two options (3, 10). The first option is the certainty of living for the rest of one's life in a particular health condition; the other option is a gamble with two possible outcomes, living for the rest of one's life in perfect health or immediate death. The changes in the gamble are varied to determine the point at which a respondent is indifferent to the choice between the certain option and the gamble. The SG is a classic method of

measuring utilities, and is strongly preferred by economists. However, the poor validity and the lack of responsiveness of SG utilities demonstrated in patients with chronic musculoskeletal disease is problematic (32-35). Moreover, the TTO and RS have the advantage of being easier to understand and requiring less administration time than the SG (10, 30, 31).

SPECIFIC MEASURES

The principal intended advantage of a specific measure is to contain many items relevant to patient groups undergoing treatment for a specific disease or condition (disease-specific measures), or for a specific region or site of the body (region- and site-specific measures). Conversely, if a measure has to cover a wide range of disorders, a number of questions may be inappropriate or irrelevant for any one specific problem while, in order to keep a reasonable length, it is restricted in the number of items it can devote to each the tapped areas (1, 2).

Disease-specific measures

Disease-specific measures are designed to assess specific diagnostic groups or patient populations, often with the goal of measuring responsiveness to treatment or "clinically important" changes. [These are changes that clinicians and patients think are discernible and important, have been detected with an intervention of known efficacy, or are related to well-established physiologic measures.] An obvious disadvantage of some disease-specific measures is that they do not allow comparative judgements between outcomes of diverse treatments for patients with different health problems, e.g. for resource allocation studies (4). In this case, the combined use of these disease-specific measures and generic measures is suggested. But there are broad disease-specific measures (such as the Arthritis Impact Measurement Scales, the McMaster Toronto Arthritis Patient Preference Questionnaire, the Functional Status Index, the Health Assessment Questionnaire, the Bath Ankylosing Spondylitis Functional Index, and the Quality of Life Questionnaire of the European Foundation for Osteoporosis) that include general aspects of functional status together with specific references to states or changes of particular concern to the target population. So, generic measures and these disease-specific measures overlap considerably.

The Arthritis Impact Measurement Scales (AIMS) is a multidimensional health status instrument, widely used in arthritis patients (36). It consists of 9 scales: mobility, physical activity, dexterity, household activities, activities of daily living, social activities, anxiety, depression, and pain. Each scale contains 4 to 7 items and each item contains 2 to 6 possible responses (36). Later, Meenan et al. completed a major revision of AIMS, called AIMS2 (37, 38). AIMS2 has 78 questions, of which the first 57 are aggregated into 12 scales: mobility level, walking and bending, hand and finger function, arm function, self-care tasks, household tasks, social activity, support from family and friends, pain, work limitation, lev-

el of tension, and mood. Meenan et al. (37) identified three dimensions for the variables represented by the AIMS2 health status scales (with arthritic pain and work as separate dimensions): a physical dimension, a psychological dimension and a social interaction dimension. The physical functioning component consists of 6 sub-scales: mobility level (5 items), walking and bending (5 items), hand and finger function (5 items), arm function (5 items), self-care tasks (4 items), and household tasks (4 items). For each item, patients are asked to rate frequency of difficulties in performing the specified task over the past month, using a 5 point scale that ranges from "all days" (1) to "no days" (5). The physical functioning component score is calculated by: (a) adding items in each of the 6 sub-scales to obtain a raw sub-scale score; (b) normalising each sub-scale score to a range of 0-10; (c) summing the 6 normalised sub-scale scores, and (d) dividing by 6. It ranges from 0 to 10, where 10 reflects poor status. Scoring procedure for the pain scale involves summing the 5 items to derive a raw score and then normalising this score in a range of 0 (no pain) to 10 (severe pain). Psychological functioning is assessed by 2 sub-scales: depression (5 items) and anxiety (5 items). Social functioning is also assessed by 2 sub-scales, social activity (5 items) and family support (4 items). The scoring procedures for the psychosocial components are identical to those for the physical functioning or the pain components. AIMS2 is a sophisticated instrument whose strengths are its comprehensiveness and its self-administration. The only limitation of AIMS2 is the time required for completion, scoring and analysis.

The McMaster Toronto Arthritis Patient Preference Questionnaire (MACTAR) (39) is a functional index that measures change in impaired activities (selected by each patient), and change in rheumatoid arthritis disease activity. The term "semi-structured interview" rather than questionnaire best describes the MACTAR because interviewers fill out the answers on standard forms. The MACTAR comprises 2 parts. The first part starts with a question about patient perceived change in arthritis activity (7-point Likert scale). In addition, patients are asked to consider daily routine problems they face as a result of their disease. Once they finish identifying problems spontaneously, the interviewer reads a series of probes to assist the patient. These probes are open-ended questions covering broad areas of function: domestic care, self-care, professional activities, leisure activities, sexuality, social interaction, and roles. Patients are allowed to identify up to 10 problems. Subsequently, they are asked to identify and rank the 5 most important problems, i.e. the activities they most eagerly wish to perform without pain or discomfort. The second part of the interview contains questions on the state of physical, social and emotional function and overall health (including the change in ability to perform the five activities selected in the first part). When the questions reveal a less than optimal status, a second question investigates whether this is due to arthritis. Higher scores on the MACTAR reflect patient-perceived improvement. Scores vary from 11 to 47. The MACTAR interview

is a valid and highly responsive instrument to assess change in functional ability of patients with early RA with active disease (39) and in rheumatoid arthritis clinical trials (40). It provides insight into problems (mainly of physical function) that really matter to patients. For standard clinical trials and clinical care, feasibility of the MACTAR seems limited (due to the cost in time and personnel) and the simpler Health Assessment Questionnaire (see below) remains the instrument of choice.

The Functional Status Index (FSI) (41) was developed by Jette and Denison as part of the Pilot Geriatric Arthritis Project. It measures the degree of dependence, pain, and difficulty experienced in performing a series of daily activities. There are 2 forms of the FSI: the original version contains 45 items, and takes 60-90 minutes to complete; the short one contains 18 items, and takes 20-30 minutes to complete. The instrument is administered by an interviewer. The validity, reliability, and responsiveness of the instrument have been established, although it is not commonly used in pharmacodynamics studies. The FSI may be applicable in assessing patients with rheumatoid arthritis and generalized osteoarthritis, although generally the HAQ or AIMS instruments have been more frequently employed.

The Stanford Health Assessment Questionnaire (HAQ) (42) is designed – in its most widely used form – as a 20-item self-administered questionnaire, examining difficulties in performing 8 activities of daily living (dressing and grooming, rising, eating, walking, hygiene, reach, grip and outside activities). For each item, patients are asked to rate the level of difficulty over the past week on a 4-point scale, which ranges from 0 (no difficulty) to 3 (unable to perform). The final HAQ score is the average score of the 8 categories and ranges from 0 to 3; the higher the score the greater the disability level. The HAQ has been translated into several different languages. A user's guide is available (42). There have been two modifications to the HAQ in rheumatoid arthritis (RA) (Table 2): the modified HAQ (MHAQ) and the RA-HAQ**.** The MHAQ is a subset of 8 items taken from the 8 categories. Designed by Pincus from the original 20-item HAQ (43), it has had extensive use in many rheumatic disorders. The MHAQ was conceived to address several perceived problems with the HAQ: the latter was thought to be too long (20 questions and a list of more than 20 aids and/or devices), and perceived as complicated and time-consuming to score. By contrast, the MHAQ does not consider aids or devices, has only 8 questions, is simple to score, and has the same range as the HAQ (43,44). The total difficulty score (MHAQ score) is expressed as the mean score and requires a minimum of 6 responses to be computed. The 3rd HAQ is called the RA-HAQ because its 8 questions were derived from the HAQ and because it was validated in an international sample of RA patients. The RA-HAQ differs from the MHAQ in 3 of the 8 questions (44) (Table 2). The RA-HAQ has near perfect characteristics according to the Rasch item response theory model and is scored on a 0-3 scale.

TABLE 2. The HAQ, MHAQ, and RA-HAQ questionnaires item sets (44).

HAQ	*MHAQ*	*RA-HAQ*	*Question*	*Sub-scale*
*	*	*	Dress yourself	Dressing
*			Shampoo your hair	and grooming
*		*	Stand up from a chair	Rising
*	*		Get in and out of bed	
*			Cut your meat	Eating
*	*	*	Lift a full cup or glass to mouth	
*			Open a new carton of milk	
*	*		Walk outdoors on flat ground	Walking
*		*	Climb 5 steps	
*	*	*	Wash and dry entire body	Hygiene
*			Take a bath	
*			Get on and off the toilet	
*			Reach and get down a 5 lb. object	Reach
*	*	*	Bend down and pick up clothing	
*		*	Open car doors	Grip
*			Open jars (previously opened)	
*			Turn taps on and off	
*		*	Run errands and stop	Activities
*	*		Get in and out of car	
*			Do chores	

The Fibromyalgia Impact Questionnaire (FIQ) (45) is an assessment and outcome instrument developed to measure the components of health status that are believed to be most affected by fibromyalgia. The first part contains 10 items and focuses on the patient's ability to perform daily tasks involving large muscles (i.e. cooking, cleaning, walking, shopping, homemaking, socialising, mobility, etc.). The responses are scaled in a Likert format from 0=always able to do, to 3=never able to do. The 10 scores are added together and divided by the number of the valid ones to yield a physical functioning score. The next 2 items refer to the number of days felt good and the number of days the patient missed work. The last 7 items (ability to do one's job, pain, fatigue, morning tiredness, stiffness, anxiety, and depression) are measured by VAS. The instructions for the first part and the 7 VASs ask patients to describe their abilities or feelings in the past week. The items "physical impairment", "number of days felt good", and "number of days missed work" are subjected to a normalisation procedure so that these scores can be expressed on a scale ranging from 0 to 10, with 10 indicating greater impairment. A total score of the FIQ is calculated by adding the physical functioning score, number of days felt good, pain, fatigue, morning tiredness, stiffness, anxiety, and depression, and ranges from 0 to 80, with 80 indicating maximum fibromyalgia impact.

The Bath Ankylosing Spondylitis Functional Index (BASFI) (46) was designed by a team of rheumatologists, physical therapists, and research associates, with a major input from patients with ankylosing spondylitis, and has been selected as a core measure of function in this disease (47). It consists of 8 questions on activities relating to the functional anatomy of patients, and 2 additional questions that assess the patient's ability to cope with everyday life. The questions reflect activities of daily living and include: "putting on socks or tights without help or aids", "bending forward from the waist to pick up a pen from the floor without an aid", "reaching up to a high shelf", "getting out of an armless dining-room chair without using your hands", "getting up off the floor without help from lying on your back", "standing unsupported for 10 minutes withosut discomfort", "climbing 12-15 steps without using a handrail or walking aid", "looking over your shoulder without turning your body", "doing physically demanding activities", and "doing a full day's activities whether at home or at work". Each question is answered on a 10-cm VAS. The mean of the 10 scales gives the BASFI score (0-10) (47).

The Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) (48) was developed by the European Foundation for Osteoporosis as a specific self-administered questionnaire for patients with vertebral fractures. The QUALEFFO includes 48 questions (subsequently reduced to 41) and 6 VASs. The questions concern the following 5 domains: pain, physical function (activities of daily living, jobs around the house, moving), social function (leisure and social activities), general health perception and mood. A multi-centre case-control validation study demonstrated good test-retest reliability and internal consistency of the questionnaire, as well as the ability to discriminate between women with vertebral fractures and non-fracture controls. Among the osteoporosis-targeted questionnaires, the QUALEFFO is one of the most widely used, but very few studies have directly compared it with alternative instruments (49).

Region- or site-specific measures

In the last decades, many reports have presented methods to assess the outcomes of patients with single-joint problems (hip, knee, shoulder, elbow, etc.) (50-54). While the majority of them have been developed to assess the outcome of surgical treatment, there is an increasing interest in monitoring other therapeutic interventions (such as drug treatment). The major components considered in most scores are symptoms, clinical signs, and physical function. Items are usually measured on ordinal scales. Scores for each component are obtained by summing the ratings of single items, and in most instruments component scores are added to an overall index. In some cases, the index value is converted into categorical rankings (e.g. 90-100 points = excellent; 75-89 = good; 60-74 = fair, and so on). Unfortunately, controversy exists as to what format most precisely defines patient results, and the use of an array of instruments

(with different components and arbitrary weights derived from different individual clinical judgements) makes comparison of data very difficult. Moreover, the unidimensionality of some measures is often questionable, and studies on the reliability and validity of many instruments have seldom been conducted and only in recent years (52). Questionnaires or related forms of assessment that patients complete by themselves are generally easier to organise and collect than those requiring a clinical examination, and a substantial amount of data has been collected demonstrating that reports from patients can be highly reliable, valid and sensitive to clinical change (2, 4). So, most recent instruments are patient-completed measures. An overview of the main characteristics of some of the site-specific measures presented in this paragraph is shown in Tables 3 and 4.

REGION-SPECIFIC MEASURES

There is growing interest in 2 regional outcome measures: the Disabilities of Arm, Shoulder and Hand Questionnaire (for the upper extremity), and the Western Ontario and McMaster Universities Osteoarthritis Index (for the lower extremity). They conceptualise the upper or lower extremity as a single functional unit, and evaluate both symptoms and disability that are relevant not to only one joint but to the whole extremity. This provides a practical solution to the problems of having to use multiple measures in patients with multiple impairments in an upper or lower extremity, and allows for comparison across different local disorders and for greater uniformity in research.

The Disabilities of Arm, Shoulder and Hand Questionnaire (DASH) (55,56) is a questionnaire with increasing evidence of good construct validity, test-retest reliability, and responsiveness to change in measuring disability for many single or multiple musculoskeletal disorders of the upper limb. It incorporates 30 questions related to ability to perform functional activities (21 items, related to physical functioning, such as daily activities, house/yard chores, recreational activities, self-care, etc.), severity of symptoms (6 items, assessing pain weakness, tingling/numbness, and stiffness), and psychosocial problems (3 items: social activity, work and perceived capability). The DASH also contains two optional 4-item scales concerning: a) the ability to perform sports and/or to play a musical instrument, b) the ability to work. Subjects are asked to rate their ability to do specific activities (1=no difficulty, 5= unable), the severity of their symptoms (1=none, 5= extreme), and the extent to which their symptoms limit their activities (1=not at all, 5= extremely). Scoring is done by summing up the values of the selected responses, subtracting 30 (minimum score) and then dividing by 1.2 in order to transform the raw score to fall within a 0-100 range (55).

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (57) is probably one of the most widely tested scoring systems,

TABLE 3. Site-specific measures for shoulder and low back.

	Scale type ° /s No. of ordinal levels	***Dimension: no. of items - % total score***	***Range***	***Rater****
SHOULDER				
Shoulder Pain and Disability Index	10-cm VAS	Pain: 5-50% Function /disability: 8-50%	0-100	P
Simple Shoulder Test	N (y/n)	Function: 12-100%	0-12	P
Shoulder Rating Questionnaire	O/5	Global assessment: 1-15% Pain: 4 - 40% Function /daily activity: 6-20% Recreational / athletics: 3-15% Work: 5-10% Satisfaction: 1-	17-100	P
Oxford Shoulder Score	O/5	Pain: 4-33% Function: 8-67%	12-60	P
Constant-Murlay Shoulder Assessment	Pain: O/4 Function: O/2-5 ROM: O/5-6 Strength: I (1pt/lb, up to 25 lb.)	Pain (self-report): 1-15% Function (self-report): 4-20% ROM (clinical measure): 4-40% Strength (clinical measure): 1-25%	0-100	E
ASES-s	Self-evaluation - Pain: 10-cm VAS Function: O/6 Clinical examination - Motion: I Signs: O/2-4 Strength: O/6 Instability: O/2-4	Self-evaluation - Pain: 1-50% Function 10-50% Clinical examination - Motion: 5 Signs: 11 Strength: 4 Instability: 8	0-100 (self-evaluation)	P + E
LOW BACK				
Roland-Morris Disability Questionnaire	N (y/n)	Disability: 24-100%	0-24	P
Oswestry Disability Questionnaire	O/6	Disability: 10-100%		P
Quebec Back Pain Disability Scal	O/6	Functional disability: 20-100%	0-100	P
Aberdeen Back Pain Scale	O/3-6 §	Back pain severity: 19-100%	0-72	P

° N = nominal; O = ordinal; I = interval.
* E = examiner; P = patient.
§ Forced or multiple choice.

TABLE 4. Site-specific measures for hip and knee.

	Scale type ° /s No. of ordinal levels	***Dimension: no. of items - % total score***	***Range***	***Rater****
HIP				
Lequesne algo-functional index	Pain: O/2-3 Walking: O/3-7 Daily activity: O/3	Pain: 5-33% Walking: 2-33% Daily activity: 4-33%	0-24	E / P
Harris Hip Score	Pain: O/6 Function: O/2-7 Deformity: O/4 ROM: I	Pain: 1-44% Function: walking 3-33% activity 4-14% Deformity: 1-4% ROM: 5-5%	0-100	E
Oxford Hip score	O/5	Pain: 4-33% Function: 8 - 67%	12-60	
KNEE				
Lysholm scale	Disability: O/3 Locking: O/5 Instability, pain: O/6 Swelling, function: O/4	Disability: 2-10% Locking: 1-15% Instability: 1-25% Pain: 1-25% Swelling: 1-10% Function: 2-15%	0-100	E/P
KOOS	O/5	Pain: 9 Symptoms: 7 Function, daily living: 17 Function, sports - recreation: 5 Quality of life: 4	0-100[§]	P
Knee ligament standard evaluation form - IKDC	O/4	Function (pt. assessment): 2[#] Symptoms: 4[#] ROM: 2 Clinical examination: 13 X-ray: 3 Functional test: 1	4-group classification	P+E
Cincinnati knee rating system	Symptoms: O/6 Patient grade: O/10 ADL, sports function: O/4 Sports activity: O/12 Occupational rating: O/6	Symptoms: 4-20% Patient grade: 1-0% ADL: 3 + Sports function: 3-15% Sports activity: 1-0% Occupational rating: 7-0% Clinical examination: 5-25% Instability: 2-20 % Radiographs: 3-10% Function testing: 4-10%	0-100	E

° O = ordinal; I = interval.

* E = examiner; P = patient.

§ Transformation of raw scale scores to a 0-100 scale, separately for each of the 5 dimensions. An aggregate score is not calculated.

Replaced in a recent revision (2000 IKDC subjective knee evaluation form) (118) (see also website: www.sportsmed.org/pdf/IKDC).

originally developed in English and now translated into several other languages (58). This index has gained increasing acceptance in osteoarthritis (OA) assessment since its introduction in 1986, and recently it has been recommended as a suitable clinical measure for assessing outcomes in Phase III clinical trials in patients with hip or knee osteoarthritis who have been treated by nonsurgical interventions or have had arthroplasty (59,60). The WOMAC is a self-administered questionnaire made up of 24 questions categorised into 3 sub-scales: pain (5 items), stiffness (2 items) and physical function (17 items). The Likert version of the index is rated on an ordinal scale of 0 to 4, with lower scores indicating lower levels of symptoms or disability. Each sub-scale is summated to a maximum score of 20, 8, and 68, respectively. There is also an index score, which is most commonly calculated by summating the scores for the 3 sub-scales. A visual analogue scale (VAS) version of the WOMAC (WOMAC 3.0) with similar metric properties is also available (57). In this format all 24 items are rated by the subject on a 100-mm VAS ranging from 0 (indicating no pain, stiffness or difficulty) to 100 (indicating extreme pain, stiffness or difficulty). The scoring procedures are similar to those for the Likert-scale version. Although the WOMAC is used in the OA knee and hip patient groups primarily to evaluate the effects of arthroplasty and drug interventions, the results of a structured literature review (58) illustrate the wide use of the WOMAC in other interventions (e.g. physiotherapy) and in patient groups other than hip and knee OA (e.g. those with low back pain, rheumatoid arthritis and fibromyalgia) (61).

Site-specific measures

Shoulder

The most tested patient-based instruments examining the impact of shoulder abnormalities on the ability to perform daily activities are probably the Shoulder Pain and Disability Index, and the Simple Shoulder Test.

The Shoulder Pain and Disability Index (SPADI) (62) is a self-administered questionnaire, analysing the severity of an individual's pain (5 items) and the degree of difficulty with various functional activities (8 items) requiring the upper-extremity use. To answer the questions, patients place a mark on a 10-cm VAS for each item. The scores for both dimensions (pain and function) are averaged to derive a total score. The scale underwent several psychometric scrutinies in a variety of shoulder problems (tendinitis, impingement, instability, rotator cuff syndrome, after surgical repair, etc.) with positive results. However, some limitations associated with use of the scale have been outlined (63, 64).

The Simple Shoulder Test (SST) (65) is a function scale consisting of items that ask people about their ability to tolerate or perform 12 ADL. Subjects indicate whether they are able or not to do the activity. The SST

scores range from 0 to 100 and are reported as the percentage of items to which the person responds in affirmative way. The results of a principal-component factor analysis of the SST supported a 2-factor solution: the first factor measures what a person can do with his or her shoulder; the second factor measures a person's comfort with the shoulder at rest. In addition, some findings suggest that the SST is too imprecise in following an individual patient's change over time, particularly of those with lowest and highest shoulder functioning scores (64,66).

Two other questionnaires with sound psychometric properties but not widely used are the Shoulder Rating Questionnaire and the Oxford Shoulder Score**.**

The Shoulder Rating Questionnaire (SRQ, otherwise named Hospital for Special Surgery shoulder score) (67), includes six separately scored domains: global assessment (with a VAS), pain (4 items), ADL (6 items), recreational and athletic activities (3 items), work (5 items), and satisfaction (1 item). A final, non-graded question allows the patient to indicate the two domains in which he/she believes improvement is most significant. A weighting system has been developed, multiplying each domain score according to its "importance".

The Oxford Shoulder Score (68) is a 12-item patient-based questionnaire assessing function and pain after shoulder surgical procedures other than stabilisation: each item has five categories of response, scored from 1 to 5, from least to most difficulty or severity. The scores are then added to produce a total score with a range 12-60. It represents a simple outcome measure used (mostly by English authors) to supplement clinical assessment in the follow-up of patients after shoulder surgery.

Further, two widely used shoulder rating systems including the clinician's assessment should be mentioned: the Constant-Murley Shoulder Assessment, and the American Shoulder and Elbow Surgeons Shoulder Assessment Form. Such systems (including also measures of impairment) present a greater length and complexity than the self-administered questionnaires, but some prefer them on the grounds that they better reflect the overall impact of a clinical problem on the patient.

The Constant-Murley Shoulder Assessment (CSA) (69) is a scale containing both patient-completed and clinical components. The former includes the assessment of pain (4 ordinal levels, 15 points) and ability to perform ADL or gestures (20 points); the latter analyses active forward and lateral elevation measured by a goniometer, internal/external rotation assessed by body landmarks reached in composite movements, and the strength of abduction measured using a spring balance (40 points for ROM, and 25 points for strength). The scale was claimed to be applicable to all shoulders regardless of the diagnosis (excluding instability). Re-

cently, Urvoy et al. proposed a modified version of CSA, where the relative weight of strength and motion is reduced, and that of ADL increased (70). The overall reliability of the score has been reported as low (71). The CSA shows a high correlation (>0.90) with the Shoulder Severity Index (SSI) by Patte (72), a less diffused scale with 30 questions regarding pain, function, strength, handicap, and satisfaction.

The American Shoulder and Elbow Surgeons Shoulder Assessment Form (ASES-s) (73) includes two sections: a self-evaluation and a clinical examination. The first section contains VASs for pain and instability and a 10-item (13-item in the recently modified version) ADL questionnaire (marked on a four-point ordinal scale); the clinical examination assesses shoulder motion (active and passive), signs**,** strength and instability. A shoulder score can be derived from the VASs for pain (50%) and the cumulative ADL score (50%).

A comparison of five shoulder questionnaires (SST, SPADI, the self-evaluation section of a modified ASES-s, SSI, and Subjective Shoulder Rating Scale) (74, 75) showed that all the instruments with the exception of the last presented adequate reliability and validity and a responsiveness to change superior to that of the SF-36. Two other questionnaires have recently been validated: the Shoulder Function Assessment (76), for patients with rheumatoid arthritis; and the Shoulder Disability Questionnaire, to evaluate functional status limitation in patients with soft tissue shoulder disorders (77). Conversely, there is little psychometric evaluation of the UCLA Shoulder Rating Scale, a frequently used questionnaire consisting of a self-report section with three single-item ordinal sub-scales (pain, functional level, satisfaction), and a clinical assessment of motion and strength in forward flexion. It is doubtful, however, that the UCLA is precise enough to effectively follow the progress of individual patients in the clinical setting (66).

As for practical issues in selecting an outcome measure, the use of VAS (e.g. in the SPADI and SRQ) may represent a potential difficulty for some patients (50) and takes more time to score than ordinal scales. Moreover, the instruments requiring conversion of raw scores and additional calculations (such as SRQ) are lengthy and burdensome to process compared to those needing only the sum of the item scores.

Elbow

Several investigators have designed their own elbow rating scales, mainly as a tool to quantify changes after orthopaedic surgery and to compare outcomes between groups of patients. The Hospital for Special Surgery elbow assessment scale and the Mayo Clinic performance index for the elbow have gained widespread use (78).

The Hospital for Special Surgery (HSS) Elbow Assessment Scale (HSS-e) is a 100-point rating system composed of ordinal scores for pain when

bending (15 points) and at rest (15 points), function and activity (20 points), range of motion (28 points), strength (10 points), and deformity (12 points).

The Mayo Clinic performance index for the elbow (Mayo-e) is made up of ordinal sub-scales for pain (45 points), daily function (25 points), motion (20 points), and stability (10 points), resulting in a possible maximum of 100 points.

Recently, two new tools have been developed to measure pain and disability related to elbow pathology: one instrument is the Patient-rated Elbow Evaluation. The other was created by the American Shoulder and Elbow Surgeons Research Committee. A comparative study (79) supported the use of both instruments and confirmed also the validity of the DASH (see section of region-specific measures) as outcome measures in patients with elbow pathology.

The Patient-rated Elbow Evaluation (PREE) (79) is an adaptation for the elbow of a previously validated questionnaire for wrist evaluation, containing a pain scale (5 items) and a function scale, rating both specific (11 items) and usual (4 items) activities. The total score (0-100) equally weights pain and disability, with a higher score indicating greater pain/disability.

The American Shoulder and Elbow Surgeons Elbow Assessment Form (ASES-e) (80) includes a patient rating questionnaire with three subscales (pain: 5 items; function: 12 items; satisfaction: 1 item), and a physician form for recording elbow impairments (motion, stability and strength). This instrument is very close to the ASES-s, a form proposed by the same association for shoulder assessment (see shoulder section), and the patient questionnaire is similar to the PREE.

As regards the observer-derived assessment methods, a recent paper compared five elbow-scoring systems based on a variable admixture of clinical and functional criteria (78): the Mayo-e, the systems of Ewald et al., Broberg and Morrey, and Pritchard, and the HSS-e. All methods (except the Pritchard) have a relatively simple format and a low cost, and require little training. The different parameters (range of motion, pain, ability to perform daily activities, etc.) are scored separately, then aggregated and sometimes transformed into a categorical ranking (from excellent to poor). The authors point out a greater discriminant ability of the first two systems, but a striking lack of concordance regarding the aspects of elbow function that were assessed: all five system were designed to assess pain and motion, but only four assessed also the ability to perform specific tasks, three the strength, two the stability of the elbow and another two the deformity of the joint. Despite these differences, the correlations between the raw aggregate scores were good (r ranging 0.79-

0.90). Conversely, there was a lack of agreement when the five systems were used to determine categorical rankings for the same cohort of patients. The same study suggests that also the DASH should be used to assess functional outcome following the treatment of disorders involving the elbow, in conjunction with a clinical examination and an assessment of pain (78).

Hand

Among the clinical tools that can be used for assessing function in symptomatic hand osteoarthritis, the Dreiser's Functional Index for hand osteoarthritis and the Australian/Canadian hand osteoarthritis index are recommended by the Osteoarthritis Research Society International, OARSI (81). The two indexes need further studies to investigate their utility in clinical trials, including a head-to-head comparison in terms of responsiveness.

Dreiser's Functional Index for hand osteoarthritis (FIHOA) (82) contains 10 items: 9 probe functions and one explores a pain-related issue (the extent that a patient may be reluctant to accept a handshake). This is a relatively new index and there has not been broad experience in its use. The FIHOA is physician-administered. Responses to each of the 10 questions are rated on 4-point verbal scales (from 0=no difficulty to 3=impossible). The total score (0-30) is obtained by summing the scores of the 10 items. Internal and external consistency, sensitivity and specificity, intraobserver reproducibility, responsiveness in placebo-controlled trials, and ease of use have been assessed (83).

The Australian/Canadian hand osteoarthritis index (AUSCAN LK3.0) (81) is a new self-administered questionnaire with 15 items (5 on hand pain, 1 on severity of morning stiffness and 9 on difficulty with hand functions), with responses scaled in a 5-point Likert scale. A total score is created by adding all three subscales. The index presents clinimetric properties (reliability, construct validity, and responsiveness) above acceptable standards and is available in many languages (84).

Other recently available (and less studied) indexes (81) are: a) the Hand Index developed by Duruoz et al. (85) in rheumatoid arthritis (also called Cochin hand functional disability scale), that includes 18 hand activity questions with 6 levels of answers. Patients answer questions on the basis of their experience during the last month. Global raw scores range from 0 to 90; b) the Backman's Hand Function Test (86), that requires trained investigators and specific material, and is time consuming.

Cervical spine

A systematic review (87) has compared five scales specifically designed for evaluation of neck pain and/or dysfunction (the Neck Disability Index, the Northwick Park Neck Pain Questionnaire, the Neck

Pain Disability Scale, the Copenhagen Neck Functional Disability Scale, and a patient-specific functional scale). It reported their psychometric properties and the published literature on these scales, in an effort to help clinicians and researchers in selecting the most appropriate scale for their needs. In the same period, two studies were published, validating respectively the Spanish version of one of them (88) and the French versions of three of them (89). At the moment, the two most widely studied instruments (among different patient populations and in different settings) are the Neck Disability Index and the Northwick Park Neck Pain Questionnaire. They have similar structure, burden and acceptability to patients, and ease of administering and processing. Both scales contain a question about driving, often not applicable in an elderly population.

The Neck Disability Index (NDI) (90) consists of 5 items derived from the Oswestry Disability Questionnaire (ODQ, see low-back section) and 5 items identified through feedback from practitioners, patients, and a review of the literature. The items explore pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Six response options are presented with each item, and items are scored 0 (no disability) to 5 (total disability). The NDI total score can vary from 0 to 50. The instrument has been used in different populations and validated against multiple measures of function, pain, and clinical signs/symptoms (87, 89).

The Northwick Park Neck Pain Questionnaire (NPQ) (91) is a self-administered questionnaire consisting of 9 items (adapted from the ODQ) assessing neck pain intensity, sleeping, numbness, duration of symptoms, and the interference of pain with: carrying, reading/watching TV, work, social activities, and driving. Each item contains one question and five statements of increasing difficulty (scored on a 0-4 scale) and patients are asked to tick only the box which most closely describes their current situation. The total score (0-36) is obtained by summing the scores of the 9 sections, and a percentage is calculated by dividing the patient's score by the maximum possible (depending on the number of sections answered). In the tenth item (added at the second presentation and not included in the NPQ total score) the patient evaluates the change in pain after follow up. The NPQ has proved to be a useful tool in studies of neck pain (87), correlating with objective measurements such as range of movement of the neck and semi-objective parameters such as the visual analog scale (VAS) (92).

Another scale has recently been presented and needs further investigation: the *Neck Pain and Disability Scale* (93). It is a 20-item questionnaire developed using the Million Visual Analogue Scale as a template, which measures: the intensity of pain; its interference with vocational, recreational, social, and functional aspects of living; and the presence and extent of associated emotional factors.

Lumbar spine

A standard "core set" of outcome measures for low back pain (covering several domains), proposed by an international group of back pain researchers (51, 94), includes two recommended back-specific measures of function: the Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. Both tests are short, simple to complete, and available in numerous languages (95). They are also the most widely used (in a variety of clinical situations) and extensively tested questionnaires for low back pain. Differences between the two instruments are not great: the first has been more recommended in patients with minor disability and the second in those who are likely to have persistent severe disability.

The Roland-Morris Disability Questionnaire (RDQ) (96) is a measure (derived from the SIP) assessing physical disability due to low back pain. Patients completing the RDQ are asked to place a check beside each of 24 performance-based statements (dealing mostly with a limited range of physical functions: walking, bending over, sitting, lying down, dressing, self-care, daily activities, sleeping) that currently applies to them. Each item is qualified with the phrase "because of my back pain" to distinguish back pain disability from disability due to other causes (a distinction generally difficult to make). The RDQ score is calculated by adding up the number of items checked (yes/no questions); so the score ranges from 0 (no disability) to 24 (maximum disability). The test is well understood by patients, and can be easily administered by telephone.

The Oswestry Disability Questionnaire version 2.0 (ODQ) (97) is a questionnaire including 10 six-level items: the first question rates the pain intensity, and the remaining 9 (containing both capacity- and performance-based questions) cover the disabling effect of pain on typical daily activities (personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling). Patients mark the statement in each section that most accurately describes their condition. For each item scores fall on a 0 to 5 scale, with higher values representing greater disability. The sum of the ten scores is expressed as a percentage of the maximum score. If the patient fails to complete a section, the percentage score is adjusted accordingly. Unfortunately, many modified versions of ODQ exist, not clearly superior and less investigated; the most recent one replacing the sex life section (the item most frequently found to be left blank) with a question regarding employment and home-making ability (98).

As alternative instruments recently developed, we mention the Quebec Back Pain Disability Scale and the Aberdeen Back Pain Scale.

The Quebec Back Pain Disability Scale (99) is a self-administered instrument designed to assess the level of functional disability in terms of difficulty experienced while performing 20 simple tasks representing six empirically derived categories of activities affected by back pain: bed/rest,

sitting/standing, ambulation, movement, bending/stooping, and handling of large/heavy objects. Answers can be given on a six-point verbal-numerical scale, ranging from 0 (not difficult at all) to 5 (unable to do). The item scores are summed for a total score, ranging from 0 to 100 points. The content of the scale was developed in several stages, including a literature review, experts' surveys, pilot testing and a large clinical study with a detailed psychometric analysis (99).

The Aberdeen Back Pain Scale (100) is a 19-item questionnaire for the clinical assessment of patients with low back pain (pain characteristics; pain modifiers; presence of weakness or power loss; interference with: sleep, ADL, work, sex life, leisure, etc.). Questions are either forced choice (requiring the respondent to tick one box) or multiple choice (requiring the responder to tick all boxes that apply). The responses to each forced-choice item are assigned a score in ordinal manner, whereas those to multiple-choice questions are assigned a score of one point. The scores are summed and then converted to a percentage producing a "back pain severity score" between 0 and 100. If a question is omitted by a patient, the total score is adjusted by removing also the score for that question from the denominator before calculating the percentage.

Hip

In patients with hip and knee osteoarthritis the two most widely used and validated instruments are the WOMAC (see section of region-specific measures) and the Lequesne-algofunctional indices (LAIs), whereas in surgically treated patients the Harris Hip score and the Oxford Hip score represent two commonly used instruments. Conversely, many other rating systems have been proposed and are frequently used to assess the results of replacement or osteoarthritis of the hip, but often their psychometric properties are poor or inadequately investigated (52). Moreover, several systems (assessing a mixture of symptoms, functions, clinical signs, and other) can give (e.g. for many knee measures) quite comparable results when expressed as a percentage of their maximum possible numerical scores, but they present large discrepancies when converted into the respective categorical rankings (such as excellent, good, or poor outcome), making these categories less suitable for clinical and epidemiological studies (52, 101, 102).

