ICF based assessment of spasticity treatment in stroke patients

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Handshake…

… a simple and symbolic gesture.
Culmination of a close collaboration in research medical’s and patient’s service.
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Chapter 1. Introduction

1.1. Stroke and ICF Assessment

The International Classification of Functioning, Disability and Health (ICF) (World Health Organization, 2001) provides a standard language for the description of health and is recommended as the framework for rehabilitation (White Book on Physical and Rehabilitation Medicine in Europe, 2007). The ICF contains three health-related domains: Body Functions and Structures, Activity and Participation (Figure 1). Body Functions are the physiological functions of the different body systems, and Body Structures refers to the anatomic parts of the body such as organs, limbs and their components. Activity is the patient’s ability to execute a task or an action in his/her everyday life. Participation concerns the subject’s involvement in real life situations, for instance, participation in the family, professional or cultural arena. Alterations in each dimension are respectively designated as impairment, activity limitations, and participation restrictions.

Figure 1

![Diagram of ICF health-related domains]

Figure 1 presents the three ICF health-related domains: Body Functions and Structures, Activity and Participation. These three dimensions may be influenced by contextual factors including both environmental and personal factors.
Stroke (incidence 2/1000, prevalence 5/1000) is the leading cause of permanent disability among adults in our country. The pathology is characterized by sudden onset of clinical signs related to the site in the brain where the morbid process occurs (Sommerfeld et al., 2004). One-third of stroke victims will die in the hospital setting, a rate that makes this the third leading cause of death after myocardial infarction and cancer (Rowland et al., 2002; Watkins et al., 2002). Another third will be disabled and displays a wide variety of signs that, together, constitute Upper Motor Neurone Syndrome (UMNS) (Simpson et al., 1996). This syndrome consists of negative features (weakness, paresis and lack of dexterity) and positive features (spasticity, spastic dystonia, and cocontractions) (Table 1). Stroke patients present troubles in all three ICF domains: permanent impairment and activity limitation restrict their participation. They require, therefore, prolonged rehabilitation aimed at reducing impairment to optimize activities, participation and quality of life (Dobkin 2004; Bates et al., 2005).

### Table 1

<table>
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<th>The UMN syndrome</th>
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<tr>
<td><strong>Negative Signs</strong></td>
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<td>Muscle weakness</td>
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<td>Loss of dexterity</td>
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<tr>
<td>Paresis</td>
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<td>Fatigability</td>
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<td>Impaired control and coordination of movement</td>
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Spasticity is a well-recognized complication of stroke as one of the positive components of UMNS. This impairment (Body Functions and Structures domain) occurs in approximately 20% of patients after three months (Sommerfeld et al., 2004) and 40% after 12 months (Watkins et al., 2002). Spasticity, derived from the Greek word "spasmos", meaning to pull (Elovic and Zafonte, 2001), has been defined as "a motor disorder characterized by velocity
dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyper-excitability of the stretch reflex” (Barnes, 2001; Lance et al., 1980). Its physiopathology has not been clearly established and could be due to changes in the balance of excitatory and inhibitory inputs to the motor neuron pool (Ozcakir and Sivrioglu, 2007).

Spasticity is characterized by increased muscle tone (sustained high tone spasms, intermittent spasms, or a mixture of the two) (Turner-Stokes and Ward, 2002), abnormal limb posture, excessive contraction of antagonist muscles, and hyperactive reflexes (Finch et al., 2002). In the long term, untreated spasticity may lead to secondary complications such as muscle stiffness, contractures and pain (Van Kuijk et al., 2002).

The clinical presentation of spasticity is extremely heterogeneous secondary to the neurological impairments, and the personal and environmental factors of each patient. Some may demonstrate different postural patterns, for instance, shoulder adduction, elbow and wrist flexion in the upper limb, or hip adduction, knee extension and ankle plantar flexion of the lower limb. The degree of spasticity may also change according to the position of the subject and the task being performed.

Spasticity may be a severe problem for some stroke patients. This impairment may limit the achievement of daily activities such as walking, eating, drinking, taking a bath or dressing; and, finally, may restrict social participation. Participation restrictions represent the problems the patient experiences in the fulfillment of social roles (e.g. being a spouse, parent, worker, or friend) that are regarded as common, considering their age, sex, and the society and culture in which they live. Spasticity may restrict participation of the patient in familial life (gathering family, etc.), in ceremonies (marriage, etc.) and leisure activities (sport, etc.). Moreover, participation implies that the person is able to control their own life in every life situation. For example, a spastic stroke patient who is able to move around using a wheelchair may be restricted when he want to go to the theatre or cinema because there are no ramps into the building (participation restriction in arts and culture).