The Lequesne Algofunctional Indices (LAIs) (103) are two indices (one applicable to the hip, LAI-h; the other to the knee, LAI-k) containing 5 items for pain/discomfort (8 points), 2 for walking (8 points), and 4 for ADL (8 points). The two indices are identical, with the exception of 1 pain item and the 4 ADL items, that are slightly different. The global score ranges from 0 to 24, with higher values indicating greater severity/disability. Degree of disability corresponding to different scores of the indices are as follows: minor (1-4 points), moderate (5-7 points), severe (8-10 points), very severe (11-13 points), extremely severe (>14 points). The

indices were recommended as a measure for OA trials in the 1985 European League Against Rheumatism (EULAR) guidelines for antirheumatic drugs research, and in the SADOA guidelines in 1994. Although the metric properties of the LAIs have been established (103, 104), separate subsections (pain, stiffness and physical function) have not been sufficiently validated for independent applications (105). The LAIs were validated as an interview technique made by a trained investigator, but they have sometimes been used in a self-administered form (106).

The Harris Hip Score (HHS) (107) is a staff-administered evaluation system used for various hip disabilities and methods of treatment. The HHS is one of the most widely used hip questionnaires throughout the world. It gives a maximum of 100 points and the domains assessed include pain (44 points), function (47 points), deformity (4 points), and range of motion (5 points). Function is subdivided into four ADL (sitting, putting on socks and tying a shoe, stair climbing, public transportation – 14 points), and three items on gait (limp, support, distance walked – 33 points). For patients who have undergone modern total hip replacement procedures, the deformity and motion domains have been defined as unnecessary (108). The reliability and the validity of the HHS have been recently tested (110), but its internal consistency needs to be better investigated.

The Oxford Hip Score (109) is a 12-item patient-based questionnaire specifically assessing function and pain after total hip replacement: each item has five categories of response, scored from 1 to 5, from least to most difficulty or severity. The scores are then added to produce a total score with a range 12-60. The instrument is easy to complete, simple and quick to process, and its psychometric properties have been well-studied, even though its clinical use is not wide.

Knee

The number of scoring systems designed for use in patients with knee pathologies is extremely high. In general, there are two main types of scale: one for patients with ligament injuries and the results of their surgical reconstruction (110-112) and the other for patients with rheumatic diseases (osteoarthritis, rheumatoid arthritis, etc.) and sequelae of bone fractures or arthroplasty (52). Among the most used patient-completed outcome measures, we cite the WOMAC and the knee version of the LAIs (see hip section) for patients with osteoarthritis (57), and the Lysholm scale for knee ligament injured/reconstructed patients.

The Lysholm scale, in its modified version (LS) (113), is a 100-point self-administered scale consisting of 8 items (giving more emphasis to symptoms than to function): limp (5 points), use of support (5 points), locking (15 points), instability (25 points), pain (25 points), swelling (10 points), stair climbing (10 points), squatting (5 points). The same authors, recognising also the need to evaluate the patient's activity level, proposed

as an adjunct to the LS a numerical scale (the Tegner activity level), grading certain activities according to how troublesome they are to perform (113). The LS has been extensively tested, is easy to use for both research and clinical follow-up of patients, and probably represents the ideal gold standard for comparison with the latest outcome measures (111).

In addition, two promising new instruments are the Oxford Knee score (114), a questionnaire for patients with total knee replacement with the same 12-item structure as the Oxford Hip score (see above), and the Knee Injury and Osteoarthritis Outcome Score (KOOS).

The KOOS (115) is a self-administered questionnaire for assessment of young and middle-aged subjects with anterior cruciate ligament (ACL) injury, meniscus injury, or post-traumatic osteoarthritis. It consists of 5 subscales: pain (9 items); symptoms, such as swelling, grinding, stiffness, etc. (7 items); daily living function (17 items); sports and recreational activities (5 items); and knee-related quality of life (4 items). To ensure content validity for older subjects with osteoarthritis, the questions from the WOMAC (pain: 5 items; stiffness: 2 items; function: 17 items) were included in their full and original form in the KOOS, so enabling the WOMAC scores to be calculated from the KOOS responses. The five dimensions are scored separately (an aggregated score is not calculated). All items are scored from 0 to 4, and each of the five scores is calculated as a sum of the items included; then the scores are transformed to a 0-100 scale (from extreme knee problems to no knee problems) and can be visualised as a profile. The KOOS is a recent well-designed scale requiring additional validation.

Furthermore, two well-known outcome measures including also examination findings (such as knee joint laxity, X-ray findings and so on) are the International Knee Documentation Committee (IKDC) knee evaluation form, and the Cincinnati Knee Rating System. A third widely-used (but psychometrically less tested) scoring system is the Hospital for Special Surgery knee rating form (116), that integrates a composite of subjective assessment of symptoms and activities and both clinical and functional examination.

The International Knee Documentation Committee (IKDC) knee evaluation form (117) is an evaluation system for patients with anterior cruciate ligament reconstruction, grading in 4 levels (A - normal, B - nearly normal, C - abnormal, D - severely abnormal) the results related to each of the following four problem areas: patient subjective assessment, symptoms, range of motion, ligament examination. These are supplemented by other areas that are documented but not included in the evaluation (compartmental findings, X-ray findings, one-leg-hop test, etc.). The lowest grade within a group determines the group grade, and the worst group grade determines the final result. Recently, the system has been revised and a subjective component included and validated (118) designed to measure symptoms, function, and

sports activity in patients with a variety of knee conditions, including ligament and meniscal injuries, articular cartilage lesions, and patello-femoral pain. This new subjective form expands and replaces the function and symptoms categories in the original version; the scoring system is, however, quite complicated and further psychometric testing is needed.

The Cincinnati Knee Rating System (119) is an assessment method for knees with acute ACL injuries consisting of 13 scales: a) 4 symptom rating scales assessing pain, swelling, and partial and full giving way; b) a patient-perception scale of the overall knee condition; c) 3 ADL function scales for walking, stair climbing and squatting; d) 3 sports-activities function scales for running, jumping, and hard twisting/cutting/pivoting; e) a sports activity scale; and f) an occupational rating scale. Besides the 13 scales, an overall rating score can be calculated on a 0-100 scale by summing a maximum of 20 points for symptoms, 15 points for functional daily and sports activities, 25 points for physical examination (knee effusion, range of motion, etc.), 20 points for knee stability testing (arthrometer and pivot-shift), 10 points for X-ray findings, and 10 points for functional testing. Some modifications of the rating scales have been proposed by the original authors, respectively for chronically affected knees, for patients not returning to strenuous athletics, and for multiple ligament ruptures (119). Although the scale is time-consuming (for both observer and patient) and quite complex to complete, it is a well-refined instrument and probably the one that most precisely defines outcome of ACL injury in athletically active patients.

CONCLUSION

This paper reviews the most widely used and studied measures in orthopaedic and rheumatologic rehabilitation. Only instruments with detailed psychometric examinations have been described. Many other tools have not been considered because they lack extensive statistical analyses (sometimes because they are too recent) or were simply judged inferior to the tools presented here. Besides the relative, general merits of the instruments indicated in this paper, a careful scrutiny of each measure is imperative prior to its selection, considering the match of the instrument to the specific purpose and requirements of the trial in question (4, 52). In fact, instruments may have varying strengths and weaknesses depending on the population and the reasons for their use, so the user's final decision must be context-specific (74, 75). Unfortunately, there are still too few head-to-head comparisons of the technical properties of outcome measures designed for similar clinical applications.

A number of papers present guidelines for the scientific criteria and practical attributes that should be considered in selecting measures (4) and/or in carefully evaluating their psychometric characteristics (7). At first, there should be published evidence of acceptable levels of scale reliability, validity, and responsiveness to change: the first two summarise if the measure is reproducible and internally consistent (reliability) and if it

measures what it purports to measure (validity), whereas 'responsiveness' is the ability to identify changes or differences that are clinically or individually meaningful. It has been proposed (120) that for instruments designed for discriminative (measuring cross-sectional differences between individuals or groups) and predictive (attempting to classify individuals into a set of predefined categories for estimating prognosis) purposes, the demonstration of reliability and validity can be sufficient to ensure usefulness, while for evaluative instruments (designed to measure change within people over time) responsiveness is also required. Moreover, the choice of individual vs. group application influences both the level of reliability required, and the strategies for validating it (121). So, the requirements for a measure become increasingly stringent as one moves from the lowest level of use (e.g. description of health status in cross-sectional and large sample surveys) to the highest (guidance in individual clinical decisions).

The investigator has also to consider, as directly as possible, the following features of an instrument: a) the appropriateness, i.e. how well the content of the instrument matches the purposes and questions which the specific clinical trial is intended to address (e.g. analysing if the scale has been already tested on the types of person to whom the user is intending to apply it). In fact, we stress that instruments do not have properties of being reliable, valid and so on in some universal sense but, rather, in relation to a specific use; b) the precision (or sensitivity), i.e. the exactness of the measure, which is mainly based on the number and accuracy of distinctions made. The issue of precision can be raised in relation to both response categories and numerical values, as well as to the relationship between the range of difficulty of the items and the "true" distribution of what is being measured. With complex statistical methods (such as the Rasch model) it is often possible to examine the hierarchical order and spacing of items along the underlying construct (122), but sometimes also very simple techniques (such as ordering the items according to their mean scores or the proportion of patients having difficulty with each item) may provide an easy system for examining the interval characteristics of an instrument (123).

Furthermore, some pragmatic issues are important in selecting an evaluation tool (4, 124); they concern interpretability (measures should give results which are easily understood by others), acceptability (how acceptable it is for respondents to complete: response rate, time to complete, cultural applicability, and so on), and feasibility (ease of administration and processing, i.e. extent of effort, burden and disruption to staff and clinical care arising from the use, including for example the professional expertise required to apply or interpret the instrument, and the presence of a clear instruction manual).

The user has to decide on the basis of the properties required for the intended purpose, the previous use of the measure in similar situations, and practicality (an appropriate balance between the detail/accuracy required and the effort of collecting data). As McDowell and Newell stated

(1), it is often prudent in clinical research to apply more than one measurement, wherever possible. This has the advantage of possibly reinforcing the conclusions of the study and increasing our general understanding of the comparability of the measurements used**.** In most outcome studies a patient-based measure (self-report) can provide reliable and valid judgements of health status and of the benefits of treatment, and represents an acceptable first-choice instrument to apply. Where necessary, this information has to be supplemented (or replaced) by the assessments of health professionals or others, e.g. when the instrument is not sufficiently sensitive to portray accurately the extreme ends of the spectrum of interest, or when the patient is judged as unreliable.

An additional source of concern is that the great majority of the reviewed instruments have been developed in English-speaking countries and when measures have to be used in other than the source context there is need for a cross-cultural adaptation to the new country, culture and/or language (125, 126) in order to maximise the attainment of semantic, idiomatic, experiential and conceptual equivalence between the source and target measures.

Finally, evidence concerning the extent of the usefulness of most of these measures to better understand the complex relationships between interventions, clinical and context variables, and outcomes is only gradually becoming available, and scores have generally been used to make comparisons in aggregate more than for the assessment and screening of individuals. There is an interesting body of evidence accruing to show that QOL data can have prognostic significance, with baseline measures predicting which patients with advanced disease are most likely to respond to treatment, i.e. predicting to whom treatment is worth offering. Consequently we have a responsibility to ensure that measures are psychometrically sound, and that they are administered thoughtfully and analysed correctly.

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CHAPTER 4
CLINICAL AND RADIOLOGICAL ASSESSMENT OF PATIENTS WITH SPINAL CORD AND CAUDA EQUINA INJURIES

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Spinal injuries, with neurological damage, are catastrophic events with devastating medical, psychosocial, financial and economic consequences.

The impact of the injury on the individual and those related to him/her can be minimised with good management of all aspects of paralysis from the time of the injury and on an ongoing basis.

A thorough and accurate assessment of the patient and documentation of information are of paramount importance as the first steps in good management.

Considering that the spinal cord injury (SCI) affects the physiology of almost all systems of the body any assessment should encompass more than spinal column or spinal cord functions.

Considering that the physiological impairment and the consequent system dysfunction caused by SCI are dynamic in nature, the importance of frequent reassessments and repeated documentation especially during the first weeks and months following the injury cannot be overemphasised.

Considering that in the absence of full recovery the majority of patients with spinal cord injuries have sensory impairment or loss below the level of their injury;

associated injuries and/or pathological complications can develop without the knowledge of the patient and can be easily missed by the Clinician. This further highlights the importance of thorough, documented, assessments on an ongoing basis during the lifetime of the patient.

Fortunately the incidence of spinal cord injuries is the lowest of all major trauma. A combination of low incidence and high complexity, however, necessitate an even more thorough systematic assessment than usual in order to ensure safety for the patient and medico-legal protection for the Clinician.

CLINICAL ASSESSMENT IN THE ACUTE STAGE

Missed injuries are regularly reported in the literature (1-4) and it is probable that many more missed spinal cord injuries are unreported. Delaying diagnosis can result in further neurological deficit (4, 5) which is likely to result in more paresis or paralysis and further impairment, disability and malfunction of the various systems of the body. It is indeed a disaster to miss a spinal fracture as it can always be alleged that the neurological impairment is caused or at best aggravated by failure to diagnose the fracture promptly and initiate treatment or at least take appropriate precautions. It is therefore paramount that all efforts are expended in the Accident and Emergency Departments in order not to miss an injury to the spinal axis with or without an associated spinal cord injury. Missing or delaying a diagnosis of a spinal column injury without cord damage is a potential catastrophe to both the patient and the institution involved. A high level of suspicion is a prerequisite to early diagnosis in patients presenting following major trauma.

DIAGNOSIS OF SCI IN THE CONSCIOUS PATIENT

A conscious alert patient who is able to communicate and has no symptoms of pain, rigidity or tenderness in the spine following trauma is unlikely to have sustained a spinal column injury (6). There are however some rare exceptions, especially in elderly patients with pure ligamentous lesions when an injury can be present in the absence of pain. Extreme pain from other associated injuries may also mask pain from a spinal fracture with consequences to the timely diagnosis of a spinal injury (7).

Neck pain, loss of consciousness following injury (regardless of duration) and/or neurologic deficit are clinical predictors of unstable cervical spinal injuries requiring immediate radiological investigation of the cervical spine (8, 9).

The clinical diagnosis of a spinal cord injury in the conscious patient without major associated injuries can be made without difficulty. Loss or impairment of motor power, sensation and reflexes are indicative (individually or in combination) of a spinal cord or a cauda equina injury.

It is essential to determine at the earliest stage possible both the level and the density of the neural tissue damage. The level of the injury is defined by the last normal dermatome and myotome. It is now internationally accepted by all experts in the field that the dermatomal and my-

otomal distributions may be abnormal for three segments below that level i.e. both sensation and motor power could be present but impaired in three segmental distributions below the last normal segment. For example if the last normal sensation is at the dermatomal distribution of C5 but there is hypoaesthesia or analgesia in the dermatomal distribution of C6, C7 and C8 the level of the injury would be defined as C5. Because however there is some impairment of sensation in the dermatomal distribution of C6, C7 and C8 it can be logically assumed that the spinal cord segments C6, C7 and C8 are not completely damaged and these segments are considered to be the "zone of partial preservation".

The density of the damaged area in the spinal cord is defined by the presence or absence of sparing of sensation with or without sparing of motor power below the zone of partial preservation.

Absence of motor power including voluntary contraction of the anal sphincter and loss of sensation including anal sensation below the zone of partial preservation may be indicative of a clinically complete cord injury at the time of the examination. It is important however to appreciate that not all clinically complete injuries in the early hours or days following SCI remain clinically complete (10, 11). Spinal shock can also mimic an initially complete injury following which significant recovery can occur.

The presence of sensation, however patchy or impaired, below the level of the zone of partial preservation is indicative of some anatomical sparing of sensory tract and possibly also of cortico-spinal tracts which may be dormant in function at the time of the examination. Sensory sparing limited to the anal canal without motor sparing below the zone of partial preservation is also indicative of an incomplete SCI. A number of such patients can subsequently recover significantly. A rectal examination to elicit sensation in the S5 dermatome is therefore an essential component of the neurological examination of patients diagnosed or suspected to have sustained a SCI.

An accurate and thorough neurological examination at an early stage following the injury is paramount for monitoring purposes and for prognosis.

A repeated accurate neurological assessment, with thorough documentation initially at frequent intervals (3-4 hours) is not only essential for the adequate clinical management of this dynamic and potentially rapidly deteriorating neurology with consequences to the general condition of the patient; it would also help resolve some of the controversies around the various available methods of management of SCI (conservative versus surgical decompression and/or stabilisation).

It is not advisable to rely entirely on the neurological and general examination carried out in the accident and emergency department as the patient's attention may be distracted by anxiety and pain which may also limit his/her performance of motor functions and response to sensory testing.

DIAGNOSIS IN THE SEMICONSCIOUS OR UNCONSCIOUS PATIENT

Unconscious or semiconscious patients with head injuries and the intoxicated patient present particular problems to the clinician which can

result in delays of the diagnosis of a spinal injury (12). It is therefore, in my opinion imperative that such patients, following major trauma, are managed as if they have a spinal injury until otherwise proven clinically when the patient becomes alert and radiologically when indicated.

In such patients a clear entry should be made in the medical records that the patient's neurological assessment could not be made because of the poor level of consciousness. This fact should also be communicated verbally to the nursing staff looking after the patient.

I would strongly advise that a written instruction: *"Do not sit the patient up in bed or out of bed prior to the exclusion of a spinal injury clinically and radiologically when the patient regains consciousness"* is clearly documented in the medical records and communicated verbally to the nursing staff.

This simple, logical and easy documentation can prevent paralysis, further neurological deterioration and litigation against the clinician and/or the Institution.

The general examination of the unconscious patient can also yield clinical signs which, in combination, can increase the clinician's level of suspicion regarding the presence of a neurological impairment of spinal cord origin.

The following signs are strongly suggestive of a cervical spinal cord injury:

Facial or scalp lacerations; myosis of one or both or pupil(s); bruising or swelling of the neck; absence of chest expansion during inspiration associated with increasing abdominal girth and retraction of intercostal muscles (diaphragmatic breathing);the pattern of spontaneous movement of the limbs; difference in tone between the proximal and distal muscles in the upper limbs; difference between the tone of the muscles in the upper and the lower limbs; response to painful stimuli by pressure over bony prominences along the segmental dermatomal distribution of the cord throughout the body; the combination of hypotension and bradycardia; and the presence of priapism are in combination diagnostic of a cervical cord injury.

Bruising over the chest or thoracolumbar spine in the absence of diaphragmatic breathing together with absent responses to painful stimuli applied to the bony prominences of the lower limbs in association with absent reflexes of the lower limbs could be indicative of a lower thoracic cord or cauda equina injury.

Unlike a patient with head injury who is likely to be incontinent to urine on presentation at the accident and emergency department, a patient with combined head and spine injury is likely to be dry and develop retention of urine for some time before developing overflow incontinence.

PITFALLS IN THE NEUROLOGICAL ASSESSMENT

One of the commonest problems encountered by clinicians who subsequently see the patients in Spinal Injuries Centres is the misdiagnosis of the level of injury. Often patients with mid-cervical or lower cervical in-

juries are initially diagnosed as upper thoracic injuries, even when the patient has been fully conscious, alert and co-operative.

It is important to remember that sensory preservation in the subclavicular area may be due to intact innervation from the fourth cervical dermatome through the supraclavicular nerves rather than the third and fourth thoracic dermatomes. It is therefore advisable to assess the sensation in the upper trunk along the mid axillary line rather than the midclavicular line of the chest. In a busy accident and emergency department it is very easy to mistake passive movements for active movements. For example, a patient with a C5 lesion in spinal shock will be able to actively move the deltoid and biceps muscles resulting in active abduction of the shoulder and flexion of the elbow which invariably will result in passive movement of the wrist and fingers. If voluntary and reproducible wrist and finger active movements cannot be demonstrated such movements of fingers should not be interpreted nor documented as normal movements.

Involuntary twitching of the paralysed muscles of the lower extremities may be seen in the accident and emergency department soon after spinal cord injury for a varying period of time. This does not indicate preservation of voluntary power in the lower extremities. The presence of the bulbocavernosous reflex without preservation of sensation and/or voluntary motor power in the lower sacral segmental distribution is not indicative of an incomplete lesion. An apparently normal Babinski response (downgoing plantar flexion of the big toe in response to plantar stimulation) can be seen in patients with complete and incomplete SCI for many days or weeks following the injury.

Patients with dense SCI become poikilothermic and can easily develop hypothermia or hyperthermia depending on the ambient temperature. Ensure monitoring of the temperature especially during the clinical examination as hypothermia can exaggerate the bradycardia of a tetraplegic or high paraplegic patient leading to cardiac arrest.

ASSESSMENT FOR ASSOCIATED INJURIES

Double injury and occasionally multiple non contiguous injuries of the spinal axis are not uncommon following major trauma. Following the diagnosis of a primary injury in the spinal axis, the diagnosis of a secondary injury is often delayed. The incidence of multi level spinal injuries is reported to be as high as 16.7% (13).

Early recognition is important for the assessment and the planning of the treatment in order to avoid further neurological damage when the non damaging second spinal fracture is proximal to the primary injury. In our series, 55% of patients with multi level injuries had incomplete neurological lesions on admission (14). Although no definite pattern of injury in terms of the relationship between the primary and the secondary level could be identified, the lower cervical and cervicothoracic lesions were the most frequently involved followed by the upper cervical region. Once

spinal injury has been identified it is my strong recommendation to examine the whole spine clinically and radiologically.

The incidence of extra-spinal fractures associated with spinal cord injuries is reported to be 28% in a large recent study (15, 16).

When all levels of spinal cord injuries were pooled the most common areas of fracture reported were chest followed by lower extremity, upper extremity, head, pelvis and others.

Loss or impairment of sensation below the level of the spinal cord injury presents one of the greatest challenges to the clinician in the diagnosis of associated injuries. A thorough clinical examination is paramount to the diagnosis. The importance of bruises, lacerations or swellings in these patients cannot be overestimated. Facial bruises with or without bruises in the neck in an unconscious patient should heighten the suspicion of a cervical spinal injury possibly with associated facial, dental or mandibular injuries. Although there could be any combination of associated injuries with the injury of the spinal axis, there are nonetheless certain patterns of association. Head injuries, facial injuries, dental and mandibular injuries can be associated with cervical injuries and vice versa (18). Thoracic injuries can be associated with fractures of the sternum (19), fracture ribs, haemothorax, fracture clavicle, or fracture scapula (20). A case of upper thoracic spine fracture was reported to be associated with tracheo-oesophageal perforation (21).

Abdominal injuries are not uncommonly associated with thoracolumbar fractures and lumbar fractures (17, 22). Children involved in motor vehicle collisions are particularly at a high risk. In one series, almost 10% of adults with blunt trauma of the thoracolumbar spine had associated abdominal injuries (22). Solid organs and visceral injuries (spleen, kidneys and adrenals, liver, small intestine and mesentrey) have been reported. Patients who sustained multilevel vertebral fractures were more severely injured and had a higher number of solid organ injuries (22). Blunt abdominal aortic trauma in association with thoracolumbar spine fractures have been reported mainly when the fracture is caused by a distractive mechanism with or without translation (23).

RADIOGRAPHIC ASSESSMENT

In the Accident and Emergency department AP and lateral x rays of the spine are still the commonest procedures and the most useful for the diagnosis or the exclusion of an injury to the spinal axis. The absence of a fracture does not exclude a serious ligamentous injury of the spine nor indeed a serious cord damage. A thorough assessment of the x rays is therefore necessary.

Spinal cord injuries without radiological abnormality (SCIWORA) have been reported in the literature for many decades.

X-Ray

The following is a systematic assessment of an x ray of the spine.

ANTERO-POSTERIOR VIEW

Check alignment of the spinous processes, which, in a good supine x ray should lie along the mid-vertebral line. A sideways shift is indicative of an injury to the spinal axis at and around the spinal shift.

Check the configuration of the vertebral bodies. A reduction of the height of any vertebral body is suggestive of an injury to that vertebra.

Check the interpedicular distance. Widening of the interpedicular distance is suggestive of a spinal fracture at that level.

These above radiological signs can be present either individually or in combination.

LATERAL VIEW

Whenever possible start with the examination of the prevertebral shadow area as an enlarged prevertebral shadow can be the only radiological manifestation of a serious spinal injury (24).

Follow the anterior and posterior vertebral lines. A step anteriorly or posteriorly along these lines is likely to be caused by displacement of a vertebra over an adjacent one. Document the level of the injury and identify if the fracture is through vertebral body or intervertebral disc. Examine the configuration of the vertebral bodies, the endplates as well as the intervertebral disc.

The spinal canal occupies the space between the posterior vertebral line and the line running through the base of the spinous processes. Disruption of alignment in either lines could distort the appearance of the spinal canal with encroachment from the vertebral body or disc (anteriorly) or from the bony components of the vertebral ring or soft tissue (posteriorly). The distances between the interspinous processes should be almost equal. A relatively increased distance between two spinous processes in relation to others within the same region of the spine is likely to be a sign of an underlying spinal injury.

The cervicodorsal junction and upper thoracic vertebrae are usually difficult to visualise despite pulling down on the arms while taking a lateral x ray. The quality of the exposure will improve if the shoulders are gently pushed downwards by an attendant while two other attendants pull on the arms from both the elbow and the wrist.The attendant pushing down on the shoulders will have to remove his hands while the X-ray is being taken. Alternatively swimmer's views can be taken to demonstrate the cervicodorsal area.

Oblique views are indicated if malalignment is suspected on the lateral x rays.

Magnetic Resonance Imaging (MRI)

Although x rays and computerised tomography scans are very valuable in the assessment of the injury to the spinal axis, information about the neural tissues and the soft tissue can only be indirectly extrapolated by an experienced clinician. The MRI is the only modality that offers direct visualization of the neural and soft tissues (discs, ligaments mus-

cles). The presence of intramedullary haemorrhage (hypointense lesion) on the T2-weighted image at the site of the injury in the acute stage is usually associated with severe sensory and motor impairment and poor prognosis (25). Oedema on the other hand (hyperintense lesion) confined to one segment on the T2-weighted image is associated with a less dense lesion and good prognosis (25-29). Oedema extending to more than one segment is associated with poorer sparing and prognosis (30). Selden et al. (31) established that four MRI findings were prognosticators of poor neurological outcome: presence of cord haemorrhage, length of spinal cord haemorrhage, length of spinal cord oedema and cord compression. In the acute stage MRI can also help visualise discreet injuries such as bone bruising to the vertebral bodies that have not fractured

MRI is the investigation of choice to monitor the spinal cord for changes such as cord atrophy, myelomalacia and post traumatic syringomyelia on the medium and long term. An MRI is recommend at three yearly intervals to monitor the injured spinal cord in view of the high incidence of radiologically evident post traumatic syringomyelia (32).

ASSESSMENT OF THE CARDIOVASCULAR SYSTEM

Bradycardia with a pulse of 45-60 per minute associated with hypotension and a systolic blood pressure of 80-90 in the presence of warm peripheries, visible veins and good peripheral pulse volume following trauma is indicative of a spinal cord injury. Unlike patients with haemorrhagic shock who exhibit tachycardia in association with hypotension, cold peripheries and poor volume pulse, and who require bigger intravascular volume replacements, great care should be taken with intravenous fluid administration to patients with physiological bradycardia and hypotension caused by SCI. The impaired sympathetic system of the patient which is responsible for the hypotension and partly responsible for the bradycardia, is usually unable to cope with excess amount of fluid. The patient can easily develop pulmonary oedema and respiratory failure.

Bradycardia can be aggravated by hypoxia, hypothermia and tracheal suction all of which can cause cardiac standstill. The highest risk is during the stage of spinal areflexia “spinal shock” when the vagus nerve activity is unopposed by the sympathetic nervous system activity. The patient without a previous history of cardiac disease responds readily to cardiac massage and atropine 0.3mg intravenously provided the cause of the cardiac standstill is effectively treated.

ASSESSMENT OF THE RESPIRATORY SYSTEM

The presence of diaphragmatic breathing (absence of chest expansion during inspiration associated with increasing girth with or without retraction of intercostal muscles) in a trauma patient is strongly suggestive

of a cervical or upper thoracic cord injury. Frequent clinical examinations of the chest to ensure good air entry throughout the lung and exclude associated chest injuries, haemothorax or pneumothorax, are of paramount importance. These should be combined with monitoring of the vital capacity and oxygen saturation. An initial chest Xray is advisable in all patients suspected of having sustained a SCI. Patients with thoracic vertebra injuries are at higher risk of developing haemothorax than patients with cervical or thoraco-lumbar injuries. Frequently the haemothorax does not become apparent until the third or fourth day following the injury hence the need for the repeat chest x-ray.

A vital capacity below one litre in a tetraplegic patient requires intensive monitoring and chest physiotherapy. If, despite these measures, the vital capacity drops further (below 600) and the oxygen saturation cannot be maintained ventilation may have to be considered.

With these simple measures the great majority of patients with C5 lesions or below do not require ventilation unless they have associated major chest trauma, an ascending lesion involving the phrenic nerves motor neurones or indeed a respiratory problem prior to their injury. Ventilation should, whenever possible, be avoided since during tracheal suction stimulation of the vagus nerve can result in further bradycardia and cardiac standstill. It is also difficult to wean tetraplegic patients off ventilators. Intensive physiotherapy, frequent assessment of the neurology and the breathing, as well as timely intervention can prevent death from hypoxia due to retention of secretions and respiratory failure. Hypoxia can cause death by aggravating the bradycardia to a cardiac standstill. Hypoxia can also destabilise the physiologically impaired, traumatised spinal cord further, resulting in further neurological deterioration (33). An ascent of the neurological lesion by one or two segments due to oedema of the spinal cord that involves the motor neurones of the phrenic nerves in a patient with a C5 lesion is likely to necessitate ventilation for 2-3 weeks, spontaneous respiration however usually gradually recovers.

ASSESSMENT OF THE ABDOMEN

A conscious, alert and co-operative patient who is unable to cough or who is only able to effect a weak cough in the absence of rigidity or with loss of tone in the abdominal musculature is highly likely to have sustained a SCI above the level of D6. A weak cough associated with a positive Beaver's sign (movement of the umbilicus proximally during a cough) indicates paralysis of the lower abdominal muscles with some function of the upper abdominal muscles. In Brown Séquard syndrome the umbilicus can sometimes be seen shifting laterally from the mid-line opposite the side of the hemi-cord lesion when the patient is asked to cough. Auscultation of the bowels may or may not reveal absent bowel sounds. Delayed paralytic ileus is not uncommon following spinal injury with neurological damage. It is therefore important to avoid oral fluids and food intake for 24-48 hours following injury. During this period monitoring of the abdomen with documentation of a girth chart and regular auscultation for bowel sounds should

be ensured. Occasionally the bowel sounds remain silent for longer and parental feeding should be considered. Early oral intake of food and or fluid in the presence of paralytic ileus is likely to cause abdominal distension and further embarrassment to respiration. Death can therefore occur from respiratory failure, a cardiac arrest from hypoxia or a combination of both.

ASSESSMENT OF BLADDER AND URINARY SYSTEM

A palpable distended bladder in an unconscious patient who lies in a dry bed is very suggestive of a spinal cord injury in shock or a cauda equina lesion. A distended bladder which does not cause discomfort to a conscious patient on palpation especially when the patient is unable to void urine is similarly a useful diagnostic sign of an injury to the spine. Unconscious patients with head injury, an intact spinal cord and cauda equina are likely to be incontinent upon admission to the accident and emergency department.

An indwelling catheter should be inserted for 48 hours in the bladder in order to facilitate hourly or two hourly measurement of the urinary output. The presence of haematuria should be investigated with an intravenous urogram or an ultrasound scan of the urinary system in order to exclude renal damage or damage elsewhere in the urinary tract.

Oliguria is commonly observed following SCI and is expected to last for a few days. Vigorous intravenous fluid infusion should be avoided.

It is not advisable to leave an indwelling catheter in the bladder for longer than 48 hours as it is likely to be a source of urethral and bladder complications.

Following removal of the indwelling catheter four hourly intermittent catheterisation by the nursing staff should be carried out and the residual volume should be recorded on each occasion. This is to ensure that the residual urine does not exceed 500 cc in order to avoid bladder over distension. A week or two following the injury a number of patients will develop polyuria for variable periods of time. Various strategies are usually adopted including reduction of fluid intake, increase of the frequency of intermittent catheterisation or the insertion of an indwelling catheter for a short period of time until the urinary output is readjusted.

Patients with upper motor neurone lesions may start to develop reflex micturition 3 to 4 weeks following the injury. Effective reflex micturition may not however be established before 3 to 5 months following the injury. During this period the patient on intermittent catheterisation should be advised to keep an accurate record of the voided and of the residual urine.

ASSESSMENT OF LEVEL OF CONSCIOUSNESS

It is paramount to make a quick clinical assessment of the level of consciousness in the accident and emergency department and with each subsequent neurological examination until the patient recovers consciousness completely. The level of consciousness influences the interpretation of the neurological findings and examination. The Glasgow coma scale (34) is the most commonly used and useful scoring system.

PSYCHO-SOCIAL ASSESSMENT, ASSESSMENT OF COGNITIVE FUNCTIONS

It is good practice to assess cognitive functions during the early stages of mobilisation and before intensive rehabilitation commences. Cognitive functions can significantly influence the method and the content of the rehabilitation process as well as its outcome. The psychological state of the patient prior to and after the injury, the social and vocational background, the adequacy of the accommodation are all equally important aspects that are also likely to influence the rehabilitation process and its outcome.

ELECTROPHYSIOLOGIC ASSESSMENT

Numerous electrophysiologic tests are available however they are not widely nor routinely used except in some clinical settings. The commonest are nerve conduction studies, somatosensory evoked potentials, and motor evoked potentials

Nerve conduction studies (NCS)

NCS are commonly used and can help differentiate between upper motor neurone (UMN) and lower motor neurone (LMN) lesions in both upper and lower limbs. In a root lesion, plexus lesion or peripheral nerve damage both motor and/or sensory conduction are impaired. In the upper limbs study of the median and ulnar nerves can predict recovery of hand function (35,36). In the lower limbs study of the peroneal and tibial nerves can help differentiate between conus or cauda equina and epiconal lesions (37).

Somatosensory evoked potentials (SSEP)

SSEP evaluate primarily the function of the dorsal columns but can also reflect function in other spinal tracts and in peripheral nerves. They may help differentiate between complete and incomplete lesions in the acute stage following injury as they are not affected by the state of consciousness of the patient nor by spinal shock. In the acute SCI patient, recording of tibial and pudendal SSEP has been found to be predictive of ambulation (38, 39) and of the function of the somatic component of the external urethral sphincter. They cannot however predict recovery of detrusor muscle functions (40).

Motor Evoked Potentials (MEP)

MEP can be elicited by magnetic or electrical cortical stimulation. MEP assess the function of the cortico-spinal tract (41) by recording from different peripheral muscles during cortical stimulation thus enabling the assessment of both level and extent of the lesion (42). Magnetic cortical stimulation can be applied to conscious patients as it is less painful and more powerful than electrical stimulation. Unfortunately it is not advisable to use magnetic stimulation in the presence of metal implants.

In general patients with early MEP recovery have the best chance of recovery of motor and ambulatory functions (43, 44).

ASSESSMENT AND DOCUMENTATION OF FUNCTION

The Functional Independence Measure

The Functional Independence Measure (FIM) was designed by a US task force in 1983 to assess the " burden of care" caused by disability. The burden of care is the amount of time and energy which the carer who assists the disabled individual expends in achieving a defined task with and/or without an assistive device. The lack of an assistive device can therefore increase the burden of care as the carer will probably spend more time and energy without the assistive device to achieve that particular task. FIM was published by Hamilton and Granger in 1987 (45) and is to date the prevailing primary ADL (Activity of Daily Living) measure for all types of disability, including spinal cord lesions (SCL).

The tool was intended to assist in estimating the cost of rehabilitation (46). FIM is widely used to evaluate functional progress and outcomes by the rehabilitation team which seeks to maximise the score by focusing on the goals of rehabilitation in order to maximise independence and minimise the assistance required by patients to perform the tasks of daily living.

The FIM score consists of 18 activities (13 motor and 5 cognitive) assessed individually but grouped under 6 areas: self care, sphincter control, transfers, locomotion, communication and social cognition.

"Self care" tasks includes six activities: eating, grooming, bathing, dressing upper body, dressing lower body and toileting. "Sphincter control" relates to bladder and bowel care assessed separately "Transfer" is assessed under three activities. Transfer between bed, chair and wheelchair are documented together under one activity. Toilet transfer is documented separately.Both tub and shower transfers are documented together as one activity. "Locomotion", mobility (ability to walk and or use the wheelchair) is documented separately from ability to manage stairs (2 separate activities). With "Communication", comprehension and expression are scored separately. For "Social Cognition" social interaction, problem solving and memory are assessed as three separate activities

Each activity is scored 1 through 7 based on the individual's contribution to carrying out the task with a score of 1 denoting a requirement of total assistance with a task and a score of 7 describing complete independence in achieving a task timely and safely. A subject with a score of 1 can only contribute less than 25% to the activity thus requiring total assistance. A score of 2 means that the subject is capable of contributing 25% or more in carrying out the activity but requires maximum assistance. Complete dependence describes patients with scores of 1 and 2 as the former requires "Total Assistance" and the later or maximal assistance. Patients with modified dependence are scored 3,4 or 5 depending on their requirements of moderate assistance, minimal assistance or supervision only to achieve a task as well as their contribution of 50 % or more, 76% or more and 100% respectively. Patients with scores of 1 to 5 usually require personal assistance from a carer or a helper. Patients with "Modified Independence" (a score of 6) are likely to require some assistive

device or equipment to live independently without a carer. The total score ranges from 18 to 126 points.

FIM has been translated into many languages and is used by clinicians and various allied professions, through observation or interview (46, 47) and by patients as self report questionnaire (48). It has been used both for inpatients and in the community

Many studies bear out the reliability of the FIM (45, 49, 50) and its validity in various age groups (51-56) and various impairment groups (45, 50, 52, 57, 58). Several authors have found FIM to be appropriate for Spinal Cord Lesions (SCL) patients (48, 59, 60). Some demonstrated the efficacy of FIM in predicting the cost of care support in patients with SCL (57). Others however raised doubts about its sensitivity to functional changes in patients with SCL (61, 62) and other populations of patients such as patients with cognitive impairment (63).

FIM has been criticised for its lack of unidimensionality (64, 65).

The Spinal Cord Independence Measure

The Spinal Cord Independence Measure (SCIM) was developed at the Loewenstein Rehabilitation Center in Israel and is gaining increasing popularity for its sensitivity to changes of function in SCI patients. It was published in 1997 by Catz and Itzkovich (62) and has been evaluated in a few countries. The focus of the objective of care and rehabilitation using the SCIM is not merely on the burden of care but also on the well being of the patient. In other words an evaluation using the SCIM of the patient's capacity to perform daily tasks independently encompasses the economic burden of care to include comfort and the medical condition of the patient. Independence or activity achieved with costlier, heavier or more challenging assistive devices or with medical shortcomings and /or discomfort is considered to be of lower value and is scored lower (66). SCIM includes only tasks relevant to SCL patients. Functional achievements are rated according to their importance for the patients.

The measure consists of 28 items divided into 3 subscales (areas of function) Self Care (score 0 to 20), Respiration and Sphincter Management (0 to 40), and Mobility (0 to 40). Mobility is scored separately for room/toilet and for indoors/ outdoors. The total score ranges between 0 and 100. The scoring guidelines of the SCIM are detailed on the evaluation form to avoid the need for a manual. Catz et al (62, 67) found the SCIM to be more sensitive to functional changes in patients with SCL than the FIM. The updated version of SCIM (SCIM II) was further developed to improve some of the original scoring criteria (68). It was found to be suitable for use by both a multidisciplinary team and by a single nurse, through observation or interview. Scoring by a team and observation was however found to be slightly more accurate than by a single nurse through interview (69). Investigations of SCIM II included Rasch and factor analysis. These indicated that SCIM II possesses characteristics of valid and reliable scales, such as unidimensionality, unique and independent informativeness of most SCIM items, applicability of item testing,

compliance of total patient ability with ability to perform single tasks (internal consistency), clarity of task categories, discrimination between estimated levels of task difficulty and between patients with different estimated functional levels, hierarchical arrangement of tasks and categories, and similarity of scoring across subject subgroups and raters (68, 70). After international consultation a third version of SCIM is being created in order to further refine and prepare it for future multi-culture validation.

STANDARDS FOR NEUROLOGICAL EXAMINATION AND DOCUMENTATION

Michaelis in the late sixties conducted an international enquiry in paraplegia and tetraplegia in order to establish an agreement on terminology and timing of examination for accurate prognosis. Unfortunately no agreement between specialists from 15 countries could be reached (71). In the same year Frankel published the Frankel's Classification in which the density of the neurological lesion could be described as complete or incomplete depending on the absence or presence of sensation and motor power below the level of the lesion. Patients with incomplete injuries could be further subdivided into three groups depending on the degree of sensory and motor sparing. Based on this Classification, Frankel published the outcome of postural reduction and conservative management of a large series of patients with spinal injuries at all levels. Using the Frankel's grid (72) he demonstrated for the first time that neurological progress of groups of patients could be easily described by the assessor and easily understood by the reader (Fig. 1). Since 1980 a number of classifications have been proposed but very few were found useful. In 1982, the American Spinal Injuries Association developed the Standards for Neurological Classification of spinal injured patients (73). This was revised on 4 occasions, the last being in the year 2000. Since 1992 the ASIA standards have become internationally accepted.

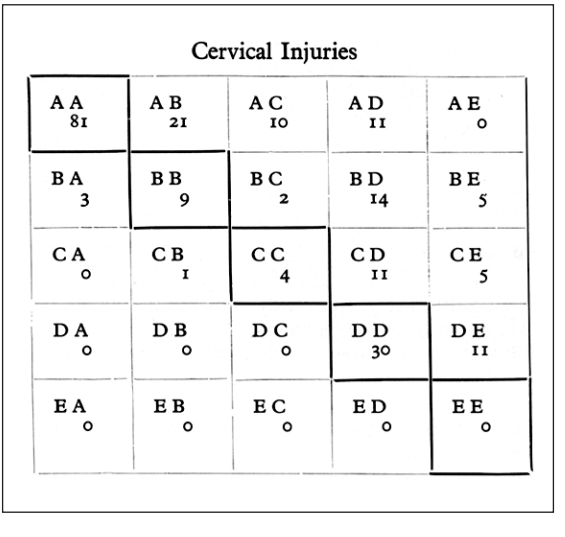

FIGURE 1. Example of Frankel's grid (10). In each square of the grid are two letters of the alphabet, the first related to the neurological lesion on admission and the second to the neurological lesion on discharge. Using the Frankel's grid (72) neurological progress of groups of patients can be easily described by the assessor and easily understood by the reader.

Frankel's classification

This method of classification was developed as a system to evaluate and document the neurological progress of an individual patient, large numbers of patients or subgroups of patients with spinal injuries following a full neurological examination. The Frankel Classification (72) is still the most commonly used classification by clinicians from all disciplines.

Patients are grouped into five categories, based on their clinical neurological presentation. These categories range from patients with complete sensory and motor loss below the level of the injury (Frankel A), to patients with no somato-sensory loss and no sphincter disturbance; however, abnormal reflexes may be present (Frankel E). The three categories inbetween describe various degrees of sparing below the level of the lesion. Frankel B describes sensory sparing only including sacral sparing however with complete absence of motor power. Frankel C describes sensory and motor sparing below the level of the lesion, however the motor power is poor and of no practical use to the patient. Frankel D describes sparing of sensation and motor power below the level of the lesion which many patients could use to walk, with or without aids. Frankel E patients have normal motor power, sensation and sphincter functions.

The advantage of the Frankel Classification is that with one letter of the alphabet (from A to E) one is able to describe and/or understand in general terms both the density of neurological damage at a particular level, the presence or absence of sparing, the modality(ies) functions spared and the usefulness of the motor functions spared, if any, below the level of the injury. Furthermore, any significant influence of treatment and/or time resulting in significant change of density and function can easily be documented by repeating the assessment for the individual patient or the group of patients and documenting the findings in the Frankel grid (Fig. 1).

The sphincter functions are not described in Frankel group A,B,C and D. They are presumed to be undisturbed in Frankel E. Similarly the quality of ambulation and the need of lower limb orthosis and/or arm support are not specified in Frankel D. Although the Frankel Classification is good at measuring significant changes in neurology and function, it is not however sensitive enough to elicit small changes in neurology when the patient has not improved or deteriorated sufficiently to move from one Frankel grade to another. As a tool of measurement it is good at measuring most of what matters to the patient and the clinician but not necessarily what is required for the rigours of research and accurate comparison between methods of treatment. The Frankel Classification however remains the most practical method of describing the progress of a patient or a group of patients in the clinical situation.

For research purposes the Frankel classification or its modified version by ASIA requires combining with a method to quantify loss and gain of both sensation and motor power numerically, quantitatively and in percentage terms (79). The method of percentage of loss from normal and percentage of recovery or loss following treatment were described and recommended by El Masry et al (79) as an alternative to simple numeri-

cal calculations in order to avoid the problems of parametric measurements.

Ambulation and sphincter functions will also require additional specific documentation.

The ASIA/IMSOP classification

Unfortunately agreement between clinicians and groups of clinicians about definitions of the level of injury and methods of documentation have always been difficult to obtain. The need for some consensus became however paramount as claims about effectiveness of various pharmacological agents and treatment modalities were being increasingly made. The Standards of Neurological Classification of SCI from trauma and disease were first published by the American Spinal Injuries Association in 1982 (73). The Standards evolved in definitions and acceptance by consultation between ASIA and the International community of spinal cord specialists. Donovan and colleagues showed that even among experienced clinicians discrepancies occurred in classifying patients (74). His work with colleagues led to the revision of the original standards (75). Despite a number of changes that had been made, Priebe and Waring found that although there had been some improvement in the new version the inter-observer reliability of patient classification was less than optimal (76). They made a number of recommendations to improve reliability including the institution of formal training. Initially the standards incorporated the Frankel Classification. In 1992 the ASIA Classification was further modified together with the Frankel classification which was renamed the ASIA Impairment Scale. The 1992 revision also incorporated the Functional Independence Measure (FIM). The revised version was endorsed by the International Medical Society Of Paraplegia (IMSOP) and published as a joint document by the American Spinal Injury Association /International Medical Society of Paraplegia (ASIA/IMSOP1992) (77) (Fig. 2 and 3). Dittuno et al published the 'International standards booklet for neurological and functional classification of spinal cord injury (78). A training package of 4 videos and a reference manual have been developed since 1994 by a committee to ensure standardisation of examination and documentation. This package can be obtained from the ASIA office in Chicago Illinois. El Masry et al. (79) tested the validity of testing the chosen muscles by the ASIA and by the National Acute Spinal Cord Injury Study (NASCIS) group in representing the standard motor examination. The assessment of the individual patient was carried out by the same examiner. Using a quantitative formula of motor deficit percentage (loss) and motor recovery percentage (gain) they concluded that the chosen muscles recommended by both ASIA and NASCIS were representative of the conventional motor scoring in the population of patients examined. El Masry et al recommended that in the majority of cases the ASIA motor scoring system is used to assess muscle strength in individuals with SCI because it offers a smaller number of muscles to be tested and because it is reliable. It is important however not to miss

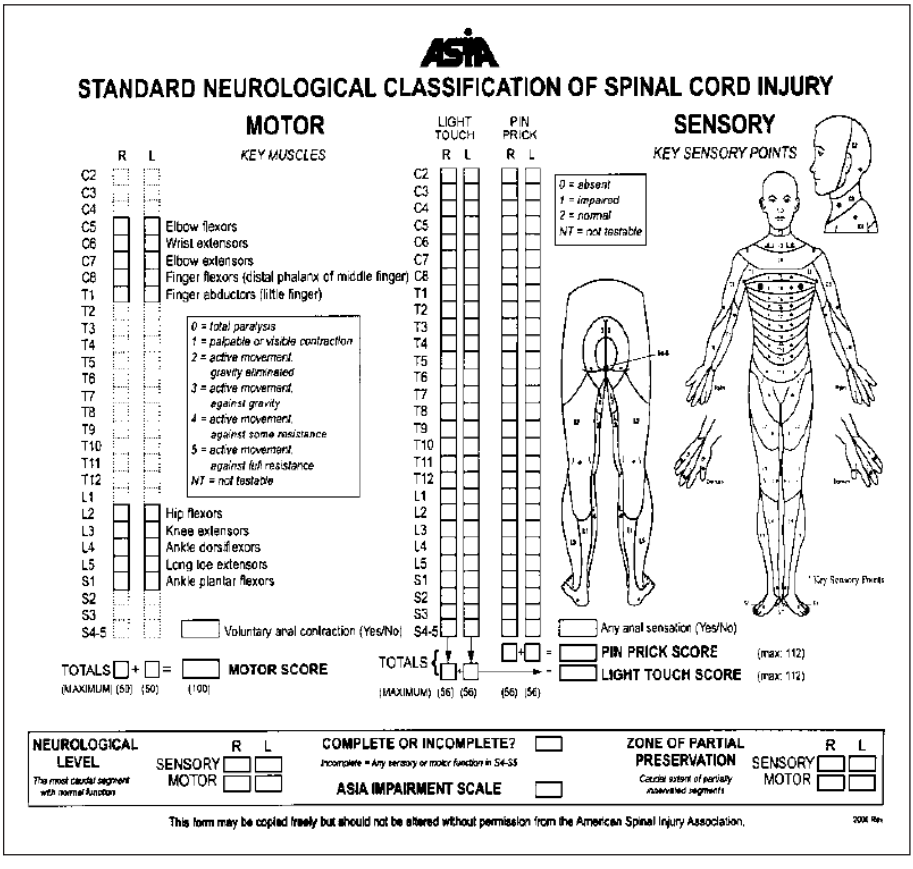

FIGURE 2. The standard neurological classification of spinal cord injury.

movements in other muscles than those recommended by ASIA for testing. For example, the hip adductors may be spared in an ASIA C patient or may be the first to reappear.

The inter-rater reliability of the 1992 standards was tested (80-82) and found to be poor especially in the scoring of incomplete SCIs. Further efforts were recommended in intensive training. Donovan et al found that further clarification was required to determine the sensory level and to score muscles inhibited in strength by pain (80). Further revisions of the ASIA/IMSOP Classification were published in 1997 (83) and in the year 2000. In the last revision the FIM was discarded and no longer considered a requirement.

The current guidelines, definitions, precautions and methods of classification based on the last revision of the year 2000 are summarised below:

SENSORY TESTING

- Sensation of pin prick and light touch are tested separately throughout the 28 dermatomes on each side of the body and are documented in the ASIA chart.

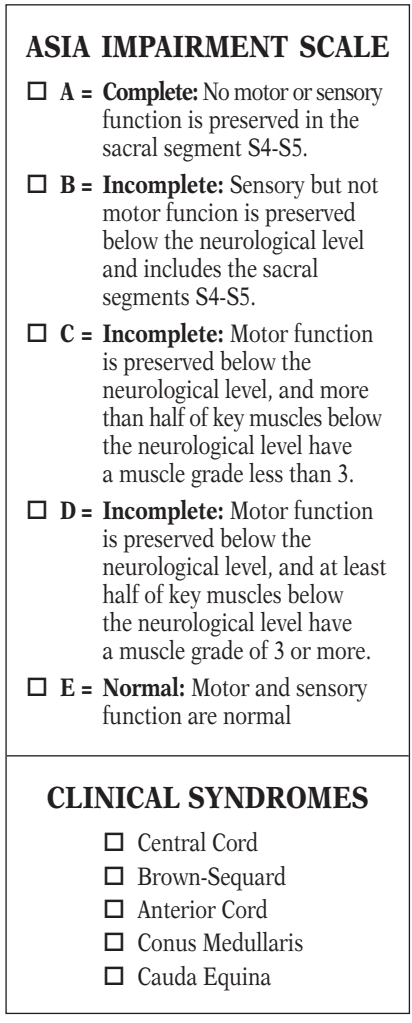

FIGURE 3. The ASIA impairment scale.

- Anal sensation is tested in S4 S5 combined, and is an essential component of the sensory testing and documentation.
- Deep rectal pressure is examined by digital examination with gentle pressure on the rectal wall. It is recorded as present or absent.
- The sensory level is documented for each side separately.
- The appreciation of pin prick sensation is compared between the face and the area tested and is scored on a three point scale (0 to 2). A score of zero denotes anaesthesia or inability to distinguish between sharp and dull. A score of 1 implies ability to differentiate between sharp and dull but there is hypoaesthesia or hyperaesthesia. In case of doubt 8 out of 10 questions have to be correct in order that the area is given a score of 1. A score of 2 implies that pin prick is felt as normal as it is felt on the face.
- Light touch is assessed using a cotton-tip swab stroking the skin over a distance not to exceed 1cm. A score of 2 describes normal light touch sensation, 1 sensation is impaired compared to face and 0 means absent sensation.
- When testing the dermatomes between C6 and C8 the dorsal surface of the proximal phalanges of the fingers and thumb are recommended. In the chest and abdomen the mid-clavicular line is recommended.
- The Sensory Level based on sensory testing is determined for each side separately as the most distal (caudal) segment with normal sensation 2/2.
- The Zone of Partial Preservation (ZPP) is the area between the sensory level and the most caudal segment where any abnormal sensation is present. For documentation purposes it is this latter segment only that is to be documented.
- The sensory index is the score of each modality on each side (up to 56 points each modality and 112 points each side). If an area of the skin cannot be tested for some reason e.g. skin lesions, grazes or damage the dermatome should be scored as non tested (NT).

- Position and vibration tests although important for balance especially if the patient regains ability to ambulate are unfortunately optional and cannot be recorded on the ASIA chart.

MOTOR POWER

- The motor power is assessed by manual testing based on the MRC scale from 0-5 (see chart).
- Five muscles from each upper limb and each lower limb are chosen to represent the body musculature (see chart). These muscles were chosen because of their consistency being innervated by the same in segments and because of the ease of testing in the supine position.
- Limiting factors such as pain may inhibit full use of power in which case a power of 4/5 may be documented as 5/5 with an asterisk (*).
- Muscles that for some reason cannot be tested e.g. severe pain, excess spasticity, a fracture, or the presence of contracture that limits the range of movement to more than 50% of normal; the muscle should not be scored and should be documented as not testable (NT).
- Optional muscles (diaphragm, deltoids, abdominal, medial hamstrings & hip adductors) may also be tested but are not included in the motor index score. Their power can be described as absent, weak or normal.
- The motor level is the most distal (caudal) key muscle group that is graded 3/5 or greater provided the adjacent group of muscle proximally is graded 5.
- If a muscle required for the determination of the motor level is non testable, the designation of the motor level on that side should be deferred.
- The motor level is identified separately on each side of the body.
- The motor index score is calculated by adding the muscle scores of each key muscle group totalling a maximum of 100.
- For those myotomes that are not clinically testable by a manual muscle examination i.e., C1 to C4, T2 to L1 and S2 to S5, the motor level is presumed to be the same as the sensory level (83).

The Neurologic level of injury (NLI) is the most distal level at which both sensory and motor functions are intact. The NLI is documented separately for each side of the body (see chart).

The criterion for a 'complete injury' is "the absence of sensory and motor functions in the lowest sacral segments (S4 and S5). The definition of an 'incomplete injury' is based on "the preservation of sensation or motor function below the NLI that includes the lowest sacral segments S4 & S5".

The zone of partial preservation (ZPP) refers to the dermatomes and myotomes distal to the neurological level that exhibits partially innervated in patients with complete injuries. The extent of the ZPP is defined by the most distal segment with any sensory and/or motor sparing. The ZPP cannot be used in incomplete injuries.

The ASIA Impairment Scale (modified Frankel classification)

There are certain subtle differences between the original and modified Frankel classifications (ASIA impairment scale 2000). In Group A there is almost no difference between the two classifications except for the wording. In group B it is mandatory in the ASIA impairment scale that sacral sensation (intact or impaired) is present. This was not mandatory in the original Frankel Classification. This means that a patient who may have an incomplete spinal cord damage could be classed as 'complete' because the sensory tracts from the sacral dermatomes have been damaged while sensory tracts from other dermatomes distal to the level of injury have not. The other fundamental difference between the two classifications is in Group C & D where the general description of the quality of the function of the muscles, below the level of injury, in supporting ambulation in the original Frankel classification has been replaced by a specific MRC grade of the muscles tested in the ASIA Classification. In other words it is no longer possible to assume from the ASIA impairment scale that the patient in group D has enough useful motor power to move the limbs and walk. A numerical description of sensation is required using the ASIA but not the original Frankel classification.

Unfortunately both complete absence of pinprick sensation (anaesthesia) and inability to differentiate between sharp and dull (analgesia) are described as zero by ASIA despite the fact there may be some differences in the prognostic value between the two. An unpublished modification of numerical sensory documentation by El Masri is currently being used to in order to evaluate the prognostic value of the different sensory appreciations of the spino-thalamic tract. Pin Prick (PP) and cotton wool (CW) sensations are also tested separately. In this modification complete anaesthesia to PP and/or CW sensation is described as Zero. A score of One is subdivided into A, B and C. One A describes diminished PP or CW sensations compared to the face. One B describes dull sensation to PP and/or vague sensation to CW. One C describes hypersensitivity to PP and/or CW sensations. Normal PP and/or CW sensations are documented with a score of Two

The various known patterns of identifiable sparing (syndromes) in incomplete traumatic spinal injuries (El Masri 1999) (84) have been incorporated in the documentation of the ASIA classification (Fig. 3).

NATURAL HISTORY OF RECOVERY AND INFLUENCE OF TREATMENT ON RECOVERY

Accurate assessment and documentation are important for prognosis and planning of the rehabilitation process. Furthermore, in a field where there is ongoing controversy about the best method of treatment to the injured spine, assessment and documentation are paramount to quantify the actual benefit (or harm) of the various methods of treatment.

In general the major factor that determines the density of the lesion to the spinal cord is the damage sustained by the impact of the injury on the spinal cord during the accident. Other factors include the adequacy of the containment of the physiological instability of the injured spinal cord (85) as well as the biomechanical instability of the injured spinal column. Further mechanical damage of the neural tissue at the time of the accident is obviously likely to cause neurological deterioration or lack of neurological recovery. The injured spinal cord which has sustained damage to the blood brain barrier, cell membrane disturbances and auto regulatory disturbances is also vulnerable to non-mechanical damage from complications outside the spinal canal namely hypoxia, hypotension, sepsis and anaemia (85). These complications can easily occur when there is a multi-system physiological impairment and malfunction as is the case with all patients with cord injury. Fortunately, with expert care the majority of these complications can be prevented. With good management of the multi-system dysfunction and of the spinal injury the great majority of patients with incomplete spinal cord injuries recover significantly. In general the majority of patients who present with motor power sparing or start regaining motor power within the first 48 to 72 hours following injury should walk again (86). Patients with spino-thalamic sensory sparing between the level of the injury and the 5th sacral dermatome but with no motor sparing also have a good chance of significant recovery (87-89). Over sixty percent of these patients will recover significantly to ambulate (88). Patients with complete sensory and motor loss on presentation have about a 10% chance of recovery (10). Zonal root recovery of motor function in one or two segments below the level of the lesion usually occurs in patients whose neurological level is higher than the fracture level and in patients who have pinprick sensation in the area where the myotome is initially non-functioning (90). In these two groups of patients zonal recovery of the paralysed muscles usually occur. Bony encroachment in the spinal canal and the size of the spinal canal do not appear to be of prognostic value for recovery in patients with incomplete spinal cord injuries or patients with intact neurology (86,88,91-96). There is some evidence that old age can adversely affect functional outcome in patients with paraplegia (97) and neurological outcome in patients with tetraplegia (98, 99).

To date no treatment (medical, surgical or pharmacological) directed primarily to the spinal cord or the spinal axis in humans has shown any significant added benefit to neurological recovery. Neurological recovery can occur naturally in patients with incomplete injuries provided the Spinal Cord is protected from both mechanical and non-mechanical damage. It is probable however that there will be various methods of treatment in the near future, which are likely to be worthwhile evaluating. It is therefore paramount that members of the community of specialists in the field of spinal injuries endeavour to use methods of assessment that are easily applicable and reflect accurately both qualitatively and quantitatively major as well as minor improvements or deterioration in the neurology of these patients.

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CHAPTER 5
ASSESSMENT IN OTHER CENTRAL NEUROLOGICAL DISEASES

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The principal disorders of the central nervous system, stroke, traumatic brain injury (TBI), Multiple Sclerosis (MS), and idiopathic Parkinson's disease, lead to complex and often interrelated impairment and disability.

Numerous functional systems are damaged and disrupted to different degrees including sensory, sensorial, as well as motor involvement, along with impairment of visceral functions and, especially, cognitive functions. The frequency of these disorders and the problems of public health that ensue from them in terms of initial rehabilitation management, and functional consequences due to the frequent sequelae or progressive nature of the disorders, call for a rigorous method of assessment. According to the concepts of the International Classification of Impairments, Disabilities and Handicaps (ICIDH), numerous evaluation tools are used or have been specifically elaborated. We do not intend to draw up an exhaustive list of these tools but rather to illustrate the method of assessment, underscoring the advantages and limits of the available instruments, taking neurological aspects into consideration.

STROKE ASSESSMENT

In industrialized nations, stroke is the first cause of acquired handicap in adults

and the third cause of mortality. In spite of precautionary measures and, because of the ageing of the population, the incidence of stroke remains particularly high (1). Survival after stroke has improved sharply despite the presence in many patients of sequelae reducing their physical and, often, psychosocial autonomy (2).

Several obstacles should be considered in assessments after established stroke:

- the variability of the clinical pictures, which hinders comparison from one patient to the next and constitution of homogeneous groups of patients;
- the existence of multiple impairments, predominant among which is more or less severe hemiplegia and which interact with each other (hemianesthesia, homonymous hemianopia, paralysis of cranial nerves, sphincter dysfunction, impaired swallowing, etc.);
- cognitive disorders in nearly half of the cases of supratentorial lesions, including aphasia, unilateral neglect, agnosia, and apraxia;
- the presence of comorbidity, which influences patient outcome and the potential for recovery, notably cardiovascular disorders and complications of diabetes mellitus.

These obstacles should guide the choice of evaluation tool and the elaboration of a rehabilitation protocol. For example, the use of questionnaires, visual analog scales and all tools requiring verbal responses can be validated only after careful verification of the patient's capacity to receive the information and formulate appropriate responses.

Assessment of neurological impairments

During the initial phase of stroke, as in the early phase of rehabilitation, it is important to establish a diagnosis and prognosis. In this respect, a clinical neurologic examination remains the most effective means of attaining these objectives. In various international scales, the most relevant elements of this examination have been standardized and relative importance has been attributed to them.

- ***Unified Neurological Stroke Scale*** (3) combines the middle cerebral artery infarction scale (Orgogozo's scale) and the Scandinavian Neurological Stroke Scale. This is a simple, quickly administered scale, conceived for early evaluation in the first weeks after infarct of the middle cerebral artery and for haemorrhagic stroke. This scale is primarily a motor assessment. During the period of rehabilitation, it has poor sensitivity to changes. The validation study showed good correlation with the *Barthel index*, the *Rankin scale*, and the *Sickness Impact Profile* (incapacity and handicap scales considered below).
- ***NIH Stroke Scale*** (NIHSS) (4) is extensively used in the USA. This scale also measures the severity of impairments in the early phase of cerebral infarction. Following application of Rasch analysis, the initial version of the NIHSS, which contained fifteen items, has been proposed in a revised version with thirteen items for use in early rehabilitation (5).

- ***European Stroke Scale*** (6): a rapid test containing fourteen items, this scale has good interobserver and intraobserver reproducibility, and excellent internal consistency. The *European Stroke Scale* is correlated to the *Barthel index* and to the *Rankin scale*.

These three scales are the most widely used for global rapid evaluation in diagnostic and prognostic applications. Other tests exist differing little from the latter three (the *Canadian Stroke Scale* and *Scandinavian Stroke Scale*, in particular). To these may be added a more precise assessment of impaired consciousness, the *Glasgow Coma Scale* (GCS) (7) designed to assess traumatic coma is, for example, often used in the initial phase of stroke. The oral part of this scale is, however, not reliable for aphasic patients.

In physical medicine and rehabilitation it is important to have more specific tools responding to metrological criteria of validity, sensitivity and reproducibility.

For motor deficit (hemiplegia), three assessment tools tend to be used:

- ***The Fugl-Meyer scale*** (8). This is the oldest and most complete. It was inspired by principles of recovery described by Brunnstrom. The reproducibility is excellent but its application is demanding and it takes a long time to administer. This scale is available in several languages.
- ***The Motor Assessment Scale*** (9). Faster and easier to administer than the previous one, it was inspired by specific rehabilitation concepts ("motor relearning program"). It consists of eight motor tasks performed during therapy and evaluates spasticity in an overall manner but this item has poor interobserver and intraobserver reproducibility.
- ***The Toulouse Motor Work-up*** (10): validated only in French, it is simple and well correlated to disability scales including the Barthel index or FIM (see below).

There is no tool for ***evaluating spasticity*** specific to hemiplegic patients. Spasticity assessment is included in the motor deficit scales mentioned above. In therapeutic trials, the *modified Ashworth Scale* is applicable in cases of cerebral and spinal cord spasticity (11).

Cognitive impairment after stroke is evaluated using numerous specific tests and batteries of tests including the *Boston Diagnostic Aphasia Examination* for speech impairment, visual graphic evaluations and other tests for unilateral neglect, and anosognosia scales for awareness of impairment. These tools are considered below ("Assessment in cognitive impairment"). The particular demands of this evaluation merit mention. For example, a simple but nonspecific generic instrument such as the *Mini Mental State Examination* (MMSE) proposed by Folstein (12) to detect post-stroke dementia fails to take into account the variety and intricacy of

neuropsychological deficits. The MMSE overestimates the consequences of aphasia and underestimates those of unilateral neglect. The same remark applies to the *Blessed Dementia Rating Scale* (13), used in some cases of post-stroke assessment (14). Part B of the Blessed Dementia Rating Scale is similar to the MMSE with the same limitations.

The **evaluation of depression** after stroke poses a major practical problem, because frequent depressive states play a considerable role in the process of adaptation during the rehabilitation period, then at home. There is no specific instrument to evaluate post-stroke depression. For this population, the *General Health Questionnaire* appears to be more sensitive and successful than the Hamilton Anxiety and Depression Rating Scales (15).

Assessment of disabilities

Independence regarding activities of daily living after stroke, during the course of rehabilitation, or at the stage of sequelae is usually assessed using generic scales.

- ***The Barthel index*** is the oldest and was initially conceived specifically for this population (16). It is currently widely used to evaluate the care load of patients with physical impairments of various natures in hospitals. Correlated to neurological scores, the scores of the Barthel Index established early after stroke are predictive of the mortality, functional recovery, and duration of stay in rehabilitation units, and orientation at discharge from units of Physical and Rehabilitation Medicine (17). It is noteworthy that the *Barthel Index*, available in several languages, evaluates ten simple activities of daily living: feeding, bathing, grooming, dressing, bowel control, bladder control, toilet use, transfers, mobility, and stairs. The score extends from 0 to 100; to each category corresponds specific maximum scores of variable value. Completion is simple, underlining the excellent reproducibility. However this tool shows poor sensitivity to change, because of the system of attributing value and the limited number of activities evaluated. Above all, in case of stroke, this score fails to take cognitive disability into account.
- The ***Functional Independence Measure*** (FIM): described in another chapter of the present book (see Assessment of patients with spinal cord injuries) has been studied in depth in cerebral vascular disease (18). To it has more recently been added the ***Functional Assessment Measure*** (FAM) (19), which specifically addresses cognitive and psychosocial consequences in patients with brain damage. In fact, the FAM is predominantly used for patients with head injuries (see below).
- The ***Frenchay Activities Index*** (20) was specifically elaborated for post-stroke hemiplegia. It contains fifteen items, which investigate personal hygiene, mobility and activities using an ordinal scale of 1 to 4 for every item according to the degree of independence. The score is therefore situated between 15 and 60. Three subsections are as-

sessed: domestic activities, leisure and work activities, and outside activities. Easy to use and fast (5 minutes on the average), certain authors also consider it as a quality-of-life scale (21).

Measurement of handicap and quality of life

Most studies involving cerebral vascular disease use the same generic scales as those developed in rheumatology and orthopedics: the *Medical Outcomes Study 36-Item Short Form Health Survey* (SF-36), *Sickness Impact Profile*, *Nottingham Health Profile* (see chapter by Franco Franchignoni and Fausto Salaffi).

- ***The Rankin Handicap Scale*** (22) was designed for the overall evaluation of outcome after stroke. Extensively used with the Barthel index in therapeutic trials, it is short, simple and consists of six levels according to outcome. The reproducibility is good.
- ***The Reintegration to Normal Living Index*** (RNLI) was conceived and validated from the beginning in both English and French (23). It is used in the form of a self assessment form investigating mobility, personal hygiene, leisure activities, family role, social activities, personal relationships, and self image in eleven categories. Values are attributed using a visual analog scale or a three-level ordinal scale. A high score corresponds to good "reintegration" in life. In cerebral vascular disease, comparison of scores obtained by telephone or by direct interview and the responses of the patients or by close friends or family are generally consistent (24). The RNLI is sensitive to changes (25). Comparable in conception to the RNLI, a questionnaire specific for stroke called the *Subjective Index of Physical and Social Outcome* has recently been proposed (26).

ASSESSMENT IN TRAUMATIC BRAIN INJURY (TBI)

Assessment of the multiple consequences of severe head injury is certainly one of the most difficult problems of PMR. This is true in all stages, from coma to physical therapy and psychosocial rehabilitation. In the majority of cases, outcome after TBI includes the persistence of cognitive disorders, which are prominently involved in the assessments. Nonetheless, more or less complex associated neuromotor syndromes, and, above all, psychoemotional and behavioral disorders also occur. The evaluation plays a major role in guiding therapeutic choices during the phase of recovery and in organizing cognitive and physical rehabilitation. Later, it takes on a medicolegal aspect. In general, all instruments based upon questionnaires or subjective analyses raise questions concerning the reliability of measurements. In this respect, neuro-psychometric tools are limited in cases of persistent memory disorders or anosognosia. The current tendency is to opt for evaluation in a specific "real-life" situation (27).

Assessment of neurological impairment consecutive to TBI calls for specific scales, regarding which numerous studies have confirmed the substantial prognostic contribution.

1) The evaluation of the **severity and duration of coma** led Teasdale and Jennett to propose as early as 1974 the ***Glasgow Coma Scale*** (GCS) (7) classifying cranial trauma in three levels: severe TBI (GCS < 8), moderate TBI (GCS between 9 and 12), and mild TBI (GCS ≥ 13). The Glasgow-Liège Scale (28) and the Extended Glasgow Coma Scale (GCS - E) (29) render the GCS more sensitive, the former for deep coma, the latter for mild brain injury.