However, the exact impact of spasticity on activity and participation limitations remains difficult to assess. Sommerfeld et al. (2004) reported that severe motor and activity problems are seen equally in non-spastic and spastic post-stroke patients and concluded that the focus on spasticity in stroke rehabilitation is not of great clinical
importance. This author recommended that treating spasticity after stroke should only occur in certain situations including prevention of developing a contracture or reduction of local pain. As claimed by Cramer (2004), spasticity remains a key dividing point among major schools of physiotherapy, with some aiming to inhibit and others aiming to encourage spasticity and its accompanying motor abnormalities. Indeed, spasticity is not always harmful. Patients with upper motor neuron weakness may rely on the increased tone to maintain their ability to stand and walk (Turner-Stokes and Ward, 2002). A significant reduction in spasticity may, therefore, not lead to a functional improvement.

The assessment of a stroke patient should be, at present, performed following the ICF framework. In the first ICF domain (Body Structures and Functions), overall neurologic impairments secondary to stroke can be assessed by using the National Institutes of Health Stroke Scale (Roth, 1998), the Stroke Impairment Assessment Set (Chino et al., 1996), and the Fugl-Meyer Assessment (Duncan et al., 1983). Spasticity can be assessed using the Ashworth scale (Ashworth, 1964) or the Tardieu scale (Tardieu et al., 1954). Gait pattern can be assessed by visual assessment with various tools (Lord et al., 1998; Pirpiris et al., 2001; Mackey et al., 2003; Toro et al., 2007) and can also be quantitatively analyzed in a gait laboratory, which provides detailed quantification of kinematic, kinetic, energetic, and electromyographic data during walking.

In the second ICF domain (Activity), the functional measures can be objective (e.g., 6-minute walk test or 10-meter walk test) or subjective (e.g., Visual Analog Scale). These can focus on a specific function [e.g., Functional Walking Category (Perry et al., 1995), Functional Ambulation Categories (Brun et al., 2000)] or on overall ADL functions [e.g., Barthel Index or Functional Independence Measure (Granger et al., 1993)].

Finally, the third ICF domain (Participation and Quality of Life) notably includes the Satisfaction With Life Scale (SWLS) and the 36-item Short-Form Health Survey (SF-36) (Ware, 1993).

Unfortunately, these scales have certain limitations in measuring activity and participation. Indeed, the majority of these tools are ordinal scales that permit only
limited computation and low-powered nonparametric statistics (Conrad and Smith, 2004; Hobart, 2002). Tests that measure performance (e.g., 6-minute walk test or 10-meter walk test) are useful (simple, quick, inexpensive) and well validated. However, these tests describe a subject’s performance in an artificial and motivating environment that might not be related to the patient’s capacity during his daily life.

**Questionnaires** are very useful to assess no quantifiable variables as presented in the activity and participation domains. Activity and participation limitations are rarely assessed directly, in the manner of physical variables (e.g., the gait variables quantitatively analyzed in a gait laboratory), but are instead measured indirectly by how they manifest (Hobart et al., 2007). The activity and participation variables are usually assessed by measuring related behaviours, defined by sets of standardized items. Such a characteristic is referred to as a latent variable in the same sense as pain, manual or locomotion ability, or quality of life (Tesio, 2003). The latent variable is a characteristic or attribute that cannot be directly observed, hidden within the person, and can be inferred from the behaviors of the person. Typically, activity limitations are measured by item questionnaires which are usually accepted to measure the behaviors (also named items) expected to be representative of the property itself or the variable to be assessed (Merbitz et al, 1989).

In 1960 Georg Rasch proposed a unitary and statistical approach to the study of these person’s behaviours and perceptions allowing the measurement of a latent variable that cannot be quantified by a measuring device. However the **Rasch model** allows overcoming the limitations of the traditional psychometrics method (e.g. ordinal scales). This model is a probabilistic approach and belongs to the family of “Item Response Theory” (IRT) models. They are based on the assumption that patients with a higher level of activity should have a higher probability, relative to patients with a lower activity level, to successfully achieve any item. The model states that the probability to pass a given item only depends on the item difficulty and the subject ability, and it estimates the item difficulty and subject ability from the proportion of responses to each item on a common linear scale (Rasch, 1992). The latent variable (activity limitations) can actually be conceptualized as a continuum representing infinite activity levels from “less active” to “most active.” Measuring a patient’s activity limitations involves determining the patient location
along this continuum. The items of a questionnaire are the graduations of the scale, and therefore, they must cover the whole range of activity limitations assessed in the studied population.