2) **Evaluation during the phase of awakening from traumatic coma** is based essentially on observation of the behavior and is extended with changes over time. Scales exist that quantify and classify behavioral reactions. They are designed to detect changes, in some cases, even small changes, that are not distinguished by the GCS.
   - ***The Rancho Los Amigos Levels of Cognitive Functioning Scale*** (LCFS) (30), extensively used in the United States, classifies the behavior of head injury patients in eight categories by observation of a certain number of signs, attitudes or responses: no response (I), generalized responses (II), focal response (III), vague and agitated (IV), vague, but not agitated (V), vague, but appropriate (VI), appropriate, but automatic (VII), or reasoned and appropriate (VIII). This scale, which is useful to compare populations of patients with head injuries, nevertheless has poor reproducibility and only tenuous validation (31).
   - ***Wessex Head Injury Matrix*** (WHIM) (32) is also based upon the observation of a large number of behaviors, attitudes and responses to certain situations. Three domains receive particular attention: motor capacities, cognitive capacities and social interactions. Application of the WHIM is situated between the end of the coma (spontaneous opening of eyes) and the possibility of performing psychological tests and more specific disability assessments, which are often only possible to conduct after a long delay. Fifty-eight items are listed and classified (Sixty-two items in the French version) according to a specified sequence of recovery. These items are grouped into four categories:
     - Items 1 to 15: basic behavior corresponding to reflex and more or less appropriate activity;
     - Items 16 to 29: essentially investigating visual behavior, designed to detect recovery of social interactions, communication and signs of emotional behavior directed toward family and friends. The resumption of verbal communication marks the end of this second group of signs;
     - Items 30 to 46 study the aspects of behavior requiring recovery of attention and cognitive organization;
     - Items 47 to 58: this last group is marked by the resolution of post-traumatic amnesia (PTA), i.e., the recovery of orientation and memory (see below).

The reliability of the WHIM has been verified, the interobserver reproducibility being good as is the test-retest reliability. Use of the WHIM requires thorough preliminary training. The prognostic validity of the WHIM was not yet been established.

3) **Post Traumatic Amnesia** (PTA) corresponds to the period during which the injured subject, upon regaining consciousness after a coma, remains incapable of retaining new information. The duration of PTA is a marker of severity of head injury, notably in terms of cognitive consequences (33). The end of PTA corresponds to recovery of spatiotemporal orientation and recovery of memory. Within the framework of a prospective evaluation of PTA duration, several tools have been developed involving quantitative measurements performed daily to assess orientation and anterograde amnesia in case of mild or moderate head injury. The most widely used tool is the Galveston Orientation and Amnesia Test (GOAT) developed by Levin (34). A score equal to or greater than 75/100 obtained three successive days indicates the end of PTA. Validity and reproducibility of this quantitative determination are good.

4) **Motor deficits**: Because of their heterogeneousness and their absence of specificity (hemiplegia, triplegia, or tetraplegia, postural dysfunction, cranial nerve palsy, etc.), these deficiencies are assessed by means of generic tools or tools specifically designed for a system deficit (i.e., stroke, balance, posture: see the corresponding chapter of this book).

5) **Neuropsychological and behavioral disorders**: Their complexity and diversity increase with the severity of the head injury and the number or extent of brain lesions. They combine a frontal executive deficit, including predominantly disorders of attention and speed of processing information, a durable or, in some cases, even definitive memory disorder, as well as complex disorders of communicating capacities, judgment, decision making, and self awareness (anosognosia). For every dysfunction, there are reference psychometric assessment tools (see chapter on Assessment of cognitive impairments). However, as already mentioned, there are numerous methodological limits in assessments of patients with the most severe head injuries. This is why more general assessment tools adapted to this population have been proposed.
   - ***The Neurobehavioral Rating Scale*** (NRS) (35). The NRS and its revised version (NRS-R) (36) is used to evaluate all neuropsychological and behavior disorders observed after head injuries. The NRS was derived from a scale used in Psychiatry, the *Brief Psychiatric Rating Scale* (37), to which Levin (32) added specific items concerning disorders of memory, concentration, and vigilance state, frontal syndrome, etc. Completion calls for

a standardized guided interview. The scale contains twenty-seven items, in seven quantified levels (from 0 for no disorder to 6 for most severe disorder). The interexaminer reproducibility is good, but variable depending on the items. In the revised version, the number of quantification levels was reduced from seven to four, the item "attention/vigilance state" was separated into two distinct subitems, a "flexibility of the thought process" item was added, as was evaluation of PTA using the GOAT. Significant correlations have been demonstrated with conventional prognostic factors of head injury: age, educational level, depth and duration of the coma. Five factors can be identified using factorial analysis including disorders of memory and motivated behavior, modification of emotional states, emotional and behavioral hyperactivation, impairment of awareness and attention, and speech disorders. Three items are distinct: guilt, excessive somatic concern, and hallucinations. Interobserver agreement is high and determining the five factors is useful to establish a profile of cognitive impairment (38).

Assessment of disability after traumatic brain injury calls for both specific and generic instruments:

- ***The Patient Competency Rating Scale*** (PCRS). The PCRS (39), which is specific for this population, consists of thirty items with five-level scoring. It is completed by patients to assess their perception of their own capacities regarding physical efforts, self care, emotional control, relational possibilities, and cognitive processes. The evaluation is performed by the patient, a member of the family and a care provider. A score of anosognosia is obtained by the difference between the score of the patient and that established by the family member and/or care provider.
- ***The Functional Assessment Measure***: The FAM (19), conceived as a complement to the FIM for brain-injured patients, assesses the degree of functional dependence for activities of daily living stressing cognitive, behavioral and psychosocial dimensions poorly analyzed by the FIM (40). The twelve items of the FAM add to the eighteen items of the FIM for a scale of thirty items. These twelve items belong to domains investigated by the FIM (self care, mobility, locomotion, communication), but the last category of the FIM (awareness of surroundings) is divided into two new domains: psychosocial adaptation and cognitive functions. FAM scores are correlated to the scores of other scales of disability and to factors of severity of head injury (PTA duration, severity and duration of coma). The interobserver reproducibility is, however, poorer for items investigating cognitive dimensions, which are more abstract than the motor-related items (41).

Handicap and quality of life after head injury

Despite numerous available evaluation tools in the field of impairment and disability, notably for neuropsychological disorders, there is no

reliable correlation of disability scales with the psychosocial outcome of patients with head injuries. This is attributable to the difficulty of consideration of the veritable repercussions of psychological, behavioral and social factors.

Along with the generic evaluation tools of handicap and quality of life, specific tools have been developed for patients with head injuries.

- ***The Glasgow Outcome Scale***: The GOS (42) is the oldest. It was created to assess the overall functional outcome of brain trauma victims, regardless of severity. It describes five levels: death, persistent vegetative state, severe handicap, moderate handicap and good recovery. Both reproducibility and sensitivity are good, at least during the initial months. Later, the GOS is correlated to quality-of-life measurements and various personality tests (43). In fact, the GOS is of little use during the course of recovery, because of the poor sensitivity to changes. In contrast, it makes a real contribution to epidemiological studies and within the framework of long-term follow-up, to improve, for example, the measures of public health and social politics designed for subjects with brain injuries.
- ***The Disability Rating Scale*** (44), which is also specific, has four categories: level of consciousness, cognitive capacities for self care, physical dependence to others, and social reinsertion (work, housekeeping, school activity). Scores range from 0 to 30 and determine ten categories of disability. Sensitivity is better than for the GOS, and the reproducibility is good.
- ***The Community Integration Questionnaire***: The CIQ (45) involves a self-assessment form completed in 10 to 15 minutes, consisting of fifteen items classified in three categories: integration at home, social integration and productivity. It is a discriminating tool even though, in some cases, it does not cover all aspects of handicaps. The scores of neuropsychological tests are correlated to those of the CIQ, at least at one year after the accident (46). The CIQ is extensively used in studies of outcome after head injury, but at present it must compete with a new tool, the ***Community Integration Measure*** (CIM) (47).
- ***The Rivermead Head Injury Follow Up Questionnaire*** (48) is based upon comparison by patients of their life since the trauma with regard to their life previously. Ten items are investigated including performance of daily living activities, ability to follow a conversation, to participate in social and leisure activities, professional activity, and relationships with spouse, family, and friends.
- ***The European Head Injury Chart*** (49) has been developed in various languages of the European Community. It essentially involves a standardized, comprehensive observation, containing 175 items to assess the changing phases of head injury. The time required to complete this test is long (2 to 3 hours) limiting its practical utilization.

- Certain critical aspects of the outcome of patients with head injuries, such as return to work and social integration justify associating generic scales to the specific tools. Noteworthy among such associations are the ***Craig Hospital Assessment and Reporting Technique*** (CHART) (50) as a supplement to the GOS (42) or to the Disability Rating Scale (44) and, for working activity, the ***Employability Rating Scale*** (51).

ASSESSMENT IN MULTIPLE SCLEROSIS

A demyelinating disorder of the central nervous system, multiple sclerosis is known for its clinical heterogeneity, the variability of course profiles among patients and in the same patient, and the unpredictability of the course. Consequently, there are numerous types and degrees of impairment and disability. Furthermore, there is substantial subjective fallout from the fatigue and depression that are so frequent in this disease. Both the development of new therapeutic protocols and the adaptation of rehabilitation protocols throughout the course or the disease require sensitive and prognostic evaluation tools.

In the assessment of **impairments,** Magnetic Resonance Imaging (MRI) has become an indispensable tool to supplement clinical scales. MRI diagnostic criteria are sensitive and specific (52). Technical perfectioning of imaging studies results in improved clinical and prognostic correlations in advanced stages, notably regarding cognitive impairment. Lesions of normal appearing white matter can be revealed, and the degree of axonal degenerative changes can be determined (Magnetization Transfer Ratio, MRI spectroscopy) (53).

The overall evaluation of the impairments in multiple sclerosis depends on several instruments specific to MS, among which the most widely accepted and used internationally is the ***Expanded Disability Status Scale*** (EDSS) or ***Kurtzke Scale*** (54). It involves attributing values to seven "functional parameters" corresponding to various potentially damaged neurological systems and to functional capacities primarily regarding ambulation. The final score obtained by combination of these various parameters ranges from 0.0 (no deficit) to 10.0 (death). Discriminative validity and relative simplicity are the primary advantages of the EDSS, completion of which nevertheless requires adequate training in the clinical neurologic examination. The drawbacks include its lack of homogeneity (mixture of elements of impairment and disability), as well as the interobserver reproducibility and sensitivity to change, which are not optimal. There is also a self-assessment EDSS by questionnaire, which shows good agreement with the EDSS completed using the neurological examination (55).

The European Database for Multiple Sclerosis: EDMUS Impairment Scale (EIS) (56) was developed for research purposes. It was inspired by the EDSS with a simplified system of value attribution, but the database also includes the EDSS and an Ambulation Index specific for to the disease (see below).

Noteworthy among the other scales of multiple sclerosis overall impairment is the ***Neurological Rating Scale*** (57), which is completed by patient interviews and considers sphincter dysfunction and sexual deficiencies. ***The Multiple Sclerosis Functional Composite*** (58), which was developed for therapeutic trials by a group of experts from several countries, is a combination of three tests investigating motor function of the upper limbs, ambulation and cognitive functions.

Other evaluation tools used in multiple sclerosis address specific impairments.

- For **fatigue**, the impact of which in terms of disability and handicap is indisputable regardless of the severity of motor deficit, it is recommended to use the ***Modified Fatigue Impact Scale*** (MFIS) (59). The MFIS is a self-administered questionnaire assessing perceived repercussions of the fatigue by means of twenty-one items, classified in three subscales (physical, cognitive, and psychosocial). Every item is quantified from 0 to 4 according to the reported frequency of symptoms involving fatigue during the previous four weeks, i.e., a total score between 0 and 84.
- **Cognitive impairment** is frequent in multiple sclerosis (more than 60% of patients ten years after onset) and exhibit a rather characteristic pattern. Dysfunction of sustained attention, speed of information processing, and working memory are the earliest elements (60). Some patients ultimately develop subcortical dementia, which fortunately remains rare (61). The objectives of the evaluation differ depending on whether systematic detection, therapeutic studies, or patent cognitive complaints requiring appropriate management are involved. In a detection program, the Mini Mental State Examination (MMSE) (12) lacks sensitivity except in patent deterioration (62).
- A standardized evaluation, the ***Brief Repeatable Battery*** was proposed by Rao in 1990 (63). The sensitivity is 70%, and its specificity is 94% in distinguishing patients with cognitive impairment among those followed for multiple sclerosis. It is particularly sensitive to an impairment of sustained attention. This battery includes a measurement of verbal learning and delayed memory, visuospatial learning and working memory, the sustained attention, speed of information processing through the ***Paced Auditory Serial Attention Task*** (PASAT) (see chapter 'Assessment issues in cognitive impairment').
- Other neuropsychological tests can be proposed for an extensive evaluation, but one should avoid use of tools potentially leading to substantial functional interference: for example in patients with a visual impairment, use of the revised Wechsler Adult Intelligence Scale (WAIS) or Raven matrix subtests consisting in a classification of pictures. Another example would be use of WAIS block design or Rey Complex Figure Test in patients with pyramidal or cerebellar lesions.
- In addition, frequent **emotional problems**, can result from difficulties in coping with the disease and/or from brain damage, particularly frontal lesions. Patients with MS often have anxiety, depression,

emotional instability, and/or paradoxical euphoria. Given that the EDSS fails to adequately consider such problems, they are best assessed by means of generic instruments: the ***Montgomery and Asberg Depression Rating Scale*** (MADRS) (64) for depression, and the ***General Health Questionnaire*** (65), a self-administered questionnaire that assesses psychological distress.

Disability assessment in patients with multiple sclerosis can be partially achieved using the EDSS, which, as previously indicated, combines impairment and disability items. *The Barthel Index* (16) is rarely used in multiple sclerosis in spite of its usefulness in predicting the duration of daily help (66). ***The Extended Barthel Index***, which includes items of the FIM, appears to be simpler than the latter and just as sensitive for multiple sclerosis patients hospitalized for rehabilitation (67).

There are several well known disability assessment tools specifically designed for multiple sclerosis patients:

- ***The Hauser Ambulation Index*** (68) takes into account the quality of ambulation, the necessity of technical aids, walking speed (8 meters on level ground) and, for the patients in wheelchairs, independence for transfers. This index is easy to use and its interobserver reproducibility better than that of the EDSS.
- ***The Disability Status Scale*** (DSS) (69) is part of a battery of instruments for assessing the consequences of multiple sclerosis, the ***Minimal Record Of Disabilities*** (MRD). The DSS takes into account self care, mobility, communication, and sphincter dysfunction; the overall score predicts requirements of daily help (66).
- Other scales of disability available for MS include self-assessment using the ***MS-related Symptom Checklist*** (70) and the ***ADL Self-Care Scale for Persons with Multiple Sclerosis*** (71).

The evaluation of **handicap and quality of life** in multiple sclerosis is currently undergoing substantial expansion. The use of self-administered questionnaires is the most widely employed means. Numerous generic scales have been used: e.g., SF-36 and SIP (see above). In most cases, specific scales have been developed by adding items or specific scales to a generic scale:

- The ***Environmental Status Scale*** (ESS) constitutes the third element of the MRD in assessment of the "survival roles" of the ICDIH (72).
- ***The Multiple Sclerosis Quality of Life 54*** (MS-QOL 54) completes the SF-36 with 18 items considered as important quality-of-life factors in the disease (73). The contents and construct validities, the internal consistency, and the test-retest reproducibility of this scale are good.
- ***The Multiple Sclerosis Quality of Life Inventory*** (74) is a battery of scales of perceived health, which uses existing questionnaires and new questionnaires to measure the subjective impact of deficits (fatigue, pain and abnormal sensations, sexual function, sphincter con-

trol, visual function, cognitive function, emotional status and social functioning). Although the length of time required for completion is relatively long, this battery shows good sensitivity to changes.

- Bladder dysfunction of patients with multiple sclerosis is one of the critical factors contributing to deterioration in the quality of life. The ***Qualiveen Questionnaire***, developed for patients with spinal cord injury (75) and applied to multiple sclerosis patients, shows good validity and discriminative sensitivity in this disease (76).

ASSESSMENT IN PARKINSON'S DISEASE

In evaluating a patient with Parkinson's disease, clinicians should attempt to quantify the severity of motor dysfunction and associated impairment, their fluctuation and advances within the framework of this chronic progressive disease, and their repercussions on daily living and quality of life.

The Unified Parkinson Disease Rating Scale (UPDRS), version 3.0 (77), the result of an international consensus, is a multidimensional scale, which assesses parkinsonian signs (analytical part III: 14 items), daily living activities (part II: 13 items), complications of the treatment (part IV: 11 items with 3 sections: dyskinesia, clinical fluctuations, and other complications), mental, behavioral and mood status (part I: 4 items), the patient's overall status (part V: stages of Hoehn and Yahr, see below), and the Schwab and England scale (part VI), which assesses autonomy. Each section of the UPDRS can be used separately. Considered as the tool of reference for clinical and therapeutic research, the UPDRS is used to quantify impairment and disability, at least overall disability, at all stages of the disease. However, as any multidimensional scale, the UPDRS has limits: Certain sections are much too restricted for impairments such as speech or swallowing disorders, or neuropsychological and mood disorders. Consequently, it may be useful in addition to complete more specific scales. The time required to complete this test is long and expertise is needed for the neurological examination (30 minutes for an experienced physician). It is reliable with good homogeneity and low interexaminer variability.

The other specific scales used in Parkinson's disease are designed to make up for the insufficiencies of certain parts of the UPDRS:

- Scales of **motor fluctuations and dyskinesia**: ***The Rush Dyskinesia Scale*** (78), a modified version of the Obeso or CAPIT (79) scale, and the more recent CAPSIT scale (80).
- Scales of **dysarthria and dysphagia**: One example is the adaptation of ***Frenchay Dysarthria Assessment*** (81), which is unfortunately only available in French (82); another is the ***dysphagia scale*** proposed by Kennedy et al (83).
- **Cognitive scales** include the MMSE and, above all, the ***Mattis Dementia Rating Scale*** (84), the sensitivity of which in subcortical frontal syndrome is established with its sections that assess attention, initiative and perseveration, conceptualization and memory.

- Among the scales assessing **mood disorders** are the ***Hamilton Depression Rating Scale*** (15), and the MADRS (64), which eliminates interference involving the patient's motor impairments.

Overall evaluation, which permits correlation of patient impairments with their disability and levels of dependence, can be obtained using the multidimensional tool UPDRS.

- The first to be used was the ***Hoehn and Yahr Scale*** (85) designed to determine the stage of progression of the disease. This scale includes five stages from 0 (normal) to 5 (invalid). Two essential criteria of Parkinson's disease are retained: a diagnostic criterion - unilaterality - and a course-related criterion - the onset of postural instability. This overall assessment has poor sensitivity, notably for therapeutic follow-up.
- ***The Schwab and England Scale*** (86) primarily assesses the level of dependence of patients to their family circle. The degree of overall autonomy is judged using values from 0% (maximum impairment) to 100% (normal).

Numerous other generic or specific **functional scales** are proposed, some of which include quality-of-life concepts. Four of them warrant mention:

- The ***Parkinson's Disease Questionnaire*** (PDQ-39) (87). In thirty-nine items, this scale provides a measurement of the quality of life in eight dimensions: mobility, activities of daily living, emotional well-being, stigma, social support, cognitive disorders, communication, and bodily discomfort. The PDQ-39 is closely consistent with the UPDRS and Hoehn and Yahr stage. This scale is reliable and validated, and sensitive to changes, in contrast with the SF-36. There exists an abbreviated version, the PDQ 8.
- ***Parkinson's Disease Quality of Life-37*** (88). In thirty-seven items this scale measures quality of life in four dimensions: parkinsonian symptoms, systemic symptoms, social aspects, and emotional states.
- ***Intermediate Scale for Assessment in Parkinson's Disease*** (89). This instrument of thirteen items is essentially functional: self-care, dressing, locomotion, etc. It is very strongly correlated with the Hoehn and Yahr scale.
- ***Parkinson's Impact Scale*** (90). It evaluates ten social, emotional and economic aspects of life: "positive" self-assessment and "negative" self-assessment, relations with the family and community, work, leisure activities, ambulation, security, finances, and sexuality.

The use of these evaluation tools in daily practice is not always straightforward. It all depends on whether the issues or questions posed involve therapeutic procedures, new surgical indications, clinical research, or aid in social adaptation or in medical rehabilitation.

The neurological community recommends at least one UPDRS assessment repeated annually and, depending on the situation, complementary use of other scales, for example overall cognitive assessment using the Mattis scale, or confirmation of a depressive state using the MADRS.

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CHAPTER 6
THE PHYSIOLOGICAL BASIS OF POSTURE AND GAIT

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QUIET AND PERTURBED STANCE

When the body stands upright, reaction forces act between the body contact surface and the ground. The direction of action of such forces is normally the same of gravity, or the vertical direction. This is the case when the body is still, a situation in which the vertical projection of the centre of mass of the body remains within the feet support base. However, acceleration can act on the body in a different direction from gravity, therefore the body must resist not only gravity but also contact forces.

Standing upright is relatively simple for a rigid structure but it is a difficult task for a multilinked body, where connections between body segments are represented by muscles which behave like springs. The stiffness of these springs and the position of the various body segments determining the antigravity posture depend on the level of muscle contraction (the so-called postural tone), in turn controlled by the central nervous system (CNS) (1). The projection of the centre of mass of the body must be within the base of support formed in humans by the outer borders of feet and by two imaginery lines respectively joining the big toes and the heel (2). However, under dynamic conditions, maximal limits of

standing balance define a region of dynamic stability including velocity (3, 4), beyond which balance will be lost.

Proposed mechanical models of human body during stance

Two main models have been proposed for studying and interpreting body movements during stance: 1. Inverted pendulum model; 2. Two-link model.

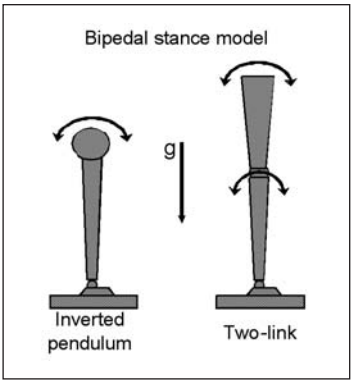

FIGURE 1. Proposed mechanical models of human body during stance. Arrows indicate direction of sway, g indicated the gravity force.

1. The inverted pendulum model (5) is particularly useful when dealing with body sway during quiet stance (Fig. 1, left). Under this condition, human body is considered an inverted pendulum with its pivot corresponding to ankle joint and its mass concentrated at the level of pelvis. Actually, ankle movements are assumed to occur only along the sagittal plane; during quiet stance, particularly with the feet close together, body oscillations are directed also in the mediolateral direction. As an inverted pendulum, the body is intrinsically unstable. Therefore, this unstable condition must be counteracted by appropriate forces.

The center-of-foot-pressure (CFP) on the support base is an indirect measure of body sway. Stabilometric recordings contain not only a static component depending solely on CFP but also a dynamic component due to inertial forces (6, 7). The higher the frequency of body oscillation, the greater is the acceleration and the larger the contribution of inertial forces to the stabilogram (8). Even during quiet stance, the contribution of the acceleration terms is substantial (9). At a frequency of sway of 0.2 Hz, the forces due to body acceleration contribute 10% to the stabilographic recordings; this contribution increases to about 50% at a frequency of 0.5 Hz and at a frequency larger than 1 Hz the stabilographic recordings reflect mainly inertial forces (5).

2. Things change when body movements are induced by a postural perturbation. In that case, it is useful to refer to a two-link model of human body (10) (Fig. 1, right). This model describes movements of the body around ankle and hip joints, assuming the knee as a rigid link. The model predicts that movements around ankle and hip joints are antiphasic. Indeed, the complexity of these antiphasic movements affecting far body segments suggests that biarticular muscles play a major role in coordinating body movements. For example, gastrocnemii muscles plantarflex the foot and flex the knee (11), whilst biceps femoris extends the hip and flexes the knee.

Passive mechanisms involved during upright stance

Quiet upright stance is maintained with minimum energetic expenditure. During quiet stance, body sway oscillations are small, and mainly in

the anterior-posterior direction. Under this condition, balance is mainly maintained through stiffness of muscles, ligaments and joints (5). The knee, hip, shoulder, and ear are in front of the ankle in all subjects. On average, the knee is about 4 cm, the hip 6, the shoulder 4, and the ear 6 cm anterior to the ankle. Thus, at both knee and hip in typical standing, there exists slight gravitational torques tending to extend the joints (12). Given these extending torques, part of the postural stabilisation of the relevant joints can be accomplished through passive viscoelastic forces generated by ligaments and muscle tendons. As a matter of fact, quiet stance requires low level tonic EMG activity in the antigravity muscle soleus, whilst all the other muscles but the biceps femoris and erectores spinae remain quiescent (13).

Sensory inputs involved in the control of posture and balance during stance

ROLE OF MULTIPLE SENSORY INPUTS

The stabilisation of human upright stance after external disturbances depends on the integrative evaluation of afferent information from proprioceptive, visual, skin foot sole and vestibular inputs (14). The availability of this sensory information may be critical to restore balance following external disturbances. The redundancy of sensory input involved in the control of balance allows to preserve equilibrium even when one or two afferent inputs are lost (15). It seems that each type of afferent input is involved in signalling sway within a specific range of response to postural perturbation with some overlapping between different inputs. However, an increase in body sway with absent or conflicting visual or proprioceptive input has been shown in static posturography and with slow movements of the support surface (16, 17, 18). Furthermore, increase in the sensitivity of the postural control system to vestibular stimulation has been reported when somatosensory information from the surface is disrupted either by peripheral neuropathy or by standing on an unstable surface (19).

VISION

Postural stability generally decreases in the absence of visual input, or in experimental conditions that alter the quality or type of visual input available. In spite of its simplicity, simple posturography may have a great clinical value because the integration of visual information in postural control is often disturbed and this disorder can be detected in many cases (see 20). Experiments with a 'moving room' apparatus, in which the visual surroundings moved in relation to the standing person, have shown that visual input can induce postural displacement in the same direction of visual flow (16, 21, 22). This shift in postural orientation is dependent on temporal and spatial frequency of visual surround.

Although there has been a suggestion that central vision can play a significant role in the regulation of postural balance (23, 24, 25), most au-

thors have proposed a more important role for peripheral vision in regulating postural sway (26). The contribution of central and peripheral vision appears to be dependent, among other factors, on the availability of somatosensory information from the base of support (27). Optimal working range of vision is below 1 Hz, i.e. higher than that of labyrinth but lower than muscle proprioception (16, 22, 28).

Skin receptors and haptic cues

Movements between the support surface and the feet generate shearing forces that can result in stretching and deformation of the skin and lead to activation of cutaneous and deep mechanoreceptors (29). Cutaneous afferent messages from the main supporting zones of the feet have sufficient spatial relevance to inform the CNS about the body position with respect to the vertical reference and consequently to induce adapted regulative postural responses (30). Suggestions for a role of somatosensory information for posture come from the significant increase in sway excursion, sway velocity and sway variance when somatosensory information from the feet is reduced by ischemia or cooling (31, 32). Cutaneous input appears to signal mainly low frequency of body sway, as occurs during quiet stance; it plays a negligible role in triggering postural adjustments to balance perturbations (33, 34).

Contact of the hand to a stationary surface, at mechanically inefficient force levels, has been shown to decrease spinal reflex excitability (35, 36). Indices of postural sway are also reduced by up to 50%. Moreover, movement of the touched surface has been able to entrain postural sway (37) suggesting that cutaneous cues from the finger, with its high receptor density, in combination with proprioceptive information from the arm, can play an important role in the stabilisation of upright posture. These findings have been interpreted as suggesting that an external point of contact provides a reference frame with respect to which vertical posture is organised (38).

Labyrinthine and neck receptors

Each labyrinth is composed of three semicircular canals, whose ampullar receptors are sensitive to angular acceleration of head in the three planes of space, whilst maculae of otolithic receptors (utricle and saccule) are respectively sensitive to horizontal and vertical (gravity) linear acceleration. Since the transduction process of these receptors has a long time-constant, their input (acceleration) is integrated. Therefore, each receptor actually measures angular or linear velocity within a range of variation of the input signal between 0.2 and 2 Hz for the canals and between 0.0 and 0.2 Hz for the maculae (10). It derives that vestibular control of posture may be important at low body sway frequency as during quiet stance, or slow perturbations of stance, but not during fast perturbations. The vestibulospinal system gain is normally very low in quiet stance on a firm surface (28, 39).

Vestibular signals control body posture primarily by controlling the trunk position in space (14). It is possible that vestibular information is

used to create an internal representation of the trunk in space because the trunk represents the natural platform for the head and because subjects generally relate to their trunk when asked to describe their orientation and movement in space. Vestibular inputs are not required for the triggering of postural responses to movements of the support surface, especially when the subject is in contact with a stable, large surface (16). Head movements induced by toe-up rotation of a platform have been measured and it has been found that these movements can occur within 20 ms after onset of perturbation (40). There would be time enough to trigger vestibulospinal responses in leg muscles; a vestibular afferent volley would result, which would elicit vestibulospinal responses in leg muscles (41). Actually, in patients with complete bilateral vestibular deficit the responses in the tibialis anterior muscle during toe-up rotation of the supporting platform still occur albeit at a reduced amplitude (40). That means that vestibulospinal input is important for modulating the amplitude of but not triggering postural responses.

These findings suggest that posture is organised with respect to a 'body schema', to the construction of which neck input contributes together with signals from vestibular, eye and limb muscles. Most likely, the posterior parietal cortex contributes to the egocentric representation of space, since many of its areas receive signals from neck muscles and from the labyrinth (42).

THE ROLE OF THE PROPRIOCEPTIVE RECEPTORS UNDER STATIC AND DYNAMIC CONDITIONS

During quiet stance, no relationship between EMG activity of triceps surae muscle and changes in the ankle angle, i.e. muscle length, due to body sway are observed (43). Therefore, it seems that postural corrections do not depend strictly on stretch reflexes evoked by lengthening of ankle muscles. This is consistent with the down-modulation of soleus Ia terminals detected during quiet stance (44), which causes decrease in H reflex excitability in spite of tonic EMG activity of the soleus muscle. Nevertheless, proprioceptive input from leg muscles does play a major role in providing important information for the postural control system. Minimal ankle stiffness is required to stand, and reflexes driven by muscle afferents significantly contribute to balance-related ankle stiffness regulation (45). Visual, vestibular and lower limb sensorimotor reflexes each contribute to ankle stiffness; however, the local proprioceptive reflexes alone are sufficient to stand under certain circumstances (46). The contribution of the afferent input from muscle spindle to the regulation of postural body orientation in standing subjects has been assessed by the use of mechanical vibration, which almost selectively induces a train of action potentials in the primary endings connected to the large-diameter group Ia afferent fibers, i.e. a false signal of muscle lengthening (47, 48). Depending on the site of vibration, the body changes its inclination in a reproducible way (Fig. 2). A backward sway deviation can be observed when postural muscles of the posterior body surface are stimulated by vibration (see above

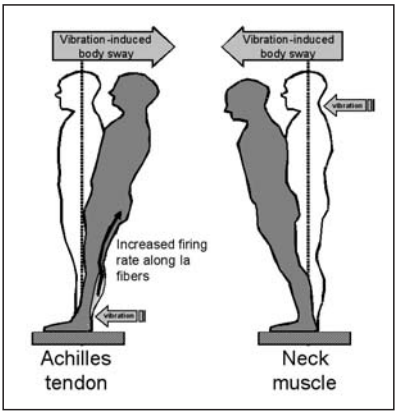

FIGURE 2. Effects of vibration of Achilles tendon or dorsal neck muscles on body inclination with respect to gravity.

the analogous effect on leg muscle vibration); the only exception being that vibration of the neck region results in a body sway forwards (49). As for leg muscle, vibratory stimulation has been used to test the integration of neck afferent input into the postural control scheme. Contrary to leg muscle, vibration of either lateral or dorsal neck region induces a prominent body sway in the direction opposite to the stimulated site (50).

Recently, a role for group II afferent fibres in balance control has been suggested from results obtained in polyneuropathic patients (51). Patients affected by sensori-motor neuropathy swayed abnormally only when the disease affected group II fibres in addition to group Ia (52).

Feedback and feedforward control modes involved during stance

Sensory signals informing the CNS about deviation from the equilibirum are involved in two modalities of balance control: continuous and discontinuous feedback mode of control. The continuous modality has been discussed in the previous paragraphs. Several studies suggest, however, that during quiet standing a subject does not only rely on a continuous feedback to control balance. On the contrary, the subject initially utilises open-loop control where there is no feedback to control balance (53). After approximately one second, open-loop control changes to closed-loop control, and the subject then relies on continuous feedback to maintain balance. Improved parametrisation techniques for the extraction of stochastic parameters from stabilograms have been proposed (54).

Proprioceptive control of body perturbations

The other modality consists in a discontinuous feedback that intervenes when upright stance is perturbed by external forces, and triggers phasic postural reactions. Postural reactions to body displacements can be easily induced by surface translation: they are triggered at about 100 ms by somatosensory signals, are direction-specific and show a distal to proximal sequence of muscle activation (55) named 'ankle strategy'.

These responses are mediated by both spindle group Ia afferent fibres (those responsible for the tendon tap reflex) and group II spindle fibres. This was assessed by recording EMG responses in flexor digitorum brevis muscle to toe-up rotation of the platform. Such perturbation induces a short- (SLR) and a medium-latency response (MLR) in the FDB (Fig. 3). SLR is known to be evoked by stretch of spindle primaries, transmitted to the spinal cord by group Ia fibres, and relayed through a monosynaptic reflex pathway. MLR is mediated by group II fibres from spindle secon-

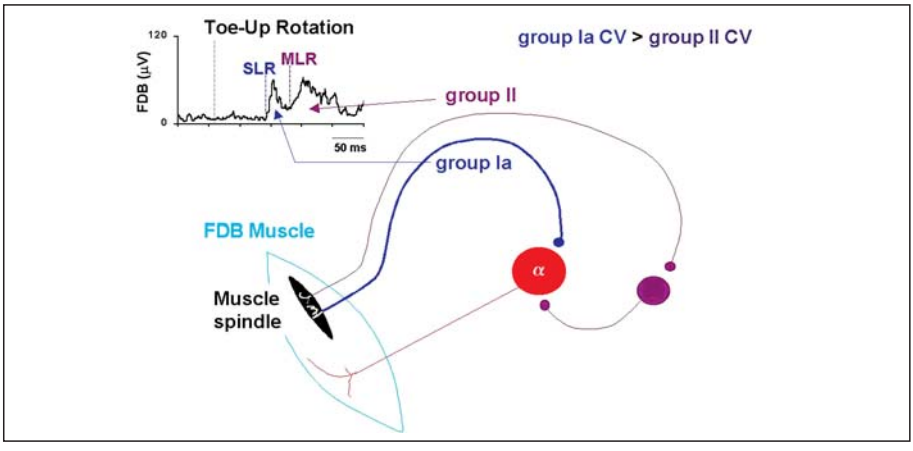

FIGURE 3. Spinal circuits mediating the short-latency response (SLR) and the medium-latency response (MLR) of flexor digitorum brevis (FDB) muscle to toe-up rotation of the supporting platform in a standing subject. The oligosynaptic circuit mediating the MLR is represented with a single interneurone for the sake of clarity. Vertical short dashed lines in the trace correspond to the latency of onset of the relevant EMG responses; the long vertical line corresponds to the onset of platform movement. CV, conduction velocity.

daries, and relayed through a spinal oligosynaptic pathway (see 34). The different peripheral and central organisation of the two responses was suggested by several evidences summarised in a series of papers from our laboratory (56, 57, 58, 59, 60). Estimation of group II CV produced a value of about 21 m/s, i.e. less than half the value of Ia fibers (51 m/s) (59). This figure is in keeping with data in the cat showing that the CV of group II fibers is about half that of group Ia. Ageing affects to a larger extent MLR than SLR (61, 62). The size of the MLR, but not of the SLR in leg muscles, is highly susceptible to changes in 'postural set' (36). It should be recalled that the excitability of the interneurones relaying this group II effect onto the motoneurons is modulated by descending monoaminergic pathways, very much as it happens in the cat (see 63).