**Figure 2**

![Activity Continuum Diagram](image)

**Figure 2**: Activity continuum. Arrows represent patient (upper arrows) and item (lower arrows) location on the activity continuum.

Figure 2 represents the activity continuum along which the patients are located from less active to most active and the items from easiest to most difficult. An item is considered easy if many patients pass the item, while an item is considered difficult when few patients pass the item. Similarly, a patient has a high level of activity if he/she passes many items, and a patient has a low level of activity if he/she fails many items. As illustrated in Figure 2, Patient A has a low activity level since his/her activity level is high enough just to pass the first item; Patient B has a moderate level of activity and is expected to successfully perform the two easiest items; and Patient C has a high activity level and can likely succeed in all items except the most difficult one. As this figure principally applies to a dichotomous response format (i.e., able/unable to achieve the daily activity), other Rasch models have been developed for polytomous response formats also called “rating scales” (e.g., impossible/difficult/easy) (Andrich, 1978). These models state that the probability of giving any response category to an item only depends on the patient’s ability, item difficulty, and threshold difficulties. Thresholds (τ), located between two adjacent response categories, correspond to the activity levels needed for the patient to have a higher probability of selecting a particular response category rather than the next lower one. In a polytomous response format (Figure 3) where activities
can be answered on a three-level scale (impossible/difficult/easy), the thresholds between successive response categories are the graduations of the scale. Therefore, patients located beneath the first threshold are most likely to be unable to accomplish the activity; patients with an activity level located between the two thresholds are expected to perform the activity with difficulty; and patients located after the second threshold are most likely to complete the activity easily.

**Figure 3**

![Activity Continuum Diagram]

**Figure 3**: Polytomous response format. The graduations of the activity continuum are represented by the item thresholds (lower arrows). The first threshold ($\tau_1$) corresponds to the activity level required to respond “difficult” rather than “impossible,” while the second threshold ($\tau_2$) is located at the activity level required to respond “easy” rather than “difficult”. Item difficulty (tick; $\delta_i$) is simply the average value of its thresholds.

If three response categories give the scale two graduations per item, it is tempting to construct questionnaires with numerous response categories for each item. Indeed, if the continuum is divided into more parts, the measurement precision, sensitivity to change, and reliability would be expected to be improved (Tesio, 2003). Nevertheless, too many response categories could cause confusion in the respondents’ minds, thereby decreasing measurement precision instead of improving it. The Rasch model also offers the ability to verify the category functioning or, in other words, to determine how well all response categories are discriminated by the patients. Successive response categories for each item should represent increasing levels of activity. For instance, a patient performing an activity with difficulty should respond with a lower level of activity than a patient performing the same activity easily. The Rasch model investigates the category functioning by verifying whether thresholds between adjacent categories are located at increasing levels of activity (Andrich, 1996). Different studies have already demonstrated that patients
can hardly discriminate among more than three response categories for assessing ability to perform daily activities (Penta et al., 2001; Arnould et al., 2004).

Rasch analysis can be also used to verify how the items contribute to the definition of the unidimensional activity construct. Unidimensionality of an instrument is met when it measures only one variable without being influenced by other factors (Wright and Linacre, 1989). For instance, a balance measures only the subject’s weight and should not be biased by other attributes such as his height, skin color, or character. Similarly, the items of the questionnaire intended to measure locomotion ability should provide a measure relating to only the locomotion ability of the subject. This measure should be unbiased by other attributes of the subject or of the items. However, unidimensionality remains a theoretical concept and is never completely realized in practice (Andrich, 1988). A part of the unidimensionality can also be verified by the invariance of scale among different subgroups of patients (Smith et al., 1998). The lack of invariance is called “differential item functioning” (DIF) (Smith et al., 1998). A DIF may induce a systematic misfit to a common scale calibrated for all subjects, and therefore constitute a threat to the invariant use of the same scale for all subjects.

Similar to the condition of unidimensionality, linearity is also important in obtaining objective measures desired in the physical sciences (Andrich, 2004; Hobart, 2002). While ordinal scores are separated by unknown distances, the unit of a linear scale is constant so that identical intervals represent the same amount of the variable purported to be measured (Wright and Linacre, 1989). The use of raw total scores has several limitations especially when quantitative comparisons are made across subjects or over time. The total score must therefore be converted into linear measures before quantitative comparisons can be made. To achieve this, the Rasch model uses a logistic transformation to convert the ordinal total scores into linear measures expressed in “logits” (i.e., log-odds unit). The logit is a probabilistic unit defined as the natural logarithm of the odds of success (i.e., the pass/fail probability ratio) of a subject to an item. This unit is constant throughout the measurement scale. At any level of the measurement scale, a 1-logit difference in subjects’ ability implies a constant ratio of their odds of success ($e^{1} = 2.71$) for any given item; a 2-logit difference always represents the odds of success in a ratio of $e^{2} = 7.39$, and so on. The Rasch model, therefore, allows the attainment of linear measures that may
be submitted to arithmetic computation and powerful parametric statistical analysis, and can be used to compare the ability of different subjects quantitatively or to follow their ability over time.

Elaborating a new questionnaire following the Rasch model is complex for various reasons. Firstly, the scientist must understand the philosophy of this model and secondly, be able to use computer software to apply rigorously the Rasch analysis. In practice a preliminary questionnaire including a large bank of items concerning the studied variable must be submitted to a representative population with minimum 100 patients. A Rasch analysis is then applied to the subjects’ responses to select the items fitting the model and respecting the principles of linearity, unidimensionality and invariance. Results from successive analyses are used to select the items that constituted the final scale. Items that did not meet any of the following criteria are eliminated. The first selection criterion is the frequency of missing values. Only items with a response rate higher than 50%, indicating that they are commonly attempted by the patients in the sample, are retained. The second criterion is the order of thresholds between response categories (ordered rating scale). If the anticipated order of response categories is correct, subjects with greater ability should select a higher response for any given item and subjects selecting a higher response for a given item should have greater ability. When these conditions are not met, the order of thresholds between successive response categories is skewed, indicating that the rating scale is not being used as anticipated for that particular item (Andrich, 1978). Only items with thresholds in the anticipated order are retained. In certain cases, the partial credit model is retained because it allows us to maintain more items and to discriminate the ability with a greater resolution than the rating scale model. In the partial credit model, items may have different response categories and a set of individual threshold estimates is provided for each item. The third criterion is the unidimensionality. The unidimensionality is tested by comparing the observed responses to an item with the expected responses predicted by the model. Based on the estimated ability of the patient and the difficulty of the item, the expected response of a subject to an item can be computed by the model. The similarity between the observed and expected responses to any item is reported by the software, through a Chi-square fit statistic (Andrich and Sheridan, 2005). The
Chi-square fit statistic cumulates the deviations from the model’s expectations. A test of significance is then applied to determine whether the Chi-square is too high to be attributed to random variations. If the p-value is less than 0.05, the item does not fit the unidimensionality criterion and is eliminated (Penta et al., 2001). The fourth criterion is the DIF test. The lack of variance in the item difficulty hierarchy among patient subgroups is tested.

Although the elaboration of a questionnaire following the Rasch model is complex, its use in clinical practice is, on the contrary, easy. The questionnaire is firstly administered to the patients on an interview basis (the patients do not realise the activities but they are asked to estimate the difficulty of performing each activity). Their responses to the questionnaire can be then submitted for an online analysis (as presented in Figure 4) on our website (http://www.rehab-scales.org). The online analysis taking into account the missing values directly converts the total score into a linear measure of activity limitations expressed in logits.

Figure 4 presents an example of an online analysis of the questionnaire ABILOCO on our website (http://www.rehab-scales.org). During the evaluation, a 2-level response scale is presented to the patients. Patients are asked to rate their perception on the response scale as 'Impossible', or 'Possible'. Activities not attempted in the last 3 months are not scored and are entered as not applicable (check the question mark '?' on the scoring sheet). Activities not realised because they are too difficult must be scored as 'Impossible'. Their responses to the questionnaire is then submitted through this online analysis that directly converts the total score into a linear measure of activity limitations expressed in logits.
1.2. MANAGEMENT OF SPASTICITY IN STROKE REHABILITATION