Postural responses can be affected by changes of posture and repetition of perturbation. Prior lean affects the latency and particularly the amplitude of EMG responses to postural perturbation (64). Functional habituation of postural reflexes induced by toe-up rotations of a supporting platform consists of a rapid attenuation of postural responses in the triceps surae muscle between the first and second perturbation as early as the second repetition, followed by slower habituation across the ensuing trials (65).

A major role of proprioceptive input in triggering balance corrections has been recently questioned (see 69 for a review). It has been suggested that postural and gait movements are centrally organised at two levels. The first one involves the generation of the basic directionally-specific response pattern based primarily on hip or trunk proprioceptive input and secondarily on vestibular inputs. This pattern specifies the spatial characteristics of muscle activation that is which muscles are primarily affected, as well as intermuscular timing, or the sequence in which muscles

are activated. The second level is involved in the shaping of centrally-set activation patterns on the basis of multi-sensorial afferent input (including proprioceptive input from all body segments and vestibular sensors) in order that movements can adapt to different task conditions.

Movement-induced perturbations

During a voluntary movement performed under upright stance, movement itself is destabilising. Therefore, the CNS cannot rely on a feedback mode of control of balance but must generate anticipatory postural adjustments (APAs) before the onset of the perturbation induced by the voluntary movement itself. This type of control of balance is regulated in a feedforward manner. APAs can be produced either A. in parallel with or B. sequentially to the motor command instead of being evoked by the destabilisation of the body (2). A. In the parallel mode of control of posturo-kinetic coordination, an almost symultaneous contraction of the postural and focal muscles is obtained. It is hypothesised that nervous pathways to control voluntary movement would affect activity of postural muscles through collateral pathways. B. In the sequential mode of control of posturo-kinetic coordination, APAs actually precede the focal movement. This type of coordination is observed when a subject performs rapid voluntary upper limb movement. A potential loss of balance following the movement is prevented by postural muscle activity prior to the onset of focal muscle activity (70). The purpose of APAs is to displace body segments in a direction that opposes the reactive forces expected from the forthcoming movement and as such maintain the centre of mass over the base of support (71, 72). It has been proposed a model according to which the precise coordination between posture and movement have the following basic requirements (73): the coupling of postural muscles, the amount of support or the instability prior to the task, and the correct coupling between the postural and focal muscle activity.

Light touch has been shown to lead to a decrease in the APAs associated with a voluntary arm movement. Since finger touch is mechanically inefficient, it cannot by itself help APAs in counteracting predicted perturbations (74). The decrease in APAs with touch has been interpreted as suggesting that sensory effects of touch allow one to estimate the current position of the COM with higher precision (75). Furthermore, the APAs in the leg are reduced in magnitude or completely absent when the challenge to equilibrium maintenance is reduced (73, 76, 77). The process of APAs is affected by initial stability of the postural system. For example, APAs are reduced or absent when an external support is given to the subject or when the subject is inclined forward (78) as well as when posture is unstable (79).

Posture and cognition

It has been suggested that maintaining postural stability does require some degree of attention (80, 81). Several studies have demonstrated a decrease in cognitive performance as the demands of a concurrent postural

task increase. Ageing and performance of tasks requiring sensory reweighting and integration further requires attentional demands for postural control (82, 83).

These studies have used cognitive measures such as memory tests and reaction time tests to imply the attentional demands of postural control. Attentional demands increase as the balance requirements of a task increase. More specifically, there is a progressive increase in the attentional demands when moving from sitting to standing to walking (80). Other studies have used more typical postural measures to assess the attentional demands of postural control. Results similarly suggest a decline in postural stability associated with demanding cognitive tasks (84, 85, 86). Dual task interference on postural control can be observed in Parkinsonian patients during performance of cognitive as well as motor tasks (87); the balance deterioration during dual task performance was significantly enhanced in patients with history of prior falls.

LOCOMOTION

Gait initiation is accomplished by an inhibition of the triceps surae muscle, leading to a posterior movement of the CFP (88, 89) and a forward acceleration of the inverted pendulum, followed by a marked increase in the tibialis anterior (90) and rectus femoris activity (91) to pull the pendulum forward. Simultaneously, the tensor fasciae latae is inhibited on the stance limb and activated on the swing limb. This pattern would increase the swing hip abductor moment and decrease the stance hip abductor moment, resulting in a momentary loading of the swing limb and unloading of the stance limb. Thus the CFP would move laterally towards the swing limb. Then a rapid shift of the CFP towards the stance limb occurs as the swing limb unloads. The CFP and CM trajectories during termination of gait are virtually mirror images of that reported for the initiation (92).

After gait initiation and when walking in normal conditions (no actual constraints), adult subjects exhibit a particular stable gait pattern, which is very reproducible from stride to stride, trial to trial but also over days. This rhythmic pattern implies the alternative, out of phase movement of the two legs. The gait cycle is the walking unit defined as the time interval between two successive identical body configurations, in general heel contact or heel strike. The gait cycle is divided in two phases: a stance phase – simple or double stance – and a swing phase. Stance and swing durations last about 60% and 40% of the cycle duration, respectively. However, these temporal gait parameters adapt to change in speed. With increase in body velocity, the stance duration substantially decreases whereas the swing duration hardly changes. As a consequence, the duration of the double stance phase significantly decreases with speed increment and even vanishes when switching from walking to running. Spatial characteristics of the gait pattern also adapt to changes in speed. The stride length linearly increases with speed increment until the speed of 2 m/s. Further increase in speed is achieved via increase in gait frequency (93).

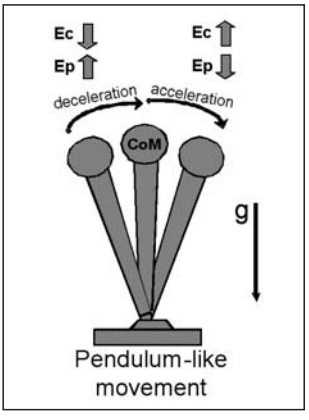

FIGURE 4. Pendulum-like movement of the body during gait. Ec, kinetic energy; Ep, potential energy.

Despite terrestrial mammals generally share this temporal and spatial organisation of the gait pattern, human walking differs in many aspects (94). Contrary to most mammals, which walk on four legs with the trunk roughly parallel to the ground, humans walk erect on two legs. A pendulum-like movement results, which converts kinetic energy (Ec) into gravitational potential energy (Ep), and inversely, thereby increasing gait efficiency (95, 96) (Fig. 4). Interestingly, model-based studies demonstrated that the human biomechanical system shows a natural propensity for locomoting on earth (97). However, bipedal locomotor movements are naturally unstable, in particular in the medio-lateral plane (98). Accurate control of propulsion and balance during human locomotion thus require the CNS to produce highly-coordinated movements of the lower limb segments, between the two limbs, and between the two limbs and the trunk (99, 100). Whole body balance is ensured by the centre of mass (CM) passing medial to the supporting foot, thus creating a continual state of dynamic imbalance towards the centreline of the plane of progression. The medial acceleration of the CM is primarily generated by a gravitational moment about the supporting foot, whose magnitude is established at initial contact by the lateral placement of the new supporting foot relative to the horizontal location of the CM. Balance of the trunk and swing leg about the supporting hip is maintained by an active hip abduction moment, which recognises the contribution of the passive accelerational moment, and counters a large destabilizing gravitational moment. Posture of the upper trunk is regulated by the spinal lateral flexors (101).

Furthermore, bipedal compared to quadrupedal walking implies a dramatic re-organization of patterns of muscle action in order to propel the two-legged body forward while ensuring equilibrium. The motor pattern for quadrupedal locomotion consists in a basic alternative activation of extensor (stance) and flexor (swing) muscles. In turn, during human walking, a mixture of extensor and flexor muscles is activated, in particular around the time of heel contact to stiffen the leg and roll over the stance foot. As soon as the foot is flat on the floor, most leg muscles become quiescent. Throughout the remaining stance phase, soleus and gastrocnemii muscles near-solely contribute to producing the necessary energetic flux for propelling the body forward while ensuring ground support (97).

Human locomotion along a straight path thus requires a complex sequence of muscle activation to displace the two legs and the body forward while maintaining balance. However, goal-directed locomotion, such as encountered in everyday life, often requires steering along curved paths. The inherently unstable bipedal gait becomes critical during curve-walking, as shown by turning difficulties in aged or diseased people (102, 103). During

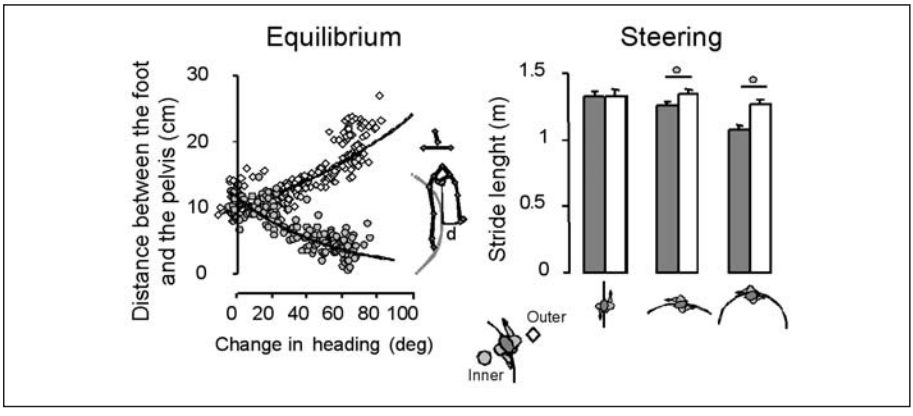

FIGURE 5. Left graph: the horizontal distance between the feet and the body centre of mass changes during curve-walking. The distance decreases for the inner foot (grey symbols) and increases for the outer foot (open symbols), as a function of the curve tightness (change in heading). Right graph: the more tight is the curved trajectory, the larger is the path covered by the outer foot with respect to the inner one.

curve-walking, adaptive changes in trunk, pelvis and leg movements occur so as to maintain equilibrium against the inertial forces that threaten balance - segment orientation gradually shifts inward with respect to the body trajectory (Fig. 5) (100, 104, 105). In addition, many temporal and spatial features of the movement of the inner and outer legs become asymmetric. Turn-related adaptations of gait parameters include ever-increasing divergences in stance duration, stride length, and foot rotations between the inner and outer leg (106), and are mirrored in limb-dependent tuning of muscle activity patterns (107). Implementation of a curve trajectory in walking humans thus requires the central nervous system to substantially accommodate gait characteristics to curve tightness in order to fulfil complex balance and propulsion requirements. Curve-walking may thus provide the appropriate context for clinical assessment of gait disorders (108).

Neural control of locomotion

Neural organisation of the act of progression is based on an interaction between subtle supraspinal regulation and basic central and peripheral elements. Original experiments made by Sherrington and colleagues (109) at the beginning of the last century demonstrated that the basic motor for walking is generated by a set of neurons referred to as the central pattern generators (CPG) for locomotion. CPG is defined as a neural circuit that can produce self-sustaining oscillation patterns of output independent of any oscillating input from the brain or the periphery (Fig. 6). Pattern is used in a broad sense to indicate alternating activity in groups of flexors and extensors.

After gait initiation, afferents deliver movement-related information to spinal and supraspinal levels. Three potential roles for afferent feedback in the production of rhythmic movements have been identified, and all 3 roles involve adapting movement to changes in the internal and ex-

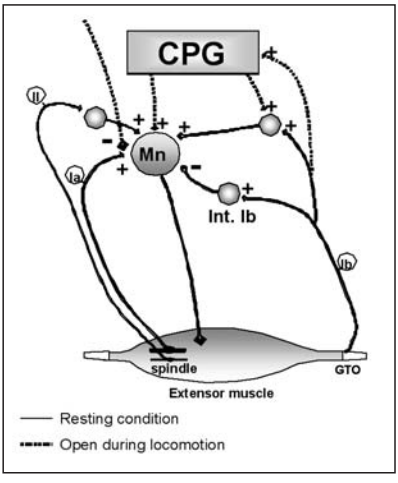

FIGURE 6. Schematic view of output and input connections of Central Pattern Generator (CPG). MN, motoneurone; Ia, spindle group Ia afferent fibres; II, spindle group II afferent fibres; GTO, Golgi tendon organ; Ib, group Ib afferent fibres; Int. Ib, Ib interneurone. During location, the Ib inhibition turns into excitation, and the Ia excitation is being depressed by presynaptic inhibition.

ternal environments (110). The first role is that of reinforcing CPG activities, particularly those involving load-bearing muscles, such as the hind-limb extensor muscles during the stance phase of gait. The second role is a timing function (phase-dependent modulation) whereby the sensory feedback provides information to ensure that the motor output is appropriate for the biomechanical state of the moving body part in terms of position, direction of movement, and force. The third role is that of facilitating phase transitions in rhythmic movements, purportedly to ensure that a certain phase of the movement is not initiated until the appropriate biomechanical state of the moving part has been achieved.

Supraspinal centres act in concert to adjust the gait pattern. In particular, the brainstem neural centres and cerebellum activate the spinal locomotor system and fine-regulate the intensity of its operation to preserve an equilibrated progression. Cortical structures control skilled locomotion when environmental constraints require subtle adaptation of lower limb trajectory (111). Despite this tripartite organisation of the walking system has clearly been demonstrated in vertebrates, no conclusive demonstration of such a control scheme has been provided in humans so far (112). Yet, the results of several studies have been interpreted as evidence for a CPG in the human lumbosacral spinal cord (113). For example, it is highly significant that continuous stimulation via epidural electrodes placed over the upper lumbar segments of clinically complete spinal cord injured (SCI) subjects generates stepping-like movements (114). Nevertheless, rhythmic activity is very rare after complete transection of the spinal cord (115). As such, while many investigations suggest the existence of human spinal CPGs, it should be pointed out that as yet it is not proven that these CPGs similarly operate during normal and SCI human walking.

The innate character of the CPG is further supported by the well-known presence of coordinated movements during the prenatal phase and by the presence of primitive step-like movements in the newborn infant (116). Afferent stimulation or neurotransmitter injection has to be provided to the spinal cord to elicit stepping. This suggests that commands for the initiation of locomotor activity must be given at some level in the CNS above the lesion. By varying the level of transection of the neural axis, it was shown that the region for initiation of locomotion is located in the brain stem, at supraspinal level (117). The existence of a mesen-

cephalic locomotor region has also been described in different vertebrate species, including non-human primates. There are clinical studies suggesting the existence of similar areas in adult humans (118).

Influence of sensory afferent input on locomotor activity

Results of studies involving deafferentation and paralysis unequivocally demonstrate that the nervous system in mammals is capable of generating rhythmic motor output in the absence of peripheral feedback (119). In humans, the question of the specific role of the various sensory modalities in the reflex control of locomotion is still open: for example, functional loss of leg afferent fibres due to peripheral neuropathy does not always lead to major alteration in the gait pattern. Vibratory tendon stimulation is known to selectively recruit spindle primary afferent fibres (see above): vibration of soleus muscle would therefore disturb organisation and execution of walking, especially if spindles fire continuously and subjects are blindfolded. But vibration induces only minor changes in duration and length of stance and swing phase, and on speed of walking and kinematics of lower limb segments. This paucity of effects is at variance with the perception of the subjects, who report illusion of leg stiffness and gait imbalance, as well as with the disturbing effects of vibration on quiet stance. This speaks for a selective gating of Ia input during locomotion and emphasises the notion that the central nervous system can cope with an unusual continuous input along the Ia fibres from a key muscle like the soleus (120). During locomotion, the input from the group II spindle fibres may be in fact much more important than that from the group Ia fibres. It is responsible for the medium-latency response of the soleus to the stretch resulting from an unexpected perturbation during human walking (121). These findings support the hypothesis that, during walking the response to a perturbation of gait is not contributed to by velocity sensitive receptors, but by length-sensitive receptors (122), in keeping with the above described negligible effects of group Ia massive input. Load-related afferent feedbacks, in particular originating in Golgi tendon organ may also contribute to regulation of timing and intensity of muscle activity during walking (123).

Descending control of dynamic equilibrium and body orientation

Neural networks located in the spinal cord are capable of generating the basic motor pattern for locomotion. Nevertheless, the complexity of body balance maintenance requires descending modulation of spinal operations in order to coordinate movements of the two legs and the trunk. Furthermore, converging evidences indicate that implementation of spatially-oriented locomotor movements relies on head-centred internal references. It has been shown that if the head is horizontally turned or the eyes are laterally rotated, vibration of dorsal neck muscles during stepping-in-place causes stepping in the direction of the naso-occipital axis or of the gaze, respectively (124). Unilateral long-lasting vibration applied to the neck sternomastoid muscle is able to profoundly affect body orienta-

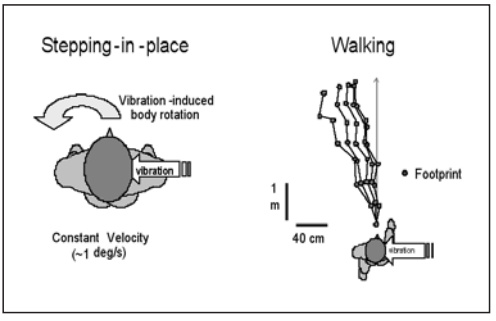

FIGURE 7. Effects of unilateral vibration of sternomastoid muscle during stepping-in-place (left panel) and walking (right panel) induces body rotation and gait deviation, respectively, toward the side opposite to the vibrated muscle.

tion during walking, running or stepping-in-place (Fig. 7). The walk trajectory deviates, or the body rotates during stepping, to the side opposite to the vibrated muscle (50, 105, 125). These findings confirm and extend the notion that the neck proprioceptive input plays a major role in body orientation and equilibrium control during locomotion. Nevertheless, the body rotation does not seem to depend on the same mechanisms which modify the erect posture, rather, the asymmetric neck input would seem to modify the egocentric body-centred co-ordinate system.

CONCLUSION

The findings from recent investigations have allowed attributing a role of the fibres from the secondary termination of the muscle spindles in the reflex control of posture and locomotion. On the other hand, the role of the primary terminations, those responsible for the tendon tap, seems to be less powerful than previously thought; however, this input gains a new role in the construction of the spatial reference frames that the subject use during their orientation in space during a goal-directed task. These new approaches have also opened a window on the capacity of the central nervous system to coordinate posture and movement under commonly encountered conditions (but paradoxically uncommonly studied), such as changes in direction during walking. The integration of the descending command with the ongoing input from the periphery (originating from the evolving movement) becomes much more critical under these conditions than under quiet stance. Not unsurprisingly, the risk of falling is higher during navigation in our environment than when simple movements are performed under quiet stance condition.

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CHAPTER 7
ASSESSMENT OF POSTURE AND BALANCE IN AGEING AND DISEASE

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The purpose of the assessment of posture and balance is rarely to diagnose a disease. Most neurological and many musculoskeletal disorders result in impaired balance (1). Further, the difficulty in using balance assessments in diagnosis is that patients with different diseases may have the same balance impairment and patients with the same disease may have different balance impairments. The issue is further complicated by the fact that even ageing itself deteriorates both the nervous and the muscoloskeletal system to a point where impairment and disability may ensue.

The primary purposes of posture and balance assessment are 1. to identify whether or not a problem exists in order to predict risk of fall, 2. to determine the underlying cause of the problem in order to manage or treat it effectively and 3. to determine whether treatment is needed or has been effective.

In this review, we summarise recent findings obtained in normal ageing and neurological diseases using posturographic tests allowing to study stability during quiet stance, postural reactions to external disturbances and anticipatory postural adjustments to perturbations caused by self-paced movements (e.g lifting an object). In the second part, we consider clinical tests

of balance which can be easily and reliably administered on in- or out-patient basis. In the last part of the review, the main instruments and the variables commonly used in the clinical posture and movement evaluations will be summarised. In particular, the working basic principles of the instruments today largely used in the posture and the movement laboratory are described with reference to the kinematic and kinetic obtainable measures.

AGEING

Various studies have shown that postural sway reaches an adult-like response at around 10 years of age and then remains fairly stable until around 30 years. From this age onward, postural sway deteriorates (i.e. increases) with age (2-7). Increase in body sway is not connected with changes in the subjective perception of own sway since this capability is preserved with ageing (8).

Changes in posture with age are of concern because of their association with impaired mobility and the possibility of falls. Balance has been assessed by calculating the whole-body centre of gravity and the partial centres of gravity above the knee and hip. Compared to a young reference population, the older subjects have greater kyphosis, a more posterior hip position, and show a more anterior centre of gravity above the hips (i.e., they lean forwards). Elderly subjects who are inactive tend to lean more (9). Anterior-posterior limits of stability are decreased in elderly compared to young subjects (10). The decrease in voluntary inclination might be accounted for by the known reduction of the so-called 'ankle strategy' occurring with age (11).

Postural sway increases linearly with age, but the relative contributions of the sensory systems to balance do not change with age (12). Medio-lateral measures of balance are predictive of elderly community-dwelling fallers (13). Balance decrements are greatest for elderly subjects when visual and proprioceptive cues are diminished (14-16). Based on data from the stabilogram-diffusion analysis of centre of foot pressure (CFP) obtained from healthy elderly and young populations, age-related differences in postural control strategies have been shown (17, 18). It has been hypothesised that the differences may reflect an increase in the net stiffness of the muscoloskeletal system via increased muscular activity in the elderly. This increased stiffness would provide an improved ability to resist and correct for transient perturbations (compared to less stiff systems). This would occur at the expense of increased short-term fluctuation across the joints and higher levels of short-term postural sway, i.e. an increased reliance on open-loop control mechanisms of balance.

Elderly subjects have difficulties adapting to new sensory conditions, and are more affected by reduced or conflicting sensory conditions than are young subjects. The peak-to-peak amplitude of sway and root-mean-square energy of sway are significantly greater in healthy elderly subjects than young subjects, both during quiet stance and during visual perturbation (19). These effects are more pronounced when proprioceptive in-

formation is rendered unreliable by sway-referencing the moving posture platform on which subjects stand. These results agree with those of Sundermier et al. (20), who also have shown that elderly subjects with a history of falling are more visually dependent than matched non-fallers. Several investigators have suggested that these postural deficits may be due to reduced peripheral visual sensitivity, although this view is not always accepted. In particular, there is a tendency towards decreased stability in elderly subjects following a transition from eyes-closed (EC) to eyes-open (EO) conditions, paradoxically increasing peripheral sensory information (6). According to the authors, these results suggest that poorer central integrative mechanisms, rather than decreased peripheral proprioceptive information, are the culprit for the elderly's difficulty in reconfiguring the postural set following sensory perturbation.

After a postural perturbation, the pattern of EMG responses evoked in the leg muscles is similar between young and elderly subjects, although there were some differences in latency and amplitude (7). There is a significant relationship between latency of short-latency response (SLR) and medium-latency response (MLR) of the triceps surae muscle and age. Slope of the regression lines of tibialis anterior (TA) MLR is steeper than that of soleus SLR (21). This finding is in keeping with recent results showing that SLR and MLR are mediated by different afferent fibres (respectively, spindle group Ia and group II fibres) and central pathways (respectively, mono- and oligosynaptic spinal pathways) (22). It is conceivable that age slows the conduction velocity (CV) of large and small afferent fibres in constant proportion, producing a larger absolute increase in transmission time in the slow conducting than fast conducting fibres. An alternate, but not mutually exclusive hypothesis, is that ageing slows central synaptic transmission. Indeed, if that is the case, slowing might be larger in oligo- than monosynaptic pathways, respectively mediating the MLR and SLR (23). The progressive longer delay of the MLR than SLR with ageing might account for the increase of body sway. In this view, the increase in body sway would not depend on the damage of large afferent fibres (spindle group Ia) as suggested by some authors (24-27) but mostly of middle size spindle group II fibres.

Healthy adults demonstrate different step recovery characteristics when compared to young adults. Healthy elders are more likely to take multiple steps than young adults and more likely to grasp a hand rail (28, 29). From a clinical standpoint, balance-impaired elders take multiple steps than do healthy elderlys (30). Laboratory studies have found that when pulled forwards, elderly fallers stepped more frequently at a low perturbation level (31).

Body segment co-ordination during dynamic equilibrium on a moving platform has been assessed in elderly subjects (32). At low translation frequency (0.2 Hz), with EO, subjects behave like a non-inverted pendulum, whereby the head tends to be stabilized more than the hip, the legs taking up most of the imposed displacement. Ageing is associated with greater head stabilization, and a looser coupling between head and hip.

With EC, the body attitude changes to an inverted pendulum, whereby the head overshoots the platform displacement. Ageing is associated with reduced head stabilization, and a stronger coupling between head and hip. When the frequency of platform translation increases to 0.6 Hz, with EC the general picture is similar to the above, but vision is no longer able to counteract in older subjects the imposed head displacement. At this frequency, with both EO and EC, there is a poor coupling between body segments across all ages. Periodical shift of the support base may be a valid protocol to test the ability to control balance in the elderly, and may be a useful tool to assess age-related changes of the sensorimotor mechanisms underlying dynamic equilibrium.

NEUROLOGICAL DISEASES

Among the elderlys and those suffering from neurological disorders, falls are a major problem. Thirty to seventy percent of falls in elders are the result of trips, slips and misteps (2,33, 34). In the elderly, falls rank among the top three incapacitating ailments. For those suffering from degenerative neurological disorders such as Parkinson's disease, the problem appears even more substantial (35). As a consequence, a great deal of studies have been devoted to the study of posture and balance alterations in elderly subjects and patients affected by neurological diseases.

Parkinson's disease (PD)

Among the deficits described in PD, those affecting posture and locomotion are usually reported to occur in the later stages of the disease (stages III and IV) (36). These deficits include a postural instability with falling, slowness of gait initiation along with short steps and a freezing phenomenon which makes gait initiation extremely difficult or no longer possible (37-42). Disorders of movement function related to posture, balance, and gait are common occurrences for many persons with Parkinson's disease. Numerous studies have identified a broad variety and heterogeneous distribution of postural and locomotor changes (43). In patients with Parkinson's disease there is reduced load sensitivity and decreased leg extensor activation, which might contribute to the movement disorder in gait (44, 45).

Increased sway is not a good predictor of postural instability since many very unstable patients with PD show slight increase in sway oscillations during stance (7, 46, 47). The anterior-posterior stability limits of PD are markedly reduced (10). The main impairment occurs in the lateral plane (48), where the stability depends mainly on the hip joint control (49); the balance control becomes more dependent on ankle dorsiflexors' activity and on vision (50, 51). The deficit does not result mainly from a miscalculation by the sensory input monitoring balance (52) or an inappropriate perception of their balance (8) but rather on difficulty in accurately controlling the output stage, at which many dysfunctions have been reported to occur (51). It is interesting to mention that treatment with levodopa increases postural sway abnormalities, whereas treatment with

deep brain stimulation improves postural sway (53). According to the authors, the negative side effects of levodopa on posture is less severe for patients with electrodes implanted in the subthalamic nucleus (STN) than for patients with electrodes in the globus pallidus internus, perhaps due to the decreased need for levodopa intake in STN subjects (54).

Automatic postural responses in leg muscles of patients with PD differ from those of normal subjects. Postural perturbations stretching triceps surae elicit enlarged MLRs in the same muscle muscles in these patients but diminished and/or delayed responses in the shortened tibialis anterior muscle (54-58). As far as the stretch-related responses to postural perturbation are concerned, little evidence exists that the disease significantly affects these responses. In fact, latency of soleus SLR and soleus and TA MLRs is normal, and their amplitude is normal or even slightly increased (46). Parkinsonian EMG responses in trunk muscles to perturbations are not later than in elderly control subjects (59). On the contrary, quadriceps antagonist latencies are earlier than normal, resulting in coactivation at the knee not present in control subjects. EMG activation is typically fragmented, with short burst durations and high tonic levels that often return to baseline with multiple bursts. Compensatory gastrocnemius electromyographic responses resulting from backward-directed displacements is affected in PD patients. The reduced sensitivity of the gastrocnemius muscle to stretch correlates with an inability to compensate for the perturbations (51). In the patients, the gastrocnemius response is followed by enhanced activation of the tibialis anterior muscle. The angular rotation at the ankle joint induced during faster backward-directed displacements is slower than that in normal subjects, despite identical amounts of gastrocnemius electromyographic activity (51). This supports the notion of changes in intrinsic muscle stiffness in PD.

Although PD scale postural responses to both displacement velocities and amplitudes, their torque response is smaller than those of elderly controls, especially in response to the largest displacement amplitudes (59). Levodopa further reduces the already low magnitude of initial torque and EMG responses to displacement velocities and amplitudes in PD. Levodopa also significantly reduces the tonic, background levels of EMG, particularly the distal gastrocnemius and tibialis activity. By reducing tone, levodopa reduces active stiffness to perturbations without increasing EMG burst magnitudes, resulting in less resistance to external displacements and thus faster centre of mass (COM) displacements.

Functional modification of postural reflexes according to changes in postural or cognitive 'set' is impaired in patients with PD (46, 47, 56, 57). These anomalies are thought to contribute to balance impairment in PD (43, 60). In these patients, the most striking feature is an abnormal reduction in the capability of decreasing the amplitude of TA MLR when standing and holding onto a frame (46). This decreased capability correlates significantly with the increased severity of the disease as assessed through the Webster rating scale. In normal subjects, holding onto a stable frame reduces the amplitude of TA-MLR to the same extent as after

administration of tizanidine (61), suggesting that both effects are mediated by descending monoaminergic pathways. The brainstem centres of origin of the monoaminergic pathways are both accessed by the output of the motor component of the basal ganglia and affected by PD (62). This fact might explain the decreased capability of modulating the MLRs in Parkinsonians when standing supported (46). This alteration appears to be specific of the basal ganglia lesion of PD. In fact, patients with dementia of the Alzheimer type, though having abnormalities in the basal ganglia, have no difficulty in changing postural set in response to altered support conditions (63).

The coordination between posture and movement is impaired in PD not only during gait initiation but also during initiation of arm and trunk movements. During arm movements, the anticipatory postural adjustments (APAs) are reduced (64, 65) or absent, though the timing of APAs is correct (66). As the movements in PD are performed at a slower speed, the postural disturbances resulting from movement performance are smaller and APAs are no longer required (67). The slowing down of the movement may then reflect an adaptation to the PD deficits (68), based on the use of visual and other feedback loops which makes for a better control of the movement.

During forward and backward upper trunk movements performed by PD patients, principal component analysis of the coupling of hip, knee and ankle angles shows an increased variability and improper set of ratios between joint angles though the control of the kinematic synergy is still preserved (69). This may lead to COM shifts to beyond the support surface, especially in backward bending.

A concurrent verbal-cognitive (70) or motor task (71) produces a significantly larger deterioration in postural tasks in patients affected by PD than normal subjects.

Spasticity

Hemiparetic patients often stand asymmetrically and with broader stance than normals; further, sway during quiet stance is larger than in normal subjects (72). During postural perturbations, these patients show prolonged onset latencies and reduced EMG activity on the muscles of the affected side (73, 74). Further, the normal sequence of activation first in the distal and then in the proximal muscles in response to a postural perturbation is lost. In fact, in hemiparetic patients the proximal and distal muscles of the affected limb are coactivated, whilst on the so-called healthy side the timing of muscle activation is normal (75).

The Sol SLR to toe-up rotation, i.e. the counterpart of the monosynaptic stretch reflex, is increased in spastic patients with respect to normal subjects. In hemiparetic patients, the exaggeration of the stretch reflex is limited to the extensor muscles, whilst in both amyotrofic lateral sclerosis and paraparetic patients the excitability of the monosynaptic reflex arc is generalised also to the flexor muscle, leading to a TA SLR (72). At variance with the increased SLRs, the MLRs are depressed in spastic patients (76, 77). Both frequency and size of TA-MLR are reduced in all the spastic patients

studied (72) This suggests that the late responses to stretch, which are mediated by the spindle group II afferent fibres (22), are subjected to a different descending control from that acting on the SLR (61). In hemiparetic patients, the Sol MLR is negligibly modulated by changes in background EMG in the affected leg, as occurs when leaning forward, further suggesting a disturbed descending control of spinal reflexes fed by spindle group II afferent fibres (72) However, during bilateral vibration of Achilles' tendon, SLR is negligibly affected and MLR is significantly increased in amplitude, at variance with normal subjects where the SLR is decreased and the MLR hardly affected (78). While the lack of inhibitory effect of vibration on SLR confirms a reduced presynaptic inhibition on Ia terminals, the increased MLR indicates a disinhibition of group II pathway in patients, connected to the loss of descending control on group II interneurones. It seems that this disinhibition can be pointed out with the use of vibration. The changes in MLR amplitude, but not SLR, induced by vibration with respect to no-vibration condition well correlates with muscle tone assessed through the Ashworth score. This finding suggests that spastic hypertonia depends on release of group II rather than group Ia reflex pathways (79).

Posturo-kinetic coordination is altered in hemiparetic patients. APAs during upper limb flexion are delayed in both sides of the body (80). When normal subjects are asked to rise on tiptoes, TA is activated before Sol muscle in order to shift forwards the centre of gravity (CG) of the body before rising and avoid to fall backwards (81). On the contrary, when hemiparetic patients rise on tiptoes TA activity of the affected side occurs later than that on the unaffected side. In that way, patients have not time enough to shift forwards the CG, and unbalance may ensue (73).

Peripheral neuropathy

Eliminating vision does not necessarily increase postural sway in quiet stance, nor does it result in longer latencies to postural perturbations suggesting that vision is not as critical as somatosensory information for postural control (82-84). Nevertheless, vision can be an important substitute for loss of somatosensory or vestibular function (83, 85). Sway during stance on a firm surface is larger than normal in subjects with somatosensory loss due to diabetic peripheral neuropathy (86-92).

Diabetic patients with loss of somatosensory information due to peripheral neuropathy have significantly delayed latencies of postural responses to surface displacements (92, 93). As a matter of fact, patients with peripheral neuropathy have an approximately 23 times higher risk of falling than do healthy control subjects (94, 95). Trunk and CFP sway of patients with diabetic polyneuropathy, as well as of healthy subjects, decrease with light or heavy fingertip touch. This finding has implications for understanding how patients with peripheral neuropathy may benefit from a cane for postural stability in stance (96).

Patients with other types of sensory loss, as tabes dorsalis (97) or Friedreich's ataxia (98,99), show increased power spectrum of body sway during quiet stance with a peak around 1 Hz.