The management of spasticity remains a major challenge in rehabilitation medicine. Therapy for spasticity has to depend on its clinical presentation and the treatment goals for each patient. The goals may be very different, from improving of range of movement or standing balance, to more complex goals such as improving mobility. In addition to physical and occupational therapy (positioning, stretching and exercise), the available treatment options include oral pharmacological agents, soft-tissue surgery (e.g., muscle-tendon lengthening, selective neurotomy), neuromuscular blockade by local injections of phenol or botulinum toxin, and intrathecal medication. These treatments are focal or diffuse, temporary or permanent. They have advantages and disadvantages. For instance, oral antispastic medications often provide limited effects with short duration and frequently lead to side effects such as weakness, drowsiness, confusion, dizziness, and sedation (Ozcakir and Sivrioglu, 2007). Neurolysis by phenol and alcohol injections reduce spasticity but can be painful (Ozcakir and Sivrioglu, 2007). Intrathecal baclofen, administered via an implanted programmable pump, can have adverse reactions (headache, nausea, vomiting, excessive weakness and transient urinary retention) but has been reported to be effective in intractable spastic hemiplegic patients (Ozcakir and Sivrioglu, 2007).

Because spasticity in most stroke patients is a variable phenomenon over time and apparent only in some muscle groups, reversible and focal treatment seems to be the most preferable options. Simpson et al. (2008) demonstrated that Botulinum toxin type A (BoNT A) may be considered as first-line therapy in upper-extremity spasticity. Consequently intramuscular administration of BoNT A is increasingly applied in stroke patients.

BoNT A weakens the activation of spastic muscles by selectively blocking the release of acetylcholine at the neuromuscular junction (Van Kuijk et al., 2002). Its effect is dose-dependent and usually lasts for 4-6 months. The beneficial effect of BoNT A can be maintained safely with repeated injections for up to at least three consecutive treatment cycles (Bakheid et al., 2004).
The efficacy of dose-related BoNT A injection efficacy was demonstrated in placebo-controlled randomized controlled trial (RCT) on muscle tone assessed by Ashworth’s scale in the lower limb (Pittock et al., 2003; Mancini et al., 2005) as well as in the upper limb (Bakheit et al., 2000-2001). Specifically, the effects of BoNT A injection have only been shown to improve impairments. The impairment reduction may lead to a reduction in burden of care, e.g. increase in passive range of motion facilitating dressing. However, Francisco (2007) stated in a recent review that “...studies have not demonstrated unequivocally that Botulinum toxin injection is effective in improving function...” at present. The true effect of BoNT A injection on patient activity and participation in social activities remains quite uncertain. The relationship between impairment and disability is not straightforward in spastic patients. The disability may be more associated with negative upper motor syndrome signs (paresis and loss of dexterity) than positive signs (spasticity and abnormal postures). A significant reduction in spasticity may not systematically lead to a functional improvement in activity or participation.

1.3. AIMS AND CONTENT OF THE THESIS
The overall aim of this thesis is to assess the efficacy of a spasticity treatment in stroke patients within the ICF framework. Particularly, the effects of BoNT A injections in spastic lower and upper limb muscles will be investigated on impairment, activity, and social participation. The main question is to know if these injections are really effective in improving function in these patients. Indeed, no study to date has showed a benefit of spasticity treatment in terms of functional improvement in activity or participation.

Spastic hemiparesis is the classical clinical picture of neurological impairment that limits locomotion and manual ability in stroke patients, which are activities essential for daily life activities and social participation. The ICF defines locomotion as the individual’s ability to move about effectively in his environment, and manual ability as the capacity to manage daily life activities requiring the use of the upper limbs,
whatever the strategies involved. Locomotion and manual ability are classified in the ICF activity domain.

We have previously seen the interest and the importance to use Rasch-built questionnaires in the assessment of a latent variable as presented in the activity and participation domains (Section 1.1. “Stroke and Rehabilitation”). These Rasch-built questionnaires notably allow overcoming the limitations of the ordinal scales that permit only limited computation and low power non-parametric statistics (Merbitz et al., 1989; Wright and Linacre, 1989). At present, we have new Rasch-built linear and unidimensional scales assessing manual ability (ABILHAND, Penta et al., 2001) and social participation (SATIS-Stroke, Bouffioulx et al., 2008) in stroke patients with high sensitivity. But until now, none of the existing scales available to assess locomotion ability were developed following the Rasch model and locomotion activities are frequently measured by ordinal scales. Therefore, the first stage of this thesis is to develop, using the Rasch probabilistic model, a new questionnaire (ABILOCO) assessing the walking ability of adult stroke patients focusing on the ICF activity domain. The development of this Rasch-built measure of locomotion ability is presented in Chapter 2.

Chapter 2 presents the development of ABILOCO, a Rasch-built measure of locomotion ability and its validation in stroke patients. ABILOCO is a self-reporting questionnaire, focusing on the activity domain of the ICF. This questionnaire originally included 43 items representing a large sample of activities corresponding to the ICF definition of locomotion and was submitted to 100 adult stroke patients. The Rasch model selected 13 activities to define a linear and unidimensional measure of walking ability.