The opportunity to record the SLR and MLR, respectively trasmitted through spindle group Ia and group II afferent fibres, allows to functionally assess the proprioceptive component of the peripheral nerve. The SLR might be affected to a greater extent than MLR in case of a neuropathy involving large more than small fibres. Two groups of patients affected either by hereditary motor and sensory neuropathy, called Charcot-Marie-Tooth disease type 1A (CMT1A), or by diabetic neuropathy, have been compared. CMT1A represents a natural model (100,101) of almost selective axonal demyelination and loss of large-diameter myelinated nerve fibers. Conversely, diabetic patients may develop sensorimotor distal symmetric polyneuropathy involving both large and small afferent fibres (102). In CMT1A patients, the SLR of the toe flexor muscle (FDB) is absent in keeping with demyelination of the largest motor and sensory fibres, therefore also of Ia spindle fibres. It is also almost impossible to elicit an H reflex or a T response in the FDB, pointing to a real functional loss of the fibres from the spindle primary terminations. Conversely, in most of these patients, myelinated fibres of smaller calibre are much less affected, as suggested by the presence of FDB-MLR occurring at a longer latency than in normal subjects. MLR can be present in more than 90% of patients. The average motor conduction velocity (CV) of tibial nerve to FDB is about 22 and 34, respectively in CMT1A and diabetic patients, values significantly slower than in normals (45 m/s). From the motor CV, the efferent time of the MLR can be calculated, and the afferent time of the response then obtained as the difference between total latency of response and efferent time. Thus, the average estimated CV of the group II afferent fibres become 19 m/s for CMT1A patients, a figure not different from that of normal subjects (20 m/s). For diabetic patients, CV of group II fibres is 16 m/s, i.e. significantly smaller than that of normal subjects. This indicates that in CMT1A, at variance with diabetic patients, the CV of the anatomically preserved group II afferent fibers, responsible for their MLR, is hardly affected by the disease (72, 92). In this context, it is interesting to note that sway during quiet stance is hardly affected in CMT1A patients even in spite of known foot deformities, whilst sway is increased in diabetic patients. The increase of sway in the latter patients is connected to the involvement of spindle group II afferent fibres. This suggests that the signal coming from the length-sensitive spindle secondaries is better suited than that from the spindle primaries in detecting the slow changes in length of the leg muscles due to the displacements of the body centre of mass during quiet stance.

Vestibular deficit

Patients with acute unilateral lesion exhibit body oscillations mainly directed toward the affected labyrinth (103, 104). Quiet stance is usually not impaired in patients with compensated vestibular disorders (105). An adaptive increase in somatosensory loop gain occurs in patients with chronic loss of vestibular system (106, 107). However, posture can become unstable when other sensory inputs (e.g. visual, proprioceptive, somatosensory) are

manipulated (104, 108-110), when adopting unusual attitudes (111) or during movement of the head (112) or body (113). The cause of this instability may be twofold; the more basic being the impairment of vestibulo-spinal reflexes (104, 114). The second, as hypothesised by Black et al. (108), deals with the instability arising because the labyrinths give a unique signal of movement and tilt of the head and loss of these cues to spatial reference prevents the interpretation of visual and somatosensory cues to orientation.

Chronic bilateral vestibular deficit does not affect postural reflexes not even with eyes closed (82, 83, 93, 104, 115). This phenomenon suggests that integrity of labyrinthine reflexes is not a necessary condition for the occurrence of postural reflexes. However, in these patients the gain of postural reflexes is smaller than in normal subjects, both under eyes open (EO) (104) and eyes closed (EC) condition (116). Differential diagnosis of vestibular and proprioceptive deficits has been attempted using dynamic posturography (117). Measuring trunk sway in the form of roll angle and pitch angular velocity during simple clinical tests of equilibrium could distinguish patients with a well defined balance deficit from healthy controls (118). Non-linear analysis of orthostatic posture in patients with vertigo or balance disorders has been used to assess differences connected with different vestibular disorders (119).

When patients with unilateral vestibular deficit stand balancing on a platform continuously moving in an anterior-posterior direction the displacement of head and hip is significantly larger than that of normal subjects (120), under both visual conditions. Furthermore, with EC several patients do not succeed in performing the task. In spite of this, the coupling between head and platform movements is nearly normal under all conditions. In spite of larger body displacement, the basic coordination strategy for maintaining equilibrium (non-inverted and inverted pendulum with EO and EC respectively) is not overthrown by vestibular impairment, pointing to a major role of APAs in this task. These findings suggest that integrity of vestibular input is not necessary to produce appropriate APAs.

Afferent input from neck muscle vibration is integrated with concurrent vestibular input in determining the postural response. Neck vibration in normal subjects is combined with vestibular input to signal that no head movement has occurred, so it is assumed that the lower body has tilted forwards which provokes a compensatory sway (121). Conversely, in the total absence of vestibular function, the neck signal may represent a real head movement, so the preferential response is a head tilt to restore upright posture. Bilateral vibration of dorsal neck muscles has been reported to increase sway in patients with central vestibular lesions whereas patients with unilateral peripheral lesions are unaffected by vibration (122).

Cerebellar disease

Lesions in different regions of the cerebellum produce very different effects on postural control. However, postural responses do not disappear,

suggesting that cerebellum is not the neural generator of these responses (123). Lesions of the lateral hemisphere can produce profound disorders of timing for arm and hand coordination without significant effects on posture or gait (99). Lesion of the vestibulocerebellum results in impaired vertical orientation such that patients slowly drift away from upright posture, even with EO (124). The most profound deficits in dynamic postural control occur with damage to the anterior lobe of the cerebellum, which receives somatosensory inputs from throughout the body and projects to the spinal cord via the red nucleus and reticular formation. Patients with anterior lobe atrophy of the cerebellum show frequencies of 2-4 Hz in the power spectrum of body sway during quiet stance (124). This kind of ataxia is due to an excessive gain of intersegmental postural reflexes and improves with EO. This abnormal body sway may be absent with EO but can be evoked with EC and/or perturbing body posture through a toe-up rotation of the supporting platform (103). In addition to being exaggerated, EMG responses are not modulated in amplitude by the velocity of perturbation (125) compared to normal subjects (124), i.e. there is an increased gain of the underlying circuits no longer inhibited by the cerebellar output.

Babinski (126) first stated that posturo-kinetic coordination was lost in patients with cerebellar disease. Preparation and execution of movements are delayed and more variable in cerebellar patients (66). Duration of some components of the motor pattern is increased, whilst amplitude of EMG activity is reduced. Therefore, it seems that cerebellum regulates the time course and modulates the amplitude of motor patterns. Diener et al (127) found abnormal timing of postural responses in patients with cerebellar deficits while performing rapid arm elevation while standing upright. Both reactive responses and APAs are too large, or hypermetric, in anterior lobe patients (125,128).

Patients with cerebellar anterior lobe disease can be distinguished from patients with orthostatic tremor since the latter ones show high frequency peaks in power spectra of posturography and EMG recordings (12-16 Hz). No such high frequency activity is found in patients with PD, cerebellar degenerations, essential tremor or in healthy controls (129).

CLINICAL ASSESSMENT OF POSTURE AND BALANCE

Clinical tests

Clinical tests have been designed to investigate the maintenance of the standing position under quiet stance with EO or EC (Romberg test), with a narrowed base of support in a heel-to-toe standing (Sharpened Romberg), or with a reduced area of weight bearing (One-Legged Stance), to assess the capacity to perform voluntary movements potentially challenging balance (Functional Reach), and to measure the time taken to complete manoeuvres including complex sequences of functional movements, e.g. Get Up and Go test and Sit To Stand test.

Sharpened Romberg (SR)

Subjects are instructed to stand barefoot with the non-dominant foot just in front of the other (tandem stand, i.e. heel-to-toe), arms folded across the chest, with eyes open (EO) in the first trial, and with eyes closed (EC) in a second trial (130). The dominant foot can be detected with the Harris Test (131). The score corresponds to the number of seconds subjects maintain the test position. Timing starts when subjects assume the proper position and indicate to be ready. Timing stops if subjects move either foot from the proper position, open the eyes in the eyes-closed trial, or reach the 60-s time limit (132-134). Maximum score, when performance lasts less than 60 s, is the longest period recorded in three (132) or five repetitions (135) of the trial. Normal values of SR are available for both men and women. SR is more difficult to perform than the Romberg test. Half of subjects aged less than 79 years score below 30 s in SR (132). Iverson et al (132) shows that average time of SR with EC is below 25 s. Franchignoni et al (136) in a sample of subjects aged 55-71 years found that in half of subjects performance duration is below 35 s.

One-Legged Stance Test (OLST)

Subjects stand on the dominant barefoot with arms folded across the chest, with eyes open (EO) in one trial and eyes closed (EC) in a second trial (132, 135). Timing starts when the subject raises one foot off the ground and stops when a change of posture occurs (i.e. displacement of the weight-bearing foot, touching of the suspended foot to the ground, use of the suspended limb to support the weight-bearing limb, opening of the eyes when they should be closed) or when the subject reaches the 30-s time limit (135, 136). In order to reduce the ceiling effect, Briggs (132) suggests to use a 45-s time limit. Subject's score is the best score obtained in five repetitions of the test. No significant difference has been found between right and left or dominant and nondominant limbs while performing the one-legged stance test (135, 132). No significant difference was found in mean balance time between subjects who had fallen versus those who had not fallen, nor between shoes-on and shoes-off test performance (132). The one-legged stance test balance time decreases significantly as age increases (135). In subjects aged 55-75 years, interrater reliability of SR and OLST is high for the trials performed with EO or EC (136). Conversely, test-retest reliability is high for trials performed with EC and moderate with EO. Construct validity has been shown by the significant correlation with Tinetti mobility scale. Unfortunately, both OLST and SR are not sensitive in predicting subjects at risk of fall. Subjects' score is greater with EO than EC. OLST with EC is very difficult (132, 133, 135).

Functional Reach (FR)

FR evaluates the maximal distance one can reach forward beyond arm's length in a plane parallel with a levelled yardstick secured to the wall at shoulder height, while maintaining a fixed base of support in the standing position (137). Subjects, barefoot and standing upright, are positioned with

the right side of the body close to the wall. Feet are parallel, freely spaced apart (with an intermalleolar distance of 20 cm) and placed on a non-slip mat, behind a starting line that is not allowed to be stepped over. The instruction to the subject is: "Reach as far forward as you can without taking a step". Distance of reaching is measured as the difference between the starting and the ending position of the head of the third metacarpophalangeal joint of the clenched fist. If the subject takes a step or makes contact with the wall during a trial, that trial is repeated. The score is taken from the average of three valid trials. Subjects' height, age and sex has been shown to influence FR (137). Normal values have been provided only for men. Intrarater and interrater reliability (137) and test-retest reliability (136) are high. Construct validity (i.e., the extent to which results collected with a measure concur with the results predicted from the underlying theoretical model (138)) has been tested with regards to balance measures as centre of mass and centre of pressure. FR has proved to be a weak measure of the stability limits. Indeed movement of the trunk seems to influence the test more than the displacement of the centre of pressure (139). Therefore, when using FR test for assessing balance, compensatory mechanisms should be taken into account (140). FR correlates with physical frailty (141). The association between FR and recurrent falls is not confounded by age, depression, or cognition (142). FR differentiates subjects with Parkinson's disease and a known history of falls from patients with the disease and no history of falls and from control healthy subjects (143). However, patients with vestibular hypofunction show similar FR value to those of elderly subjects (139). FR is sensitive to detect changes in balance after rehabilitation (144).

GET UP AND GO TEST AND TIMED UP-AND-GO TEST (TUG)

The task consists in standing up from a chair, walking 3 m, turning 180°, returning and sitting down (145). It has been initially developed as a clinical measure of balance in elderly subjects, and scored through an ordinal scale (from 1 to 5) based on the observer's perception of stability in performing the task. Construct validity has been assessed with regards to the following variables: gait velocity, mean sway path, step length, cadence, duration of double support but only gait velocity has shown a fairly good correlation (145).

TUG test is a variation of the Get Up and Go test, using a stop-watch for measuring the time taken to perform the task (146). TUG evaluates subject's ability to maintain balance during transfers and gait (147). During performance, subjects are allowed to use the usual walking aid. Time is measured from the verbal GO istruction to complete sitting of the subject. One training trial and two evaluation trials are performed. The time taken by the subject is the mean of the two trials.

Intra- and interobserver reliability are high in elderly subjects (146-148). Conversely, test-rest reliability is rather poor in elderly subjects, that makes TUG scarcely useful in a clinical context (149). Correlation value with Berg Balance Scale is fairly good, whilst it is poor with gait velocity and Barthel Index (146).

Normal values for elderly subjects have been reported (146, 150, 151). Sensitivity and specificity for risk of fall is 87% (148). Elderly subjects taking more than 14 s for completing the TUG have a high risk of fall (148). TUG proved to be sensitive in the assessment of clinical changes during rehabilitation (152). The relationship between gait time and TUG in an elderly orthopaedic rehabilitation population is good, and its strength varies by specific diagnosis, mobility, and time point in the course of therapy (153). TUG has been shown to be a reliable instrument with adequate concurrent validity to measure the physical mobility of patients with an amputation of the lower extremity (154). In Parkinson's disease patients, test reliability and interrater reliability of the TUG measurements are high, and the measurements reflect changes in performance according to levodopa use. TUG can also be used to detect differences in performance between people with Parkinson's disease and elderly people without it (155). It has been proposed to lengthen the distance to walk from 3 to 10 m in order to increase sensitivity of the test to detect subjects at risk of fall (156). The Expanded Timed 'Up & Go' test (ETUG) (156) times the single components (e.g. sit to stand, gait initiation, turn around) in which the task is subdivided using a multimemory stopwatch.

SIT-TO-STAND (STS)

Subjects, barefoot, starting from sitting position on a 45 cm high and 38 cm deep chair (fixed to the floor), are asked to stand up 10 times to erect position and then sit down as quickly as possible, without using hands or arms to push up with from the chair. Time between the order to begin and the tenth sit-down is recorded. Results in the literature refer to 29 men and 65 women. It has been shown that when the intent is to quantify performance of lower extremity muscles, the sit-to-stand test is a practical alternative to manual muscle testing (157). However, STS performance is influenced by multiple physiological and psychological processes and may represent a particular transfer skill, rather than a simple measure of lower limb strength (158).

Multi-item ordinal scales

Clinical balance tests are helpful to document balance status and changes with intervention. Multi-item ordinal scales appear as a useful tool as far as they can easily explore simple real-life performances. They usually rate performance on a set of motor tasks on a three to five point scale or use a stop-watch to time how long the subject can maintain balance in a particular posture. Examples of these scales are a) the Fregly-Graybiel Ataxia Test and the most commonly used functional balance and gait assessment tools: b) the Performance-Oriented Mobility Assessment, and c) the Berg Balance Scale.

FREGLY-GRAYBIEL ATAXIA TEST

It is made up of eight items. Scores are given repeating the same item and summing the maximum scores thus obtained (159, 160). Some items

are not easily administered in elderly subjects with balance disorders. Normal values are provided. Validity is high and several studies have used this test as it is constructed or after modification.

Performance-Oriented Mobility Assessment (POMA)

The so-called Tinetti scale (161) encompasses both balance and gait evaluation. The balance items are scored on a 0-2 point scale, where 0 corresponds to "impossible to perform", 1 to "abnormal" and 2 to "normal". The gait items are simply scored as 0-1, depending on the abnormal or normal finding. In different papers, the number of items and the maximum scores have been changed. For example, Tinetti (161) has proposed 8 items for both balance and gait subscales, with scores ranging respectively 0-4 and 0-2. Lichtenstein et al (162) has subdivided the balance subscale in 14 items with a score ranging from 0 to 24. Cipriany-Dacko et al (163) has proposed a balance scale with a maximum of 16. The balance scale has been validated with regards to the prediction of falls in elderly (164). Interrater reliability is high (161, 163, 165). POMA score has been correlated with various clinical measures showing a rather low correlation with lower limb strength, trunk extension and neck physical examination (161). Tinetti (166) suggests that difficulty in sit-to-stand, instability in turning, short and discontinuous steps are essential items for detecting people at risk of falls. On the contrary, the relationship between neuromuscular findings and functional mobility is not predictable enough to rely on neuromuscular findings for identifying mobility problems (167). On the basis of POMA results, subjects can be grouped in 3 classes with low, medium and high risk of falls (168). Chiu et al (169) have assessed a cut-off value of 21 for the balance subscale, and have found a sensitivity and specificity of respectively 82% and 65% in detecting elderly people at risk of falls. However, it is difficult to evaluate reliability and validity of this scale since scores, number of items, and instructions used in the various studies are different from those originally proposed by Tinetti (161). A further limit resides in the low sensitivity to changes during rehabilitation. Finally, Harada et al (165) have simultaneously administered POMA and Berg Balance Scale in elderly patients undergoing a rehabilitation program: the latter evaluation has proved to be more sensitive than POMA.

Berg balance Scale (BBS)

Though the BBS encloses only items relating to balance performance, this is the most widely used and validated instrument (170). It includes 14 items that require subjects to maintain positions of varying difficulty and perform specific tasks such as standing and sitting unsupported, as well as transition phases such as sit to stand and stand to sit, turn to look over shoulders, pick up an object from the floor, turn 360° and place alternate foot on the stool. Scoring is based on the subject's ability to perform the 14 tasks independently and/or meet certain time or distance requirements. Each item is scored on a five-point ordinal scale ranging from 0

(unable to perform) to 4 (normal performance) so that the aggregate score ranges from 0 to 56: the higher the score the better the performance. The BBS can be administered in 15 min (136, 151).

Interrater reliability and internal consistency are high (171, 172). Test-retest reliability in hemiparetic patients was also high (173). Concurrent validity has been assessed with respect to the Fugl-Meyer test and the Postural Assessment Scale for Stroke Patients. It has proved to be high for patients tested 180 days after stroke (174). In particular, BBS is a scale sensitive to change in stroke patients after 14-90 days. Construct validity has been assessed correlating the BBS to other disability scales, and proved to be fairly high with Barthel Index, TUG, Tinetti balance subscale (170) and Dynamic Gate Index (175), gait velocity and measures of centre of foot pressure (173). Subjects' age does not correlate with score of BBS (151, 172). Elderly subjects able to stand upright for at least 60 s have been scored between 18 and 53 at the BBS (170). Patients with central or peripheral vestibular disfunction have a high, medium, low risk of fall respectively with a score of 0-20, 21-40 and 41-56 (176). For the central vestibular disfunction group, the BBS score has proved to be sensitive to changes. Scores lower than 45 and equal to or higher than 45 respectively separates elderly subjects at risk of fall from those not at risk (172). Depending on the value of this cut-off, sensitivity and specificity of detecting subjects at risk of falls varies greatly: a cut-off equal to 40 yields a sensitivity and specificity of respectively 45% and 96%, whilst a cut-off equal to 50% of respectively 85% and 73% (177). BBS has proved to be the most powerful functional test in discriminating faller from non-faller elderlys compared with POMA and TUG (169).

Fear of falling and fall-efficacy scales

Chronic dizziness is strongly associated with fear of falling; among dizzy patients, nearly half may express fear of falling (178). Fear of falling and participation in real-life activities need also to be analysed for a comprehensive clinical assessment of patients with balance disorders. It is important therefore to have at own disposal validated scales able to detect and quantify fear of fall of patients. The best known scale are the Fall Efficacy Scale, the Activities-Specific Balance Confidence Scale and the Survey of Activities, the Fear of Falling in the Elderly and the Fear of Falling Measure.

FALL EFFICACY SCALE (FES)

In order to study fear of falling in patients, Tinetti et al. (179) have developed the FES. This scale evaluates the degree of fear felt by the subject in performing activities of daily living. The scale is a questionnaire made up of 10 questions. Subjects have to assign a score (0-10) to each question. Each single score is summed to produce a total score (0-100). Subjects who reported avoiding activities because of fear of falling had higher FES scores, representing lower self-efficacy or confidence, than subjects not reporting fear of falling. The FES has showed good test-retest reliability in community-living elderly persons. Internal consistency is high (180).

ACTIVITIES-SPECIFIC BALANCE CONFIDENCE SCALE (ABC)

Powell and Myers (180) have developed the ABC Scale for elderly subjects. It consists of a 16-item questionnaire about a self evaluation of confidence in maintaining balance on a visual-analogue scale. This scale features also outdoor activities in addition to indoor ones as in the case of the FES. Therefore, it is used in active subjects in whom the FES would show a ceiling effect. Internal and test-retest consistency have proved to be high. Elderly subjests with high or low mobility confidence, according to their perceived need for a walking aid and personal assistance to ambulate, can be discriminated by both FES and ABC scales. However, the ABC scale seems to be a more efficient discriminator and yields a wider range of responses.

SURVEY OF ACTIVITIES AND FEAR OF FALLING IN THE ELDERLY (SAFE)

The SAFE has been developed by Lachman et al. (181). The scale deals with the decrease of activity and the worsening of quality of life as a consequence of fear of fall. The SAFE examines 11 activities of daily living, instrumental activities of daily living, movement performances and social activities. The instrument has demonstrated good internal consistency, reliability and has showed convergent validity with other fear of falling measures. Criterion validity has been examined in relation to quality of life variables. Fear of falling has been shown to be related to lower quality of life. One advantage of this measure over existing measures is the possibility for differentiating fear of falling that leads to activity restriction from fear of falling that accompanies activity.

FEAR OF FALLING MEASURE (FFM)

The FFM is made of a list of 19 items representing a continuum of activities of daily living (from the least likely to the most likely one) that could evoke a concern about falling. Each item is rated by a 3-point ordinal scale (from 0 = not at all worried to 2 = very worried). The common question to the patient is "How worried would you be if you were to perform the following activity?" Higher scores indicate higher fear of falling. FFM has been validated in community-dwelling elderly through a Rasch-analytic approach (182).

INSTRUMENTATION FOR KINETIC AND KINEMATIC MEASURES

Analysing and understanding human posture and motion is a main concern for scientists and a large number of motion analysis laboratories are equipped with expensive and sophisticated devices. Today the posture and motion analysis has been transformed from a purely academic discipline to a useful tool in the hand of physicians and therapists. An important goal in clinical posture and gait analysis is to evaluate posture, equilibrium and motor ability during walking, in a population with congenital or acquired dysfunction. Visual assessment, which is almost universally used for this purpose, has been shown to be mostly unreliable. For this reason, objective measurements have become necessary especially in

clinical applications. The quantitative analysis, only possible using the devices previously described, are important in the treatment decision, in the evaluation of treatment efficiency and the evaluation of the patient's performance. In the past, the patients were carefully observed directly as they walked up an down. Nowadays, the kinematic and kinetic systems allow to obtain important measures and parameters which can help look for a number of pathologies and posture abnormalities. In the future, the continuous scientific research and the development of new and sophisticated technologies will allow the use of quantitative gait and motion analysis as a routine part of the patient management.

Kinetic measures

In human movement, it is the study of the forces involving or producing movement.

THE DYNAMOMETRIC PLATFORM

The dynamometric platform is a rigid horizontal surface positioned on four force transducers able to measure the resultant ground reaction force exerted on the platform during the foot contact (Fig. 1). These instruments also measure the Centre of Pressure (CoP) defined as the application point of the ground reaction force vector. Two types of transducers are alternatively used: the piezoelectric or the strain gauge. The first one takes advantage of the property of some crystals, like quartz, which produces weak electric tension if mechanically stimulated along a specific direction. By using a charge amplifier it is possible to obtain a force reliable measure (183-185) The amplifier outputs can interfere to each other and produce a phenomenon named "cross-talk". With piezoelectric transducers the cross-talk phenomenon is unpredictable and the only possibility to reduce it, or rather to eliminate it, is to use special precaution during the installation phase of the device.

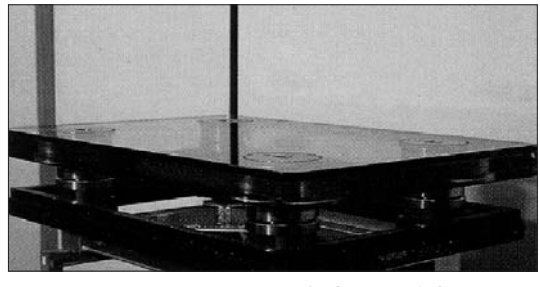

FIGURE 1. Dynamometric platform with four transducers on the corner.

The strain gauge transducers, if lengthened along a specific direction, are able to change their electrical resistance in relation to the lengthening applied. These transducers are positioned on metallic supports able to deform them under the action of the load and as a

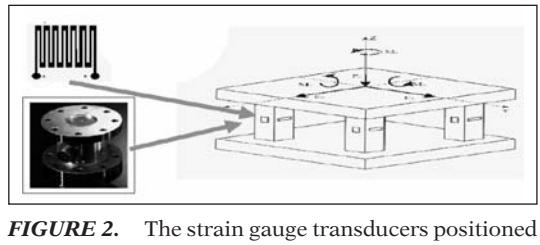

FIGURE 2. The strain gauge transducers positioned on the metallic pylon. Each pylon is placed in platform corner.

consequence to provoke a corresponding deformation of the strain gauge (186,187) (Fig. 2). Even with this kind of transducers the cross-talk phenomenon is present, but it is independent of the precision with which the installation is made. In this case the cross-talk is an intrinsic characteristic of the load cell, therefore it is well-known and eliminable.

The forceplate is basically used to obtain the measure of the forces exchanged between the feet and the supporting surface and the CoP coordinates. It can be employed for static measures (static posturography) as well as for dynamic measures (dynamic posturography, gait analysis, sit-to-stand movement, upstairs climbing and downstairs walking). In postural studies the dynamometric platform is used to measure the CoP oscillations (postural sway) during the standing position of the subject on a fixed platform or on a moving platform. This measure provides important information about the subject ability to maintain the equilibrium, in other words it gives information about the postural control. The sway acquired during a dynamic or static postural test, appears as a tangle around the equilibrium point, more or less lengthened along a medio-lateral axis or antero-posterior axis in relations with the direction of the subject oscillations. In order to quantify the magnitude of these oscillations, the CoP movements on the platform plane are considered (statokinesigram, SKG) and the following variables are computed: the area covered by the SKG, the lengthened of the SKG (normalized according to the duration of the test) and the median frequency of postural oscillations. Usually, in addition to the SKG, a temporal evolution of the medio-lateral and antero-posterior components of CoP movement (stabilogram) are analysed.

In the gait analysis or more generally in movement analysis, the parameters habitually considered are the three components of the vertical ground reaction force (vertical, anterior-posterior and medio-lateral). They are normalised according to the subject body weight and analysed as a function of time. Sometimes, during these dynamic test, in addition to the vertical ground reaction force, it can be interesting to consider the CoP movement.

Various types of forceplate are available and their prices are extremely variable compared to their dimension and the number and the type of the transducers.

The technical features of the forceplate are the following:

– high linearity;
– high rigidity (the deformations are fully detected by the transducers and they are not absorbed by the platform elasticity);
– high sensitivity;
– good dynamic response;
– repeatability of the transducers response.

In conclusion, we can say that the forceplate is an easy to use and reliable instrument (188,189). Nevertheless, in gait or in running analysis it has some disadvantages. First, only one single step for each foot can be measured; second, it is necessary that the foot entirely treads onto the plate surface; third, it is heavy to carry and an outdoor use is unlikely.

THE PEDOBAROGRAPHY PLATFORM

The pedobarography platform measures the plantar pressure distribution during the contact of the feet with the instrument. It provides the plantar pressure map represented in 2-D or 3-D dimensions, the vertical component of the ground reaction force and the CoP position. The pedobarography platform is largely used in clinical applications. In particular it is used for diagnostic purpose and for therapy or surgical evaluations (190-193). The pedobarography platform is composed by a structure positioned at ground level and covered with a large number of pressure sensors (up to 1024). The sensors are positioned in rows and in columns in order to create a matrix on the entire platform surface. Different types of sensors can be employed, in particular, resistive sensors (they change the resistance value by the changing of the pressure applied), capacitive sensors (they change the capacitive value by the changing of the pressure applied) and conductive ink or conductive polymer sensors (they take advantage of the ink and of the polymer conductive properties).

An alternative to the pedobarography platform is the GAITRite system (194-198). This device is a portable walkway, it measures temporal and spatial gait parameters (step time, gait cycle and step length, velocity, etc.) including footprint. It contains six sensors pads encapsulated in a roll up carpet to produce an active area 61 cm wide and 366 cm long covered by 13,824 sensors. The walkway is portable, can be laid over any flat surface, it requires minimal set-up and test time, and requires no placement of any device on the patient. This system is connected to a serial port of a PC. This instrument is used especially in clinical applications, to test the gait performance of patients including those using assistive devices and ambulatory aids such as: crutches, walkers or canes (199).

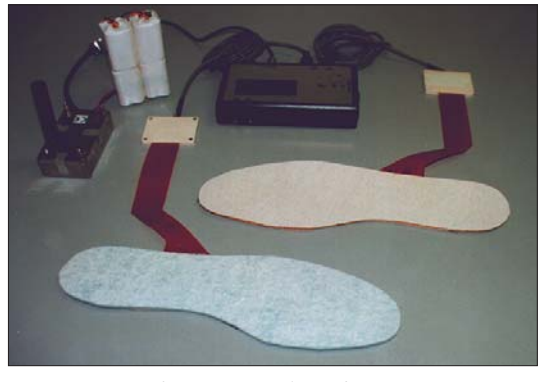

FIGURE 3. The sensorized insole system.

THE SENSORIZED INSOLE SYSTEM

The sensorized insole is a thin insole, similar to the commercial insoles used inside the shoes, covered by pressure sensors (Fig. 3). The sensorized insoles capture the pressure distribution under the feet (Fig. 4),

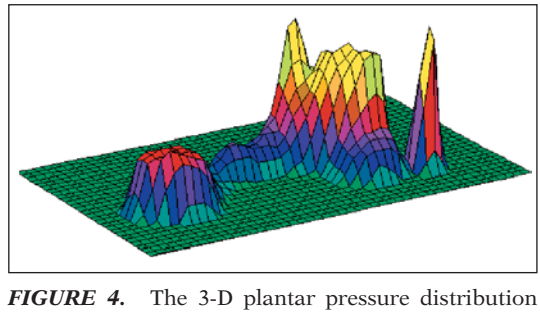

FIGURE 4. The 3-D plantar pressure distribution map during one foot-fall.

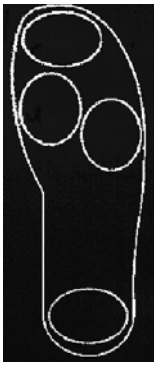

FIGURE 5. Insole with four sensors positioned under the heel and the forefoot.

and measure the vertical component of the ground reaction force, the total pressure exerted by the feet during the ground contact and finally the CoP position.

Dependently on the number and the position of the sensors, we can distinguish two types of sensorized insoles: the insoles with few sensors placed on a specific zone of the surface (discrete sensors distribution, Fig. 5) or the insoles with a large number of sensors arranged as a matrix covering the entire surface (matrix insoles, Fig. 6).

The former are characterised by four or five sensors generally placed under the heel, the metatarsal head zone and the big toe (200-204). The sensor position is personalised for each subject and therefore before starting the acquisition it is necessary to know the foot-print of the subject and subsequently to paste the sensors on the surface insole. The limited sensor number allows particularly quick signal acquisitions (up to 200 and over pressure measures per second). Therefore these types of insoles are especially used in fast movement measures like the run or other sport branches (205). On the contrary, they are not largely used in clinical applications because they only provide partial information about the modality of the foot-fall. They only provide pressure data about the sensors position and therefore with these instruments it is impossible to compute the plantar pressure map and the CoP displacement under the foot.

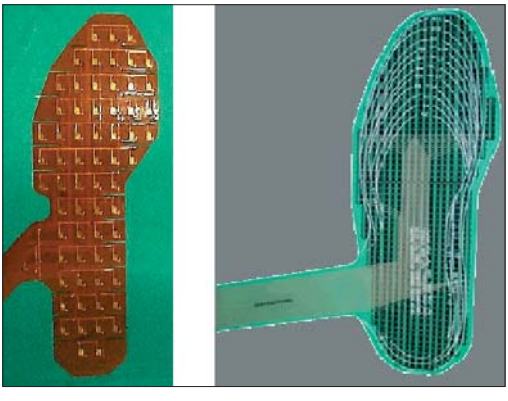

FIGURE 6. Matrix insole. The sensors are arranged in columns and in rows in order to create a matrix covering the entire plantar surface.

The matrix insoles are characterised by a large number (from 64 to 960) of sensors which cover the whole insole surface (203, 206-208). The insoles are extremely thin (from 0.5 mm to 2 mm) and they can be inserted in all types of shoes. Due to the high number of sensors, the acquisition velocity is lower (no more than 100 pressure measures per second) compared to that of the insole with a discrete distribution of sensors. The sensorized insoles data acquisition is realized in different ways. A cable can be used to connect the insoles worn by the subject to the computer. With this solution, there is no limitation in the number of transferred signals and the data can be either viewed in real time or stored for further detailed review and analysis. However, the presence of the cable limits the length of the subject displacement and could sometimes interfere with his movement. Another possibility is storing the data on the flash memory

card in a box fixed on the subject's belt. The subject is therefore completely free to move but the data analysis can be only performed at the end of the experiment when the stored data are transferred to the computer. In addition, the number of data stored in the memory card is limited depending on the sampling frequency which is being used and on the card capacity. A third solution uses a telemetric connection between the subject and the computer; the most recent systems use the Bluetooth TM technology. No cables interfere with the subject and the data can be viewed on line. The telemetry allows the user to watch the subject and at the same time to fully control the testing from a PC. The dynamic pressure data can be viewed online and the subject advised how to perform in real time.

The matrix insoles are usually used in clinical applications because they provide detailed maps of the plantar pressure distribution during the foot stance. They are employed in diagnostic purpose and in the evaluation of the foot stance during gait or run (209-211). In addition, they are used to help in choosing which ortheses or which shoes fit best (212-215).

Nowadays, different sensorized insole systems are available. These systems include the hardware and the software for the data analysis and the insole set of different measures. The disadvantage of these systems are the high price and in some cases the fragility of the insoles. On the other hand, their advantages are that the subject can move on every type of surface, even outside, and that successive gait cycles can be recorded.

Kinematic measures

Kinematics is the science of motion. In human movement, it is the study of the positions, angles, velocities, and accelerations of body segments and joints during motion.

GONIOMETRY / ELECTROGONIOMETRY

A goniometer measures joint angles (Fig. 7), in particular, it provides the measure of the mutual displacement of two adjacent body segments. Electrogoniometers, used in movement analysis, are generally precision potentiometers that change linearly their electrical resistance by the angle of axis rotation. The transducers are firmly connected to a plastic and rigid mechanism, which is attached directly on the body skin in proximity of the articulations. During the positioning phase, it is important that the axis of the potentiometer coincides with the imaginary axis of the joint rotation (Fig. 8). At the end of this phase the subject wearing the electrogoniometer is asked to move his joint. As a first point, this is to rule out the occurrence of any torsion on the parallelogram during the analysed movement. Secondly, to verify that the device is properly fixed on the skin and that it follows the joint movements.

Among the different types of electrogoniometers on sale (216-219), multi-angular electrogoniometers are also available (217, 220). These devices are very easy to use and the subject preparation and acquisition are

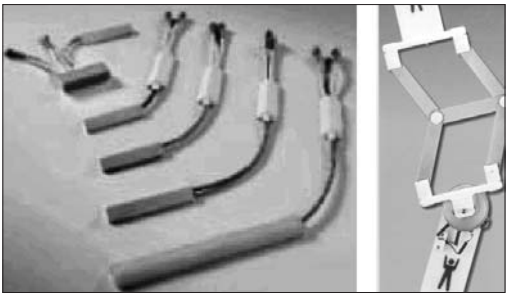

FIGURE 7. Different types of electrogoniometers.

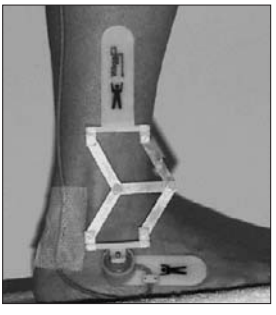

FIGURE 8. Electrogoniometer positioning example. The axis of the potentiometer coincides with the imaginary axis of joint rotation.

very rapid. Nevertheless, their repeatability and reliability are being constantly evaluated (218, 221, 222).

Accelerometry

The movement can be evaluated measuring acceleration. For this reason, in the last few years, accelerometers have found different uses in the field of kinematic motion analysis. Nowadays, there are three types of commercial accelerometers: piezoelectric, at solid state and a Micro-Electro-Mechanical System (MEMS) technology. All these devices measure the acceleration of translation. Piezoelectric accelerometers are not suitable for motion analysis because they have a low cut-off frequency (1-2 Hz) and they are not so small. The solid state accelerometers have larger pass bandwidth (0 up to hundreds of Hz). They can measure acceleration along one, two or three orthogonal axes with different ranges depending on the model (± 1g up to dozens of g). Accelerometers built in MEMS technology have been recently introduced, they have performances very similar to the previous ones, but they are lighter (few grams), smaller (few cube millimetres) and cheaper. This technology is still evolving, and promises interesting improvements. The measures involving accelerometers show a critical aspect: the acceleration measured along accelerometer axes is influenced by all the different types of acceleration; namely translational, tangential, centripetal and gravitational. This latter does not influence the piezoelectric accelerometer measure. For this reason, before performing any signal analysis, the separation of each component is necessary. In order to solve this problem, different solutions have been proposed (223-230).

Recently, accelerometry has been implied as a proof of the movement activity. In this case it is not necessary to reconstruct the kinematic movement and to solve the problem described above. The devices that are used for this purpose are basically systems for the level recording activity (231-238). This issue is more largely described in the chapter by Giordano and co-workers in this book.

Infrared camera based systems (Optoelectronic systems)

At the beginning of the eighties, systems for the movement analysis, based on special infrared camera and retroflective markers, started to develop (227,239-241) (Fig. 9). These systems, named optoelectronic sys-

tems, are able, by using mathematic algorithms and stereophotogrammetric procedure, to combine the 2D images coming from each camera to obtain a 3D image. As an individual has a 3D vision of the objects through the joint action of the two eyes (stereoscopic vision) at the same time an optoelectronic system can reconstruct the 3D position of an object through the joint action of two cameras; each of them acquires the 2D position of the object in a relative reference system defined on the camera itself. The combination of the data obtained by two cameras allows the reconstruction of the 3D position of the object in a Lab reference system.

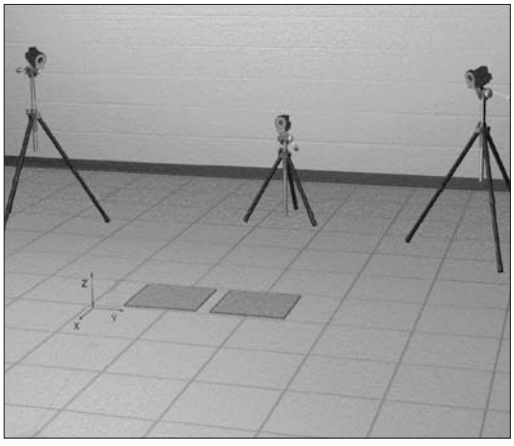

FIGURE 9. Infrared camera-based systems composed by three cameras placed on the tripods.

In order to obtain this result, not only does the system need to know the 2D of the object point of the two cameras, but it also needs to know the position of the two cameras in the Lab, whose coordinates are computed in reference to the absolute reference frame (parameters of calibration). These parameters are invariant in time and are computed during the calibration procedure. This procedure precedes the acquisition phase obligatory. Actually, if one is sure that the cameras are always remaining in the same position and that nobody accidentally moves them, the calibration procedure can be made every other day or once a week. In the modern systems this procedure has become very easy and quick.

The minimum number of cameras is two, but in motion analysis it is better to use more than two cameras, for example eight or ten. In these latter configurations, the probability that during the subject movement at least two cameras simultaneously see the markers is high. The cameras are characterised by a ring of infrared light-emitting diodes (Fig. 10) which have to light the passive markers placed on the body subject. The light reflected by the markers is detected by the light-detectors fixed on the cameras. The cameras could have a sampling rate of 50 frames/s, or 100 up to 200 frames/s. The passive markers are small retroreflective spheres reflecting the infrared light emitted by the cameras. They are attached to the subject body, preferably directly to the skin, to the articulation or to specific reference points (Fig. 11). The identification of these points is made by palpation. The number of markers used for movement analysis purpose is not fixed and it can change up to a maximum of 30. A high number of markers allows a detailed movement analysis, but this number cannot indiscriminately increase because the markers would become too near each other and eventually confused by the system leading

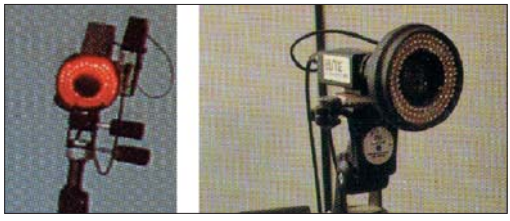

FIGURE 10. Infrared cameras with a ring of infrared light-emitting diodes which illuminate the passive markers placed on the body subject.

FIGURE 11. An example of two passive markers. They are small retroreflective spheres that reflect the infrared-light.

to a worsening of the measure. Markers detection is based on the pattern recognition technique and provides the system with great flexibility allowing its use even in the presence of brighter disturbances.

Alternatively to this kind of markers, labelled passive markers, the optoelectronic system can use the active markers. They consist of infrared light-emitting diodes that are placed on the subject. The diodes are pulsed at different times by a control unit either worn by or connected to the subject. Since each marker pulses at its own time, the light detector in the camera samples the diodes as a point in space and can calculate the 2D coordinates. The data are then transmitted to a computer for 3D calculations.

The measurement obtained by the optoelectronic system is the 3D position of each marker used for the acquisition test. Starting from these data it is possible to reconstruct the trajectories (Fig. 12), the displacement velocity and the acceleration of these markers; and also, through more complex algorithms, to compute the articulation angles and the body CoM position. All these variables are very important for a complete quantitative movement analysis.

For these reasons the optoelectronic systems are largely employed in clinical applications, in particular in the diagnostic field, in the evaluation of the physical treatments and in the quantitative evaluation of the patient

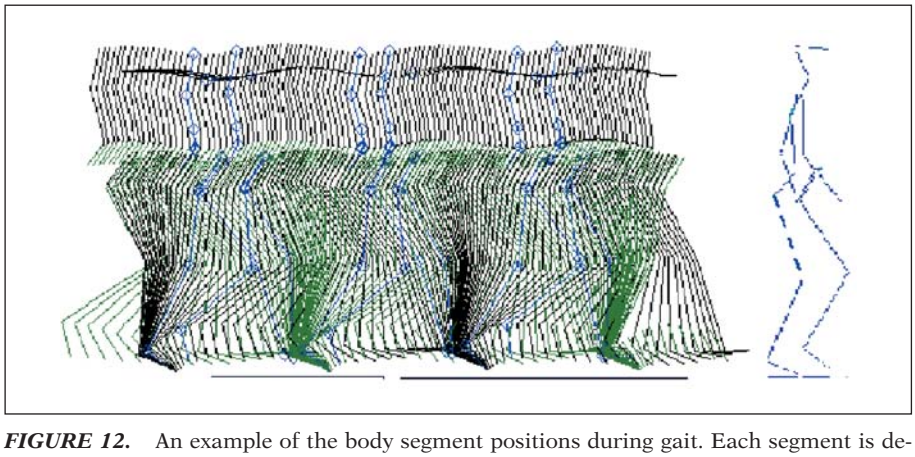

FIGURE 12. An example of the body segment positions during gait. Each segment is defined between two successive markers (blue circles).

performance. Industry also utilizes these instruments with many applications ranging from industrial design to ergonomics, from robotics to the realm of animation, videogames and virtual reality. These instruments have now completely replaced the traditional TV based system using a video camera connected to a computer. These video-cameras were relatively unsophisticated video or motion-camera systems simply recording the movement on film, videotape or in digital form for later visual inspection, possibly in slow motion or more frequently on frame-to-frame based analysis (242).

The optoelectronic systems have several advantages including the high sampling frequency useful for sport acquisitions and the freedom of the subject movement because no cables are necessary for the acquisitions. Nevertheless, they are still expensive and the post-processing analysis requires a long time.

CONCLUSIONS

This review shows that the main purpose of the assessment of posture and balance is not to diagnose a disease but to provide an evaluation of the physiological changes occurring with ageing and of the pathophysiology of the underlying disease processes as well as changes with therapy. To this aim, sophisticated but often expensive instruments are now at hand of clinicians. These instruments allow studying stability during quiet stance, postural reactions to external disturbances, anticipatory postural adjustments to perturbations caused by self-paced movements and gait. All these conditions mimic quite well known situations encountered in every-day life.

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CHAPTER 8
ASSESSMENT OF COGNITIVE IMPAIRMENT IN ADULTS

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Cognitive impairment is a major source of disability and handicap in patients with brain damage. Even in the absence of motor impairment, patients with cognitive disorders may require assistance in activities of daily living (ADLs), become socially dependent, and/or need supportive counseling and help in maintaining community activities (1). Thus improving cognitive rehabilitation constitutes a major challenge and goal for Rehabilitation Medicine. Neuropsychological assessment, the examination of the cognitive functioning in the light of brain-behavior relationships is an important component in meeting this challenge and achieving this goal.

Neuropsychological assessment is based on several knowledge sources: the neurosciences, cognitive and abnormal psychology, and test and measurement theory derived from the long-standing empirically-tested experience of educational psychological and its statistical underpinnings. This chapter concerns some methodological aspects of cognitive assessment in order to provide some understanding of how neuropsychologists assess cognition and emotional disorders in brain damaged adults.

The assessment of cognition is more complex than the assessment of joint range of motion, for example, because so many

variables must be considered and so many aspects of cognition may need to be examined for rehabilitation purposes. Moreover, the many different aspects of cognition require many different kinds of assessment techniques, much as the many different kinds of illness and injuries that benefit from rehabilitation also require many different kinds of assessment techniques.

Assessment methods generally reflect the current knowledge on the issue in question. The development of neuropsychological assessment over the past 50 years is a prime example of a discipline which has kept pace with its knowledge base. One early source for neuropsychological assessment tools was the work of educational psychologists, such as Alfred Binet, who, in the first part of the 20th century, pioneered the development of psychometric assessment (2). At that time a theory compatible with the work of Binet and other early psychologists held that mental abilities involved general resources (g) associated with specialized functions like memory or perceptions (3). All other parameters being controlled, the same tasks were thought to produce similar responses in people of similar levels of mental ability, and they called this similarity of response, "intelligence." Today, many of the psychometric tests developed in the early 20th century as tests of "intelligence" – and their more recent refinements – are still used for examining some aspects of cognition. Neuroscientific studies of cognition have demonstrated their relevance to specific aspects of brain function even though cognitive neuropsychology has shown that the concept of "intelligence' is no longer a meaningful scientific construct (4).

Also early in the 20th century, clinical neurologists provided extensive descriptions of the observable features of the major neuropsychological syndromes, such as aphasia, apraxia, inattention, and Alzheimer's disease, relating these disorders to structural brain damage. Standardized assessments, including symptom check lists, were developed from their clinical examination data. Much of this early work has been incorporated into more recently developed tests and assessment techniques used by neuropsychologists.

In the last half of the 20th century, the relatively new science of cognitive neuropsychology made major advances as it integrated the rich knowledge bases of clinical neuroscience with the statistical sophistication of psychometric assessment. Further, by drawing upon Artificial Intelligence theories and the computer sciences to conceptualize the dynamic relationships between cognitive functions and brain structures, neuropsychology has acquired a theoretical framework which has well-demonstrated clinical applicability and ecological validity, and which supports further development of both neuropsychological assessment techniques and scientific knowledge about brain function and dysfunction.

Theoretical models within this conceptual framework propose that cognitive processes are organized according to principles of modularity (i.e., specificity, hierarchy, independence), operating at different levels of activation, depending on the task (5). These modules produce, in a given context, specific representations of language, memory, perception, etc.

The introduction of single case studies brought a sharper, more finely honed perspective to this work as such studies have shown how very specific some impairments can be. Cognitive neuropsychology has truly revolutionized cognitive rehabilitation, for these models allow for explanatory hypotheses regarding the sources of neuropsychological symptoms so that therapeutic interventions can be designed to target the sources of impairment rather than its apparent (surface) manifestation. Research in cognitive neuropsychology has also produced many new assessment techniques: while these were originally designed to explore theoretical models they are now used for clinical assessments as well.

In parallel with these developments and complementary to them, rehabilitation medicine and the clinical neurosciences have highlighted the ecological value of cognitive assessment. Patient examinations have demonstrated that it is necessary to take into account the influence of environment and real-life conditions on cognitive functioning, as well as the influence of cognitive deficits on every day functioning. With this accumulating awareness of the complex nature of cognitive impairment, the International Classification of Impairments, Disabilities, and Handicaps (ICIDH) now requires not only the assessment of cognitive impairment, but also disability (Activity limitation in the ICIDH-2, or ICF) and situations in which handicap occurs (split between Participation restriction and Contextual factors) (6). This classification system has prompted the development of new examination paradigms (see, for example, the European Document for Traumatic Head Injury Patients [EBIS]) (7), which provide comprehensive and multidimensional assessment of cognitive impairment. Other advances – both conceptual and practical – are emerging.

ASSESSMENT OF COGNITIVE IMPAIRMENT

In the classical examination of cognitive disorders associated with brain damage, cognition is considered in terms of functions such as memory, attention, language, perception, each of which is assessed by tests, questionnaires, or clinical scales. A test may be defined as an observational technique which "elicits behavior samples in a standardized, replicable, and more or less artificial and restricted situation (4). Psychometric tests generate quantitative data well-suited for statistical evaluation techniques. Standard scores, for example, are raw scores scaled according normative data based on scores from a demographically defined population sample. Depending on their scores, patients' performances may also be classified in reference to a corresponding division (e.g., percentile) of the reference population. For tests with a normal (gaussian, parametric) raw score distribution, a score is considered abnormal when it falls one-and-one-half to two or more standard deviations below the mean of the reference groups. In the ideal situation, the same process with the same patient would always result in the same performance, so that the same meaning might be attributed to the same scores – whether from one patient to another or from one examination to another. Since the ideal situation is nonexistent, there is always more or less score variability from

time to time in a subject and especially in brain injured patients, and from subject to subject (see the discussion of reliability, below).

Psychometric tests are mostly used for evaluation of memory, abilities dependent on visuo-perceptual functions, learned knowledge and skills, and – to some extent – executive functions in traumatic brain injury (TBI) patients, and those with cognitive impairments due to other conditions (e.g., brain anoxia, toxic or metabolic encephalopathy, or dementia. Some collections of tests (often termed batteries) such as the Wechsler Adult Intelligence Scales (which is updated about every 15 years) or the Halstead-Reitan Battery (which has remained unchanged for decades) contain different tasks for examining a number of cognitive dimensions (8,9). In the past, scores for these different tests were summed into one or several scores, presumably communicating something about the ephemeral concept "intelligence", or the presence of a brain disorder. However, current knowledge of the complexities of brain function have rendered these summation procedures obsolete (4). Most individual tests actually examine a number of functions – not least being the ability to understand instructions or keep them in mind. A drawing task, for example, in examining the ability to copy a design, will provide information on the patient's fine motor control, visuospatial orientation, visual concept formation, perceptual accuracy, attention to details, among other capacities. Other tests involve primarily one component of cognition (10). Computerized tests are now available in which items are always delivered in the same format, automatic scoring takes into account reaction times and response delays, and the data are automatically recorded and evaluated.

The main strengths of psychometric tests are their precision, their reliability, and their generally good construct validity which allows examiners to generalize from test data to real-life predictions. Their chief limitations include difficulty in interpreting scores generated by tests of complex behaviors (e.g., drawing), as well as difficulty interpreting scores separated from the history, demographic features, attitudes, styles, and behavioral anomalies of the patient. Test users must realize that reliance on test scores alone loses very important qualitative aspects of patients' performances; e.g., hesitancies, self-corrections or unawareness of error, for untimed tests speed of response may be very relevant but not addressed by the score. Significant idiosyncrasies of speech and pragmatics will also remain undocumented. Moreover, the development, standardization, and validation of a new test takes a long time – around ten years on average – yet knowledge about cognition advances more rapidly. By missing a critical component discovered after their development is underway, some tests may be out of date even before their publication.

Clinical scales and symptom inventories derived from classical neurology are also used for assessing impairment, both cognitive and behavioral. Tasks and items are designed to elicit data specific for one or another pathological symptom or syndrome. Since symptoms are not normally distributed in either the patient or the general population, the usual normative approach is not relevant to standardization. Rather, these in-

struments provide descriptions of pathological patterns of cognitive or behavioral functioning. For instance, the well-known Boston Diagnostic Aphasia Examination (11) is a standardized and quantitative examination of aphasia signs, not a test of language skills. Clinical scales are often used in preliminary investigations to be supplemented, as needed, by more specific tests.

Cognitive neuropsychology has also devised methodologically sophisticated research protocols that can identify specific cognitive functions. Using similar methods, relationships between brain structures or brain pathology and highly specific cognitive functions or dysfunctions have also been elucidated. To identify specific cognitive functions – or dysfunctions, this methodology requires two or more tasks with known properties in a cognitive domain. For example, if two cognitive functions A and B are independent (for instance, reading words aloud via a direct, lexical route, or reading via a grapheme/phoneme conversion process in a phonological route) it should be possible to find two tasks X and Y (in this example, reading aloud non-words and reading irregular words) such that success on task X and failure on task Y would be characteristic of the impairment of A and of the integrity of B; and conversely, success on Y and failure on X would be characteristic of the impairment of B and the integrity of A. These procedures do not require normed and standardized tests. Rather, the assessment is tailored for each patient, with tasks improvised according to the hypotheses to be tested. Selective attention, working memory, written language, visual perception, and agnosia in stroke patients are some of the domains in which this kind of procedure has proven fruitful. Advantages are coherence with theoretical models and refined understanding of the specificity and brain relationships of many cognitive functions – and disorders, which had proven useful for therapy. However, this complex and time-consuming methodology, while important for research, has poor ecological validity, i.e., in itself it cannot predict real-life functioning (see below).

COGNITIVE ACTIVITY LIMITATION

This relatively recent concept emerged in rehabilitation literature when the ICIDH was applied to cognitive behavior and neuropsychology. It pertains to the ability to perform those ADLs which predominantly involve cognitive skills without regard to possible physical, motor, and social restrictions, in so far as possible. This limitation is mostly evaluated in stroke and TBI patients, or in those with cognitive decline or dementia. Questionnaires, checklists, and rating scales based on observation or interview are the most usual forms of assessment.

Self-administered questionnaires ask patients for their opinions about their own abilities and behavior. These questionnaires have the advantage of documenting self-awareness and the extent to which patients perceive their own limits with regard to cognitive skills. Conversely, they may not provide an objective or accurate account of the patient's cognitive status. Checklists and behavior rating scales that are answered by the

examiner or a significant other (relative or caregiver) rely on the respondent's daily observation of the patient's behavior; responses may also be elicited by a structured interview. These data add objectivity to self-administered questionnaires. Comparing responses to the more and less objective inquiries about the same skills provides a reasonably accurate assessment of the patient's self-awareness (see, for instance, Prigatano's Patient Competency Rating Scale (PCRS) (12). Items commonly included in such scales deal with abilities to read and write documents (e.g., bills, checks), to perform administrative tasks, to shop, or to travel outside the patient's residence (e.g., to drive a car, to take a train or bus) (7). Other items inquire about the patient's self-sufficiency at home, such as taking prescribed medications without help or managing money (e.g., balancing a bank account; see Lawton's Instrumental Activities of Daily Living (13). The Catherine Bergego Scale, which addresses the difficulties that patients with unilateral inattention (neglect) are faced with in daily living is another example (14). Communication abilities, which are often impaired in brain damaged patients, need specific assessments. Recently these authors developed the Bordeaux Verbal Communication Scale, an ordinal scale rated from a structured interview, to document the efficacy of the aphasic patient's communication in daily living and social activities: e.g., it inquires into such activities as talking with unknown versus familiar persons, asking for information, calling on the phone, going shopping, reading and writing complex material, and so on (15). Some disability scales are scored according to the degree and type of help needed to perform the task, which provides useful data for planning services (e.g., the Mayo-Portland Adaptability Inventory (MPAI) (16).

BEHAVIORAL IMPAIRMENT

Behavior is the obvious side of the neuropsychological iceberg. It is the visible product of the interaction between the person and the environment in a given situation. So it depends on many parameters, such as speed and accuracy in processing information coming from the external world, mental states about the situation (degree of awareness, affect, motivation), previous goal-directed schemes and life styles (influence of culture, education, previous experiences), and, of course, attitudes and reactions of other persons participating in the situation. Obviously it would be impossible to create an assessment tool which would take into account all these parameters. So behavioral assessment is necessarily global and descriptive, as is disability assessment.

Behavior rating scales are mostly used for patients with TBI, brain anoxia, and dementing disorders. Questionnaires, check lists, and ordinal scales include brief descriptions of symptoms or behaviors that may be observed during the course of the condition, or lists of behaviors considered abnormal with respect to social standards or compared to premorbid behavior. Ordinal descriptions of behavior, such as the Rancho Los Amigos Levels of Cognitive Functioning for TBI patients may be difficult to apply when patients do not fit exactly within a described behavioral lev-

el but fall between two of the eight scale levels (17). More recently developed scales contain many more behavioral tasks with graduated scores indicating task difficulty and degree of patient independence. The fine gradations of some instruments may permit the data to be treated much as scales with continuous variables (16, 18).

Check lists come in a variety of formats (4). Some ask for reports on correct or usual behaviors, which immediately raises the major questions: what is normal behavior? to what extent should an individual conform to social standards? Other check lists inquire about typically impaired behavior. Many check lists ask for frequency or severity data for each item which gives quantifiable data for ordinal scaling. A few behavior scales include different types of assessment; e.g., the Neurobehavioral Rating Scale-Revised (NRS-R) includes a semi-structured interview with questions about feelings and symptoms, ordinal descriptions of behavior during the interview, and brief problem-solving tasks (19, 20). The goal of these instruments is to be more comprehensive by gathering cognitive, affective, and behavioral data in the same interview. Lastly, some extensive assessments such as the EBIS document and the Mayo-Portland Adaptability Inventory use both check lists of symptoms and disability rating scales to gain information about physical, cognitive, and social functioning in the same instrument (7, 18).

ECOLOGICAL ASSESSMENT

Ecological assessment is in an intermediate position between cognitive tests, disability scales, and behavioral descriptions. Like cognitive ability scales, it developed mostly under the influence of rehabilitation medicine and pragmatic inquiry into the ecological validity of classical testing: e.g., to what extent does a memory test performed in a psychologist's office depict an amnesic patient's difficulties in daily living? And to what extent are the memory processes involved in a test the same as those required for everyday activities? (21)? Despite a general relationship between memory test scores and daily functioning (4), good scores do not necessarily predict satisfactory behavioral adjustment or ability to return to work. Conversely, some patients with effective coping strategies may function well even though memory test performance is severely impaired.

Three kinds of techniques for improving the ecological validity of cognitive assessment have been used.

Putting the laboratory in real life settings (21) involves observing patient behavior at home, during usual activities, with relatives and associates. Although observation in the natural setting provides data that is most likely to be valid, it is both costly and very time-consuming. The reliability of these observations may also be questioned as the data are not collected in a standardized manner: the examiner may have observed an atypical situation or the patient in a not usual state. Because of these limitations, real life assessments are only appropriate for clinical research or when a task is so complex and/or includes so many parameters that no other evaluation can answer the questions that prompted the examination

as, for instance, assessing the ability to drive a car in real-life traffic conditions, or the ability to return to work successfully.

Simulating real life in the laboratory requires examiners to design tests and tasks that resemble real life conditions and cognitive demands.

Self-administered questionnaires and disability rating scales, of course, can only be used with patients who never left their home or have returned.

Some laboratory techniques have the patient watch and react to videotapes or computerized virtual surroundings (see, for instance, 22). Others involve role-playing in which patient and examiner act out a fictive communication situation such as shopkeeper and customer or patient and physician's secretary (23, 24). Last, and the most difficult to check and score, some ecological tests take place in the real environment: e.g., in Shallice's Multiple Errands Test the examiner accompanies and documents observations of the patient who has to go to several shops in a shopping area and buy specified items while keeping in mind instructions about time and where to end up (25). In route-finding tests patients have to find their way to a goal in complex and unfamiliar surroundings (e.g., for an outpatient, the clinic cafeteria) (26, 27).

Ecological tests are now available for nearly all cognitive domains. Although devised to have ecological validity, these tests can be difficult to use because of standardization, scoring, and reliability problems. Another weakness is that they provide little if any information about the underlying mechanisms of impairment. These tests are best used in association with other tests of cognitive functioning. Mostly they tell about the practical needs for setting the goals and assessing the efficacy of rehabilitation programs.

ASSESSING PARTICIPATION RESTRICTION OF COGNITIVE ORIGIN

In the rehabilitation field, clinical experience and research have provided strong evidence that participation restriction, in the sense of patients' social disadvantage and impairment in their premorbid community roles and activities, is a common consequence of cognitive impairment and disability. Most studies have found restrictions in family role, return to work, in leisure and school activities, especially after stroke, dementia onset, and TBI. However, disability level may change with different situations and in different environments. This changing nature of participation restriction (handicap), by itself, makes it difficult to standardize these assessments. For instance, a baker with mild aphasia suffers a restriction of his social role when he sells bread in his shop, although this restriction disappears (or diminishes greatly) when he is alone baking in front of his oven, and may even be less when he deals with a familiar customer than with a stranger. In this case it is neither the aphasia nor communication ability that should be assessed, but the situation of this patient selling in this shop. Of course, the cognitive requirements of the social role of selling in general can be studied, but this would probably be classified as an Activity level; yet selling depends on

environmental factors as well, that is the Contextual Factors (6). Some evaluation instruments have been developed by occupational therapists to take into account these factors (28, 29). In the second version of the Occupational Performance History Interview (OPHI-II), for example, the third scale – Occupational Behaviors Settings – measures the extent to which a social group, type of occupation, or space and objects may support adaptation and provide environmental support in home, work, and leisure settings (30).

INTERPRETATION ISSUES

Cognitive assessments must be interpreted with caution. Cognitive symptoms can be opaque and ambiguous: the same surface manifestation may be subtended by different mechanisms. For example, Nespoulous and Soum outline some reasons for the weak relationships between aphasia symptoms and the underlying impairments (31): A symptom may be attributed to either of two different mechanisms depending on the sensitivity of the assessment technique and depth of analysis (e.g., saying "ti" for "tree" may result from the omission of the phoneme "r" due to a phonetic impairment, or from the verbal paraphasia, "tea". A symptom may be related either to an impairment or to a compensation process (speaking slowly may result from difficulty encoding the forthcoming word or from a voluntary control of phonetic production. A symptom may be explained by a single condition or may have arisen from multiple impairments, and so on. Moreover, great variability characterizes language organization from one person to another (32), so that the same symptom may be related to different lesions sites in different persons. Thus one must be very careful before generalizing data from one patient to another. Similar questions, relevant for all domains of cognition, are of major importance when preparing a therapy program.

Some pitfalls in the interpretation of psychometric data are always present. A score cannot be equated with the behavior it is supposed to represent! (4). A score is nothing more than a numerical value on a conventional scale, attributed to a patient's answer or reaction to more or less standardized questions or stimuli by an examiner following a set of scoring rules. Each individual test performance should be evaluated in the light of the patient's demography, history, education, and medical condition. Moreover, even when standard score transformations take into account the subject's age, gender and education, a summary score such as an IQ score – based as it is on the mean of a set of scores on the very different kinds of tests in a test battery – will usually be the arithmetic summation of levels of skills and abilities which differ in their ups and downs for different individuals and thus in itself be meaningless (e.g., one person may receive a high score copying designs with blocks but have a very limited vocabulary, another may demonstrate a splendid vocabulary but be at a loss when confronted with the design copying task, yet each of these persons may end up with the same IQ score. With brain damage, summary IQ scores, or any scores summing two or more test performances,

can be even more misleading. For example, after mild TBI, many bright patients, whose individual test scores mostly run well above the population mean, will obtain an IQ score that has been dragged down to around the mean (i.e., a score of 100) due to poor performances on tests assessing attention and/or response speed, when the individual test scores have been summed into an IQ score by a naive or poorly trained examiner. The summation IQ score will have obscured both these patients' many competencies and also their problems with attention and sluggish mental processing – problems which could benefit from rehabilitation when they are identified.

General and non-cognitive factors may interfere with the validity of the assessment. Health problems: pain, fatigue, sleep disorders, and medications can impair response speed and important aspects of attention and memory. Mood disorders, anxiety, poor motivation, fear of testing, and – most of all – depression, can impair cognitive performance. On the other hand, deliberately poor performance (malingering) in the course of a medico-legal assessment is usually easy to identify as unexpectedly low performances when evaluated in the context of daily functioning, or when errors do not make sense either in terms of usual patient test performances or knowledge of the condition presumably being evaluated. For example, when recall of the second and third trial of a word list are worse than the first, or when scores are by far better for rare items than commonplace ones in a confrontation naming test, the examiner's suspicions of poor motivation should be aroused. However, most patients want to preserve their dignity and perform at their best, even when monetary rewards for impairment are anticipated.

Other interpretation problems may come from the design of the tests themselves (4). Close-ended questionnaires and check lists with a dichotomized format (e.g., "yes or no") run the risk of reductionism: the range of observations is so highly restricted that responses may have little relationship to what the patient thinks, or feels, or can do. Many questionnaires and check lists generate a summed score based on points for positive answers. While this one-dimensional quantitative variable is readily accessible to statistical treatment, it may hide different – and sometimes, very different – answers. Like the problem with summation IQ scores, two patients receiving the same global score may suffer from different behavioral impairments. The cognitive validity of the assessment is very important. Cognitive measures should be related to naturalistic observations in so far as possible. In case of disagreement between test scores and daily observations, believe the last.

Cognitive assessment involves much more than numerical scores on tests. It also includes a qualitative dimension that takes into account all the factors that make sense of the score, including the patient's examination behavior and qualitative aspects of the test performances. For example, assessing cognitive strategies, that is, understanding *how* a patient performs a task, is often as important as finding out *what* the patient knows or can do (33).

HOW TO PLAN A COGNITIVE ASSESSMENT

An ideal test battery that could be used every time for every problem and with everybody does not and probably can not exist. The assessment battery put together for each patient depends upon the evaluation goals, available testing time, and the patient's strengths and limitations. When many tests are available for a cognitive domain of interest, the examiner should select well-validated tests with norms that fit the patient's demographic features and that target the examination objectives most closely.

Among the test characteristics that qualify a test for use, validity is both the most important and may be the most difficult to appraise. *Validity* refers to how well a task or test assesses what it is supposed to assess. *Content validity* may be especially difficult to document for many tests of cognitive functions when they are so complex that they provide information about several variables with more or less information about any one variable depending upon the subject's capacities. For example, the Arithmetic test in the Wechsler Intelligence Scale batteries probably is a good test of arithmetic ability in persons with limited arithmetic skills and relatively intact attentional functions; for a bright, mathematically skilled person who has sustained mild TBI or has multiple sclerosis it is often much more a test of attentional functions than of arithmetic; persons with average arithmetic ability whose response speed has slowed due to Parkinson's disease may achieve a score below their ability level because they fail to answer the questions quickly enough. Given these complexities, a common method for establishing content validity compares tests under development with older, widely used ones, the latter being treated as "the gold standard." Many tests become empirically validated through clinical experience and from research findings such that, in time, knowledge about what can be expected of the test accumulates from performances by demographically different subjects and a variety of patient groups. With this knowledge clinicians can draw logical and reliable conclusions from their data enabling them to take appropriate action for the patients (e.g., plan a treatment program, devise a coached job experience). Test validity studies comparing tests directly typically employ statistical procedures designed for normal (Gaussian, parametric) score distributions. However, some test scores should be reported on ordinal scales as they do not fit a normal distribution (e.g., the number of syllables in the longest sentence the subject can repeat accurately). Construct validity for these tests can be ascertained too, but by means of different kinds of statistical treatments (i.e., nonparametric evaluations) which may not have the power of parametric statistics (i.e., may require larger data sets to illustrate a phenomenon). However, test selection should focus on the known properties of the test and how they relate to the questions presented by the patient; if they have satisfactory construct validity their specific statistical attributes will rarely be relevant in the individual case.

The *face validity* of a test may or may not be a useful feature. Many patients are reluctant to take "school-like" tests or are anxious about failing or appearing stupid on a mental ability measurement. For these pa-

tients the examiner can help them understand why it may be important for them to find out what is needed for their rehabilitation or to return to work. On the other hand, some personality inventories ask questions with no face validity that some patients find intrusive or embarrassing, although they may respond well to an inventory with obvious face validity (e.g., questions about aches and pains, about feeling confused or their mind going blank).

Reliability refers to the extent to which a test will generate the same score in persons with similar abilities under similar retest conditions regardless of who is the examiner. The reliability of a test can not be determined with brain impaired subjects as their disorders make them susceptible to daily, even hourly variations in their capacities to perform on a test. Behavioral rating scales may have unnecessarily low reliability when the behavioral descriptions are too brief or too vague for consistent scoring by different examiners.

Two other important characteristics of a test are its *sensitivity* (the probability of correctly detecting abnormal functioning in an impaired individual) and its *specificity* (the probability of identifying a person who is intact with respect the condition under consideration; i.e., correctly identifying absence of the specified abnormality). Many tests commonly used for cognitive assessments will have high sensitivity because good performance depends on many different variables, yet their specificity will be very low. For example, the Trail Making Test (34), which can be failed for many different reasons, is very sensitive to brain impairments – as well as stiff fingers or a frozen shoulder – but a poor performance does not imply any specific disorders. Those tests with high specificity have typically been developed to examine only a single, usually relatively uncommon, deficit and are generally not given unless there is reason to believe that the patient may have that kind of deficit. In contrast to the Trail Making Test, the Token Test (35) with high specificity is rarely failed by any but persons with very specific communication disorders.

It is also important for examiners to select the most appropriate norms – or tests with appropriate norms – when evaluating test performances. Many tests now are normed for age and/or gender and/or education. Ideally they would have been normed for all three demographic attributes but this is still rare. A variety of norms (mostly from U.S. studies, but some Canadian data are included for some tests) have been collected for a number of widely used tests to aid examiners seeking the most appropriate normative data for evaluating their patients (36). Test selection should also be guided by appreciation that some tests do not examine very low levels of functioning (i.e., floor effects) or very high performance levels (i.e., ceiling effects) which limit what can be learned about the cognitive attributes of very impaired or highly skilled persons. Children's tests may be applicable for very impaired patients as the beginning items are typically simple, thus doing away with floor effects; these test performance can be interpreted in terms of chronological age (e.g., patients who can define only one or two words on an adult vocabulary test will all

achieve the same low score, but some of them may be able to identify only ten words on a child's picture vocabulary test while others identify 20 or more indicating that these latter patients actually have a higher level of functioning in this area despite identical scores on the adult test). Poorly educated patients run the risk of appearing more impaired than they are on academically-based tests such as those involving word usage or arithmetic. Their cognitive potential will often be better estimated by visual reasoning and construction (e.g., drawing, design copying) tests.

Test selection must take into account the patient's visual or auditory deficits and examiners must be alert to whether a patient needs glasses or hearing aids as, not infrequently, brain impaired patients will not think to bring these important devices to the examination. Test selection for aphasic patients is complicated by the fact that many have difficulty processing verbal instructions. For these patients, some functions will be untestable, others may be examined by tests from one of several batteries for nonverbal testing (e.g., SON-R, (37) and by specific techniques an imaginative and knowledgeable examiner may devise for a specific patient (e.g., assessing basic numerical abilities with chips or coins). While standardization is always desirable, common sense may have to play a greater role in determining how to test patients with sensory and/or motor impairments. Computerized tests may be reasonably well-standardized but be unsuitable for testing those rehabilitation patients who have difficulty with instructions, who require continual monitoring which would interfere with the standardization requirements, and still others who may not be able to stay on track as long as required, whether due to wavering attention, distractibility, poor memory, or fatigue.

Test selection will also differ depending upon how much information is needed about the patient. A baseline study on entry into a rehabilitation program may include a wide range of tests examining every major cognitive domain. Pre and post testing for an attention retraining program will probably focus almost exclusively on those aspects of attention being trained. In short, tests should be chosen according to the goals of the assessment. Given its specific strengths and weaknesses, each test will be more or less appropriate to one assessment situation or another.

A busy clinical practice often requires rapid detection of the presence or absence of symptoms of cognitive impairment and an estimate of their severity. These clinical assessments must be sensitive, brief, sufficiently flexible to accommodate the patient's capacity to participate, fatigue, or alertness. Some standardized clinical examinations of the major neuropsychological syndromes have been designed for this purpose, such as the Mini-Mental State Examination (MMSE) (38) or behavior scales for dementia, stroke, and TBI patients. These brief screening tests may also be used in epidemiological surveys for detecting early mild impairment in the population-at-large to identify those persons needing a more complete evaluation. These brief screening tests, which contain one or two items assessing each of a variety of functions, are a good example of tests with

high sensitivity: a low score only indicates that a problem may be present but tells nothing of its nature.

In contrast, rehabilitation planning requires an extensive inventory of the patient's cognitive strengths and weaknesses typically using many different tests and questionnaires with good ecological validity, as possible. In this way, the rehabilitation team will best be able to understand the nature of their patients' cognitive limitations, why they act – or don't act – as they do. What is still working – the preserved functions – and compensatory strategies are as important as impairments to assess. An extensive cognitive assessment will also aid in prognosis. Repeated assessments are called for in the course of rehabilitation treatment to track improvements – or setbacks – as they occur, and to aid in evaluating the efficacy of the treatments. These repeated assessments should include evaluation of the patient's quality of life, presence and extent of emotional distress, and the burden borne by relatives and caregivers. On completion of a rehabilitation program, further assessment, using the same standardized and specialized tests and questionnaires as when entering the program, is needed for outcome evaluation.

When legal issues arise, as when an injured patient makes a compensation claim, the assessment should also be extensive and satisfy validity requirements, again as much as possible. In these cases the patient's premorbid cognitive status is also relevant, requiring both extrapolation from current test performances and inclusion of historical information (e.g., employer's reports, school records).

Assessment needs vary, not only according to the patient but also according to the general purpose of the assessment. Experimental studies of cognition use assessments to test hypotheses and expand the cognitive knowledge base. Paradigms are unique, tasks and items are designed for answering conceptually limited questions. Conversely, clinical research requires standardized, generally accepted, and well-validated instruments. Group studies need reliable tests, especially if used in multi-center research programs. Single-case studies elucidating or evaluating rehabilitation processes typically include baseline and follow-up studies, and may have built-in cross-over procedures which require tests and tasks that are very sensitive to change.

In conclusion, improving the quality of assessment constitutes an important challenge for neuropsychology. Better assessments will provide for better planning of care and rehabilitation, for better communication between professionals, better evaluations of the efficacy of cognitive therapy, and better clinical research. Most of all, better assessments will help rehabilitation professionals to better know their patients' needs and understand their patients' expectations. And better assessments, by including quality of life measures, can give rehabilitation professionals insight into what it feels like to live with impaired cognition, which is probably as important as describing these impairments. In providing information that makes effective therapeutic intervention possible, neuropsychological assessment finds its legitimate place in rehabilitation.

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CHAPTER 9
ASSESSMENT OF ASSISTIVE TECHNOLOGY IN PHYSICAL MEDICINE AND REHABILITATION

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Pertinent assessment of assistive technology devices must take into consideration the diversity of available material and the wide range of users and contexts of use as well as the various points of view of the evaluators (manufacturers, economists, prescribers, healthcare providers…) whose objectives may differ (1). Though the general approach is similar to that used for drugs, the situations involved are much more complex, leading to less standardized evaluation protocols. The objective of the evaluation, the type of device under consideration and its field of application, as well as the focus of the paradigm, i.e. the patient-user, the device itself, or both, dictate the type of methodology applied. Two approaches can be taken. The first is non-specific and can be applied for any product designed for routine use, irrespective of the context. The second approach is more specific, evaluating individual devices in a particular context of use in order to focus on user-related and context-related elements (2). For the purposes of this discussion, we shall use the term assistive devices to include a broad spectrum of medical devices, e.g. prostheses, ortheses, technical aids, environmental control systems (3).

We shall consider various types of devices designed to replace, aid, or assist specific organs or correct for deficient function and facilitate activities of daily life. We shall not consider devices specifically used for rehabilitation or retraining purposes (although evaluation of such devices shares common features with that of assistive devices, their use is directly related to the recovery process). For interventions affecting the environment interacting with the disabled person, we shall limit our discussion to medical devices.

Theoretically, the procedures used to evaluate assistive technology devices should be the same as those used to evaluate drugs, considering medical devices and drugs as members of a common family of medical interventions. In practice however, the specific features of assistive devices, particularly the important component of subjective appreciation, require specific evaluation protocols.

THE EVALUATION PROCEDURE: PHASES AND FIELD OF APPLICATION

The evaluation of assistive devices involves two different phases. The first phase occurs during development and early trials; at this level, the aim is to obtain administrative approval and determine optimal prescription. Once the device has been marketed, continuing surveillance is essential to watch for unexpected adverse effects and if needed to re-examine initial indications. The main purpose of this second phase of evaluation is to verify the pertinence of individual prescriptions and assist decision making. These evaluations can concern either the device itself or its use by a given individual or group of individuals. As for any manufactured product, an assistive device must meet pre-established production standards. Certain standards result from mandatory regulatory criteria designed to protect users; others are established by the designer and the manufacturer and depend on the functional objectives assigned to the device. Each device can thus be described by a set of technical specifications. It use depends on indications, contraindications and precautions, describing the rules and limitations of use. Categories of potential users and conditions of use can thus be defined.

EVALUATION OF THE MEDICAL DEVICE ITSELF: TECHNICAL SPECIFICATIONS AND SATELLITE SERVICES

Two types of information must be considered when evaluating an assistive technology device: information obtained directly from the device, i.e. technical specifications, and use-related information, i.e. satellite services.

Technical specifications

Compliance with regulatory standards, promulgated by the official authorities of the country of use, must be verified (4). Technical specifications for materials, products, and manufacturing processes are set by official regulatory texts, definitions, or guidelines designed to guarantee

adequate performance (quality, solidity, reliability) and safety (for the user and for the environment). Compliance with international standards set by the ISO (International Standardisation Organisation) is mandatory. Complementary specifications, particularly industrial protection specifications, may be applicable in distinct geographical areas. The device and/or its constitutive elements are submitted to tests conducted by authorized laboratories to determine physical properties (resistance, robustness…) and compliance with standard or chosen specifications. Certain countries have mandatory approval procedures and some medical devices, depending on their potential class of use, require approval by independent organisms[1] for marketing or reimbursement eligibility. Device watch programs, which register incidents or accidents occurring during use, constitute an *a posteriori* evaluation.

Satellite services

A specific environment, which may have an impact on user acceptance, can be described for each assistive technology device. Product design, industrial production, distribution networks, product diffusion, attribution services, product appearance, all contribute to this environment (5, 6). They affect the conditions of maintenance and repair (distribution network), product robustness, capacity for evolution, modularity and universality, design and esthetic, as well as modalities of use, and have an impact on the lifespan of the product. Assistive technology services (counseling, consumer-directed personal assistance device, agency-directed personal assistance device, rehabilitation center, trial center…) (7) contribute to device acceptance and proper use.

EVALUATION OF USE: EFFICACY, OPERATIVE QUALITY, AND ACCEPTABILITY

The patient-user's personal subjective opinion has a decisive impact on acceptance and use. This subjective judgment affects the evaluation process, which must determine the ability of the assistive device-user couple to perform tasks which otherwise could not have been achieved (device efficacy or efficiency), assess modalities of task execution (operative quality), and examine use of the assistive device in real-life situations (acceptability).

Efficacy and operative quality

Device efficacy is primordial. Irrespective of its technological properties, the device must first and foremost provide real assistance for activities of daily life. If this crucial condition is not fulfilled, the device will be abandoned rapidly, a situation which is not exceptional and which can be a useful evaluation parameter (8, 9).

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[1] For example, in France, Agence française de sécurité sanitaire des produits de santé (Afssaps).

Considering the large number of factors involved, specific criteria of efficacy must be established in order to score a device's efficacy in terms of expected performance. Comparison between expected and real performance is the best way to evaluate functional efficacy. Since performance depends both on the device itself and on the user, the goal is to achieve concordance between device performance and user expectations. This implies a dual evaluation process conducted under clinical conditions. The first objective is to evaluate device-user performance. Evaluating a given device employed by a given user in a given clinical situation enables distinction between individual-related and context-related parameters. Difficulties encountered during use, and the corresponding circumstances or specific limitations, particularly discomfort or problems with associated tasks, can be recognized. The second objective is to establish formal indications, contraindications, precautions for use, risks, surveillance procedures, and limits of device efficacy. This requires a collective approach where individual trials are considered together. Data acquired from individual and collective trials are mandatory to obtain marketing approval and determine appropriate prescription (10) as well as eligibility for institutional or organizational funding. The way a device is used must be carefully analyzed so as to ensure that the energy output or specific movements or postures required to use the device do not have short- or long-term pathogenic effects.

Regular use and acceptability

Functional efficacy, i.e. adequate correspondence between device performance and user needs, is a necessary but not sufficient condition for regular use. Even if appropriate, an assistive device will not be used regularly for a prolonged period if it is not accepted by the user. Acceptability, a measurement of the way technical assistance is employed in everyday life, is related to how well the user tolerates the constraints and discomfort imposed by the device. Ease-of-use (after appropriate learning and/or training, which implies accessibility to the learning process), ergonomics (3, 11) (energy output and fatigue (12, 13), weight, volume, simplicity, command interface…), and device availability (anywhere, any time), reliability, and intercompatibility (combined use with other assistive technologies) as well as appropriation by the user and family or caregivers, are essential factors. The esthetic aspect of the device vehicles a specific image of technological assistance affecting both the user's self-image and the regard of others. The device should not focus attention on the user's disability (principle of transparence) and should have a favorable effect on the user's image (e.g. product design). The way a user personalizes the device, adapting it to changing body morphology, physical capacity (disease progression, aging), and lifestyle, greatly affects compliance and acceptability. Device upkeep, repair, and environmental interference must also be considered.

USER-CENTERED EVALUATION: STRATEGY

User-centered evaluation is a necessary phase when studying assistive devices. The goal is to identify factors affecting the pertinence of the

prescription and then to verify, after use, that the prescription is indeed pertinent for the given individual. This necessarily individual evaluation process must take into consideration three types of elements corresponding to the three levels of the International Classification of Functioning, Disability and Health (ICF) (14): 1) necessary or highly desirable activities which are difficult or impossible to execute and require compensation – these elements define the objective of the assistive technology (individual level), 2) user-related morphological, biological and psychological features described in terms of ability and disability, body function and structure (body level), 3) the environmental context of the activity and/or participation (role and societal level). In other words, the question is whether the "device compensates for the initial disability". Is there adequate correspondence between the assistive device and user's capacities and activity project in the context(s) in which the project is to be accomplished?

Another domain to evaluate is the user's self-assessment of the quality of the compensation, i.e. user satisfaction or impact on quality-of-life. The efficiency of a given device may in itself generate effects having a negative impact on its acceptability. The user's early enthusiasm may wear off, sometimes rapidly, particularly when the device compensates for an artificial activity. Like the placebo effect, it takes at least three months for this effect to dissipate.

- The first elements to determine concern the definition of the *activity project* and tasks which cannot be performed, preventing the accomplishment of the activity. Determined by the user who has received appropriate counseling and information, the activity project must be realistic. Likewise, the proposed technical assistance (one or more devices, possible adaptation of the environment) must be reasonably expected to be effective. A trial and error approach may be necessary to recognize an unrealistic project. The level of the user's motivation must also be assessed to determine the degree of implication.
- The second elements concern the *physical environment* (architectural, human, social), the *context* (familial, occupational, educational, leisure activities) and the *real-life situations* in which the activities requiring compensation are to be accomplished. It is thus desirable to conduct trials in real-life or simulated situations (15) in order to assess the impact on the activities requiring compensation.
- The third group of elements are *user-related*. They involve anthropological features (body integrity, pain, mobility, sensorial status, functional abilities, installation and positioning in bed or wheel chair), cognitive features (intellectual capacity, schooling, occupational activity), and behavioral and lifestyle features (personal appearance, sociability, role, familial and social activities).
- The *quality of the compensation* provided by the device is a subjective assessment determined by the user who evaluations his/her own satisfaction and quality-of-life. Comparative trials can be useful to select

the most appropriate technical solution among several with equivalent efficacy. Subjectively important satellite or secondary criteria must be considered. These trials have a determining effect on user appropriation and acceptation because they enable users to make real-life comparisons and choose their own assistive device. The decision-making process is personalized, avoiding the problem of third-party assessment.

METHODS, CRITERIA AND EVALUATION SCALES

The large number of parameters involved in the evaluation of assistive technology devices impose the use of specific methods and scales designed for objective measurements in the different domains under consideration (16). Objective quantitative measurements provide data on device efficacy. Subjective qualitative scores estimate user satisfaction. Though self-assessment must predominate, the opinion of rehabilitation professionals, care agencies, manufacturers, sales representatives, and healthcare economists can be very helpful to clarify the user's choice and improve device performance (17).

Device efficacy

Specific instruments assess impairment (ECG, Ashworth scale, goniometry, force…), activity and capacity (gait, communication, FIM), participation (job performance, school performance), and environmental factors (Environmental Quality Assessment Scale) (18) affecting device efficacy. These data can be used to set the conditions for use of the assistive device.

Achievement of an assigned task is scored successful or unsuccessful, with further precision provided by details concerning its execution: rapidity, effort, risk. Effective use of the technical assistance is assessed with an activity index (duration or frequency of device use per day) which can be determined from direct observation or monitoring recordings (remote surveillance (19), teletransmission, integrated measurements). It is also important to assess the adequacy of the user's initiatives and the appropriateness of device use. Efficacy can also be assessed indirectly with instruments measuring life improvement or independence, e.g. the Barthel score, or better the Reintegration to Normal Living Index (20). The sensitivity of these instruments may nevertheless be insufficient. Declining demand for assistance during activities of daily living also affects device efficacy (21-23).

User satisfaction

Self-assessment of user satisfaction is noted on a visual analog scale, or a more analytical scale such as the QUEST (Quebec User Evaluation of Satisfaction with assistive Technology) where satisfaction is determined from two factors related to the assistive technology device (8 items) and satellite services (4 items). QUEST can be self-administered or interview based. With regards to its psychometric properties, QUEST has been test-

ed for internal consistency, test-retest stability, content validity, and factorial validity (24-29).

Satisfaction can also be assessed using well-being or quality-of-life instruments such as the QWB (Quality of Well-Being) (30) or the PIADS (Psychosocial Impact of Assistive Device Scale) which provide a rapid and simple assessment of adaptability (reflecting attitude towards social participation and risk-taking) (31-32), competence (reflecting perceived functional capacity, independence and performance) and self-esteem (reflecting self-confidence, self-esteem per se, and emotional well-being).

The Delphi scale is another evaluation method adapted to technical assistive devices by Batavia and Hammer (33). A panel of disabled subjects, who have used assistive devices for a long period, score a category of devices or a specific assistive technology device. The scale includes a series of items determined by the panel members themselves or by expert technicians as being determinant. Seventeen factors are considered (efficacy, financial accessibility, ease-of-use, device constraints, portability and volume, intercompatibility, flexibility, adaptability, ease-of-upkeep, safety-of-use, ease-of-learning, personal acceptability, comfort-of-use, ease-of-repair, consumer information, ease-of-assembly, vulnerability). Each of these items is classed by order of importance and priority. This classification can be completed by a list of subitems detailing the principle aspects of the main items. The classification varies depending on the type of device under consideration and the type of target user. Each of the panel members has a specific deficiency (motor, auditory…) and at least five years experience with one or more technical device(s) and thus a good capacity for analyzing and classifying assistive devices. This approach offers the advantage of providing designers, manufacturers, prescribers and rehabilitation specialists with data concerning factors involved in the decision-making process for real-life use of different categories of assistive devices (wheel chairs, environmental control devices, robots, telephones, keyboards…). This method, like others (brainstorming, pertinence algorithm, assistive technology device predisposition assessment) (34, 35) provide data which can be used to identify different product properties and establish a relative weighting of the defects of the evaluated device.

CONCLUSION

Evaluation of assistive technology devices and services is indispensable to determine the true value of the devices and services proposed. Appropriate evaluation is a difficult task due to the large number and the variety of the devices and services available. Evaluation must be carefully oriented, using well-chosen judgment criteria defined in terms of precise objectives. The importance of appropriate assessment of assistive devices is clearly demonstrated by the growing number of studies devoted to identifying criteria which the disabled employ to choose the device they will effectively use for a prolonged period (36).

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CHAPTER 10
INSTRUMENTS FOR LONG-TERM MONITORING OF ACTIVITY IN PHYSICAL AND REHABILITATION MEDICINE

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Mobility is a basic physical requisite for an adequate quality of life, for both healthy and diseased people. It is reasonable that physical activities are a field of interest for Rehabilitation Medicine, a clinical discipline in which the best possible restoration of both mobility and quality of life represents an important goal of many intervention programs.

In the WHO ICF (International Classification of Functioning, Disability and Health) framework, used to describe health and health-related domains, the Activity and Participation component covers the complete range of functioning and mobility is one of its 9 domains: activity is defined as the execution of a task or action (individual perspective), while participation is defined as involvement in a life situation (social perspective). The ICF classification identifies two qualifiers for the description of activity and participation: capacity (the ability to execute a task or action) and performance (what is actually executed in the current life context).

The shift from the preceding classification (ICIDH) places a new emphasis on the assessment of abilities in performing

everyday functional motor tasks more than on the description of levels of impairment. This shift has great consequences in the adoption of techniques and methodologies for the assessment of mobility, since it calls for the objective quantification of mobility outside a laboratory and for long periods, preferably days.

Given the complex set of behaviors and heterogeneous nature of physical activity, many different types of instruments have been devised to measure mobility: they can be broadly summarized into two categories: one based on the individual recording the amount of activity, the other on instrumental monitoring.

INDIVIDUAL RECORDINGS

Physical activity is most commonly assessed, especially in epidemiological studies, by asking people to classify their level of activity. Techniques for the collection of this information include self-administered diaries, logs, recall surveys, retrospective quantitative histories or interview-administered questionnaires.

The most common formats used for these kinds of measurement (alone or in combination) are:

a) observation/ examination – when health professionals (or others) make a judgment and rate some parameters on the basis of subjective evidence and with minimal input from the patient;
b) patient's report – in the form of a structured interview or, more often, of a self-compiled questionnaire in which the subject is asked to report, with minimal influence from other persons, experienced phenomena.

Information gathered from these instruments, validated against an instrumental method as a gold standard, has often been converted into estimates of Energy Expenditure (EE, in kilo-calories, joules or metabolic equivalents METs) or some other summary measure that can be used to categorize or rank people by their physical activity level.

Each of these methods has been formulated and validated according to the respondents' age and educational levels.

Limiting the target population to adult/older adult subjects, popular interviewer and self-administered questionnaires are:

7 day Physical Activity Recall - 7d PAR (1)
Time frame: preceding 7 days
Population: adults
Activity: leisure-work
Notes: interview in which the recalled time spent by the subject in physical activity of moderate to heavy intensity is collected
Output: Kcal/week

Yale Physical Activity Survey - YPAS (2)
Time frame: typical week in preceding month
Population: older adults

Activity: household, exercise, recreational
Notes: 36-item survey
Output: Kcal/week, Total activity time (hr/week)

Minnesota Leisure Time Physical Activity questionnaire - MLTPA (3)
Time frame: past 12 months
Population: adults
Activity: leisure-household
Notes: consists of a list of 63 sports, recreational, yard, and household activities. Participants are instructed to report whether or not they performed the activity in the preceding 12 months
Output: Total Activity Metabolic Index (AMI) (intensity) x (duration) x (frequency) x (number of months/years)

Community Healthy Activities Model Program for Seniors - CHAMPS (4)
Time frame: 4 weeks
Population: older adults
Activity: leisure, household, recreational
Notes: it assesses weekly frequency and duration of various physical activities typically undertaken by older adults
Output: frequency per week, calorie expenditure per week, both for activities of at least moderate intensity and for all specified physical activities, including those of light intensity.

Physical Activity Scale for the Elderly - PASE (5)
Time frame: preceding 7 days
Population: older adults
Activity: leisure, work, household
Notes: 10-item questionnaire
Output: activity score, the amount of time spent in each activity (hours/week) or participation (yes/no) in an activity multiplied by empirically derived item weights summed over all activities

Harvard Alumni (6)
Time frame: past week or past year
Population: adults
Activity: leisure
Notes: questions only on walking, stair climbing and information on recreation and playing sports; Output: kcal/week

Kaiser Physical Activity Survey - KPAS (7)
Time frame: past year
Population: adult women
Activity: household/caregiving, work, exercise
Notes: 75-item survey designed to obtain information about women's physical activity habits
Output: Activity index from housework/caregiving, occupation, active living habits, sports/exercise items

Diaries and logs can be used to record virtually any physical activity performed during a specified period; these periods tend to be short, 1-3 days, since the level of the required detail requires intense effort by the participants.

Recall surveys generally require less effort by the respondent, although some participants can have trouble remembering details of past physical activities. Recall surveys have been used for time frames of 1 week to a lifetime (8, 9).

Retrospective quantitative histories generally require specific detail for time frames up to 1 year (10), again, there is an heavy demand on the respondent's memory and the complexity of the survey limits its application.

INSTRUMENTAL MONITORING

Direct instrumental monitoring of physical activity under free-living conditions is usually performed through energy expenditure studies, motion capture, behavioral observation or ambulatory monitoring.

Since energy expenditure (EE) methods, such as room calorimetry, indirect calorimetry and doubly labeled water, motion capture and direct behavioral observation, while invaluable in laboratory conditions, are unsuited for long-term recordings of movement, we will focus our attention on ambulatory monitoring.

Ambulatory monitoring

Ambulatory monitoring techniques require the subject to wear some form of movement recorder. These techniques may offer many advantages for an "ecological" assessment of individual performance and can be used in a natural setting, so allowing the analysis of impact on health of the manipulation of a series of factors, including intervention programs and contextual items.

Pedometers or step counters, actigraphs and movement recorders are devices that fall in this category.

Pedometers

The pedometer is a motion sensor that detects vertical movements (i.e., acceleration and deceleration) of the body: when the foot hits the ground, an impulse is produced that transfers to the pedometer case where a lever arm with a pendulum attached to a spring makes and breaks an electrical circuit. With each step, the pendulum moves and one electrical event is recorded so that these vertical movements are expressed as the number of counts or steps taken during walking or running.

Pedometers can be worn in a variety of places, usually on the waist, clipped on to a waistband or belt, over the center of the leg. Since some sites have been demonstrated to be more reliable than others, for standardization purposes, it has been suggested placing the pedometer over the dominant foot (11).

Distance covered and energy expenditure are readily, if not accurately (12, 13), computed from the steps counted by the pedometer, once a subject's stride length and weight are known.

Accelerometer-based step counters are also available: they are based on two axis accelerometers in a compact package, worn on the ankle.

ACTIGRAPHS

Actigraphs are small, portable electronic devices that detect physical motion, generate an internal signal each time they are moved, and store that information.

Usually worn on the wrist of the dominant arm or on the waist, these devices collect 'activity' data for long periods and sum it over predetermined time spans ('epochs') for practical reasons, mainly storage space saving.

Accelerometer-based devices are by far the most widely used actigraphs in long-term motion recording (14).

An accelerometer is a device that produces an electrical output (i.e. charge, voltage, current or change of resistance) that is proportional to the acceleration to which it is exposed, typically expressed in m/s^2 or in g-values, with 1 g equal to the acceleration a falling body experiences near the surface of the Earth.

Modern accelerometers are typically micro-machined silicon sensors that are based on the detection of the displacement experienced by a small mass linked to a frame by beams when the sensor is subjected to an acceleration: the applied force, hence the acceleration, can be derived from the measure of the deflection.

Piezo-resistive and variable capacitance accelerometers, very frequently used in human movement applications, respond to accelerations due to movement as well as to gravitational acceleration.

The static response of these accelerometers reflects the orientation of the accelerometer with respect to gravity and can be used to compute the angle relative to the vertical of the sensor and, consequently, of the body segment on which it is located (15, 16).

Since acceleration is a vector quantity, the sensitive part of the transducer is constructed such as to maximize the sensitivity of the sensor along one particular direction, while minimizing crosstalk due to the other acceleration components; one, two or three axis sensors are available in very compact arrangements.

The most common parameters digitally derived from the transducer signal are:

Threshold Crossing, TC: this is measured by recording a count each time the transducer signal crosses a defined threshold voltage regardless of whether the voltage is increasing or decreasing. Counts are then accumulated for each epoch and stored in the device's memory.

Time above Threshold, TAT: this is obtained by summing the time that the signal exceeds a previously defined acceleration threshold. At the end of each epoch, the value is stored in the device's memory.

Integrated Activity, IA: this is computed by summing the deviations from zero volts (i.e. the absolute value of the voltage) during the epoch and storing the value at the end of the epoch.

An estimate of the energy expenditure is produced from the derived parameters, through algorithms specific for every system.

Numerous commercial and experimental systems use these sensors (17), embedded in small sized portable microprocessor-based devices, to detect movement and to digitally record parameters derived by the acceleration signal produced by the changes in body position.

The available systems can be characterized by the number of axes, epochs, type of parameters, frequency at which the acceleration signal is sampled and location of measurement; the models more frequently encountered in the Literature are:

- MTI Actigraph (former Computer Science and Applications CSA Monitor): this is based on a piezoelectric uniaxial accelerometer, its sampling rate is 10 Hz and it stores IA, scaled to 'counts' (16 milliG per second) with epochs from 1 second to several minutes (18). It can be worn on the waist, wrist or ankle but it has been validated for the estimate of EE only if worn on the waist.
- StayHealthy RT3 (former TriTrac): the acceleration is transduced by a tri-axial sensor, and sampled at 50 Hz; the acceleration module is then integrated and stored in epochs lasting from 1 to 60 seconds, according to user's needs. It is worn on the waist (19).
- IMSystems Actitrac: based on a bi-axial piezoelectric accelerometer, this has a 40 Hz sampling rate; the integrated acceleration is stored in epochs lasting from 2 to 300 seconds. This information is converted to a reference scale of data counts (0 to 250, 1 count=12 milliG). It is worn on the wrist.
- Ambulatory Monitoring Mini Motionlogger: the acceleration is transduced by a tri-axial sensor, and sampled at 16 Hz; it can produce TC, TAT or IA parameters that are stored in epochs of 60 seconds. Clock-shaped, it is worn on the wrist

Movement recorders

A new class of devices has been developed (20-24) that can not only detect and record activities, but can also classify them into clinically relevant movement (walking, running, climbing and descending stairs, etc.) and posture (standing, sitting, lying) classes, as a consequence of a number of studies researching the information content of accelerometric data coming from sensors attached to the trunk and limbs of subjects (15, 25-28).

These movement recorders consist of a set of transducers, usually accelerometers, located on the legs and the trunk, a portable recording unit and dedicated algorithms for off-line signal processing, very similar in function and structure to the ECG Holter type recorders.

The signals produced by movement and posture are transduced and acquired by the recording unit, preprocessed and stored in high capacity memory cards. The off-line processing, which is executed after data downloading into a personal computer, automatically identifies posture

and motion patterns in a multiple-step procedure: conceptually, first some form of processing or feature extraction is performed on the signal (for instance filtering, computing mean and standard deviations or temporal transformations), then static and dynamic movement periods are detected. After that the results are fed into the movement classification algorithms, static periods determining posture and rest positions while dynamic periods are used for activity detection.

The classification algorithms presented so far have been based on thresholds (22, 29), artificial neural networks (24, 30, 31), on statistical methods (16, 21), fuzzy logic (32) or combinations of these.

The number and position of the sensors affect the detail of the information obtainable: one tri or bi-axial waist-mounted accelerometer can reliably detect rest and activity periods and can be used for classification of standing, sitting, lying and walking (33-36), while sensors placed also on legs and ankles have been used to produce estimates of spatio-temporal gait parameters (20, 37).

The typical report presents an activity diary and accumulated time spent in every specific activity or posture detected with the relative percentage of the total recording time.

As an example, we show a result obtained by our research group with a system based on the Vitaport recorder, 4 uniaxial accelerometers (2 on the trunk, one on each thigh) and a modified version of the protocol described by Bussmann (21) with discriminant analysis as the classification engine, which was part of the validation of the instrument in our clinical setting.

Normal subjects were required to perform 2 repetitions of a sequence of activities/postures in this order:

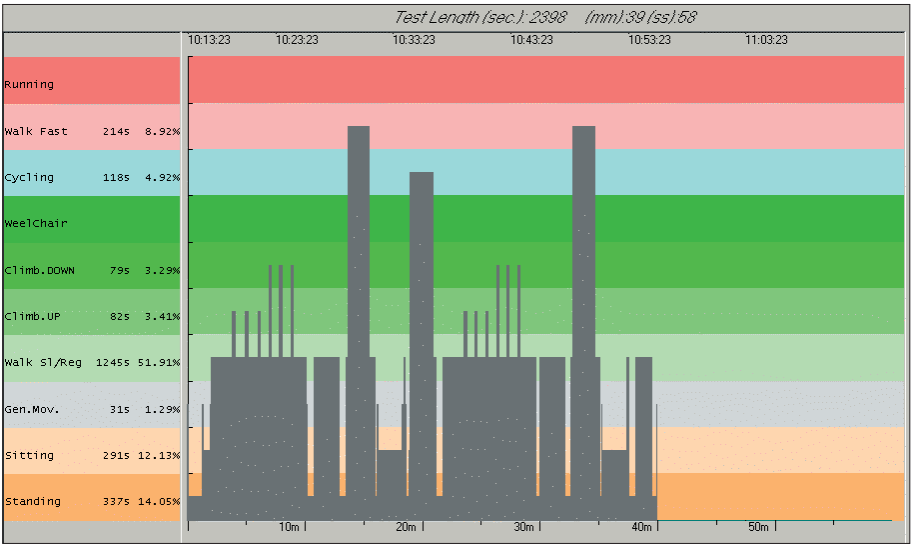
1. Standing
2. Sitting
3. Walking
4. Walking a corridor and ascending a flight of stairs (3 times)
5. Walking a corridor and descending a flight of stairs (3 times)
6. Walking
7. Resting (standing)
8. Walking on a treadmill at 4 Km/h
9. Resting (standing)
10. Walking on a treadmill at 6 Km/h
11. Resting (sitting)

The two sequences were separated by a period of exercise on a cyclette.

The figure, which presents the results of the classification procedure for one subject, is the activity log of the test, which lasted about 40 minutes: the total time spent in each activity/posture is given on the left, the upper scale is the time of the day and the lower scale is the relative test time.

The activity/posture detected is associated with the colored area into which the gray bar ends.

The graph displays details that are 10 seconds long or more, though activity data is computed each second.



The presence of unclassified generic movement (Gen. Mov.), usually in correspondence with postural transitions, seems to indicate the presence of information content which is actually unexploited by the classification algorithm and which could be relevant, for instance, in evaluation of the risk of falls (38).

Data coming from Global Positioning System (GPS) (36, 39), earth magnetic field sensors (40), gyroscopes, inclinometers (37, 41-44) and heart rate (45-48) have also been recorded along with activity using these devices, in conjunction with accelerometers or alone.

One research group has recently also developed algorithms for the classification of upper limb movements (49-51), using a set of accelerometers located on the arms.

Two commercial systems are available, Dynaport by McRoberts and Bodytrac by Imsystems, specifically designed for activity recording and classification, while two other data recorders (Vitaport by Temec and Physilog developed by the Ecole Politechnique Federale de Lausanne) have specific configuration and software developed for the same goal.

DISCUSSION

Individual recordings

A number of validation studies (52-56), in comparison with other more objective measures of physical activity or within questionnaires, have been carried out.

In general, individual recordings can be relevant in large scale epidemiological studies for monitoring changes in population activity or indicating conditions in which an increase of physical activity would be beneficial.

All these subjective instruments are easy to use and low-cost, but are retrospective, some disrupt (and/or interfere with) the analyzed performance, and most require high compliance by the subjects.

Besides method-specific issues, attempts at detailed interpretation, in terms of exercise dose and the extent of resulting health benefits, still seem premature, as shown in a recent review (57).

Instrumental monitoring: ambulatory monitoring

PEDOMETERS

Small, cheap, lightweight and unobtrusive, pedometers are effective for encouragement, motivation and confidence building.

Two recent reviews by Tudor-Locke *et al.* are available on the uses of pedometers: the first (58) focused on the concurrent validity of the measures obtained by pedometers correlated with other techniques (both instrumental and subjective), while the second (59) dealt with the ability of the measures to correlate with population-related parameters.

In general, commercially available pedometers are affected by limited sensitivity in detecting low-speed movements (for instance, while moving around the house), are prone to artifacts caused by travel in cars or public transportation systems and, of course, cannot discern activities which do not involve ambulatory locomotion, such as weight lifting, thus limiting their usefulness in measuring energy expenditure.

Accelerometer-based step counters are more accurate in detecting movements also in difficult conditions, such as in shuffling or in overweight subjects (60-62).

ACTIGRAPHS

Actigraphs are commonly used in sleep research where they have been proved to be a reliable method of activity monitoring (63-68).

Other studies have used actigraphy for monitoring waking activity in studies of bipolar disorder and depression (69-72), childhood hyperactivity (73-75) and oncology (76-78). Other areas in which activity monitoring with this technique has been extensively used are the evaluation and treatment of chronic diseases, such as COPD, Parkinson's disease, Huntington's disease, coronary heart disease, and rheumatoid arthritis (79-90).

Actigraphs, which are easy to use and affordable, with a cost up to 1500 $, are actually the only objective method for practical recording of activity over long periods.

Actigraphy lacks the ability to identify the type of movements, and the EE derived by these devices has been often questioned (91-99), the main issues seeming to be the type and intensity of the activity that the actigraph needs in order to detect movement and therefore EE, so it has to be re-evaluated case by case (100-111).

MOVEMENT RECORDERS

Other than feasibility studies, few clinical validations have been carried out with these systems, specifically in low back pain (112), ergonomics (23, 113), children and young adults (47, 114), failed back surgery (115), older adults (116), congestive heart failure (117, 118), rheumatoid arthritis (119), and transtibial amputation (120).

The major disadvantages of these systems, other than their high cost, are that they are tethered and, therefore, will lead to discomfort to the subject, especially when a large number of sensors are used, and the fact that they usually cannot be dismounted and set up again by the subject, for instance for showering, therefore preventing recordings lasting more than 1-2 days, even if batteries and storage card capacities could be increased to accommodate this. Moreover, validation is usually performed in controlled situations that are different from the real 'home' situation in which these systems are designed to operate.

CONCLUSION

Various solutions are already available to researchers and clinicians to objectively assess and monitor movement over long periods: the field and extent of application, budget constraints, level of required detail and technological limitations are the discriminant factors that drive their adoption.

For the future, active research is ongoing to help overcome the main limitations, namely the complex wiring setups and the limited length of recording for detailed movement classification: for instance, advances in wireless technology have produced a new and exciting class of sensors not requiring cables to transmit the signal to the recorder, overcoming the possible discomfort due to the wiring (121, 122) while wearable technology now includes armbands or vests with embedded sensors (123-125).

Coupled with telemedicine techniques, signals can be continuously monitored and sent directly via mobile telephone or the Internet to the analysis station, extending the recording period indefinitely (126, 127).

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