The development and the validation of ABILOCO are presented as published in the Archives of Physical Medicine and Rehabilitation. A second section of Chapter 2 demonstrates the validity and reproducibility of the ABILOCO questionnaire when administered as either a self-assessment or third-party assessment. This section is presented as published in the Archives of Physical Medicine and Rehabilitation.

With ABILOCO, we have now a questionnaire assessing the walking ability of stroke patients focusing on the ICF activity domain and presenting all Rasch psychometric qualities. ABILOCO will be very usefull in Chapter 4 to investigate
the efficacy of BoNT A injections in spastic lower limb muscles in stroke patients on the activity domain.

The Appendix presents ABILOCO-Kids, a measure of locomotion ability validated in children with cerebral palsy as published in the Journal of Rehabilitation Medicine.

Chapter 3 presents a study concerning the reliability of lower limb kinematics, mechanics and energetics in stroke patients during gait as published in the Journal of Rehabilitation Medicine.

To date, no study has yet evaluated the medium-term reliability of gait variables among adult stroke patients. This work aims thus to assess the reliability of gait variables at short (1 day) and medium (1 month) intervals and provides useful norms for the study presented in chapter 4. Indeed this observational study uses among others these gait variables to assess the efficacy of BoNT A treatment in stroke patients. It is therefore important to know when a variation between measurements of these variables is the result of a gait modification induced by the treatment and when it is related to the variability of the measurement used.

Chapter 4 investigates the efficacy of BoNT A injections in several muscles on stiff-knee gait in stroke patients following the ICF framework. Stiff-knee gait is a common pattern of impaired kinematics in these patients; it is characterised by a lack of knee flexion during the swing phase of the gait cycle. The physiopathology and treatment of stiff-knee gait has not been clearly established. The overactivity of the Rectus Femoris is often cited (Riley and Kerrigan, 1998; Sung and Bang, 2000; Stoquart et al. 2008) but the altered activity of other muscles (Triceps Surae or Vasti) could also take place in the physiopathology (Goldberg et al., 2004). To our knowledge, no previous study has evaluated BoNT A injections in multiple muscles for the treatment of stiff-knee gait.

In addition, we have previously seen in the section “1.2. Management of Spasticity in Stroke Rehabilitation” that the effects of BoNT A injections have only been shown to improve impairments and the effects of BoNT A injection on patient activity and participation in social activities remains uncertain. The main aim of
Chapter 4 is therefore to investigate the efficacy of BoNT A injections in spastic lower limb muscles on impairment, activity, and social participation in stroke patients. The secondary aim of Chapter 4 is to analyse whether simultaneous BoNT A injections into several spastic muscles are more useful in the treatment of stiff-knee gait, as opposed to one single injection into the Rectus Femoris (Stoquart et al., 2008).

This work is presented in Chapter 4 as it was published in Stroke.

Chapter 5 investigates the effect of BoNT A injections in several spastic upper limb muscles in chronic stroke patients. We know that many stroke patients present with hand disability secondary to spastic hemiparesis and that these injections effectively reduce neurological impairment (Simpson et al., 2008). However, the functional consequences of these reductions on activity and participation remain unclear as in the lower limb spasticity. We would logically hypothesize that a reduction in spasticity might lead to an improvement in patient activity. But very few studies (Elovic et al., 2008; Brashear et al., 2002) have examined the effects of managing poststroke upper limb spasticity on activity. Additionally, no study has specifically addressed the effect of upper limb BoNT A injections on social participation. Therefore, our aim with this stroke patient study is to investigate the effects on impairment, activity, and participation of BoNT A injections in spastic upper limb muscles. Similarly to the previous chapter, activity (manual ability) and participation are assessed with Rasch questionnaires, ABILHAND (Penta et al., 2001) and SATIS-Stroke (Bouffiolux et al., 2008), respectively. This chapter is presented as the article published in Stroke.

Finally, the Chapter 6 discusses the results of the different chapters and presents perspectives for future research.
Chapter 1. Introduction
2. Chapter 2

ABILOCO: A Rasch-built 13-item questionnaire to assess locomotion ability in stroke patients

2.1. Development and validation of the ABILOCO questionnaire

Abstract

Objective: To develop a questionnaire (ABILOCO), based on the Rasch measurement model, to assess locomotion ability in adult stroke patients (ICF activity domain).

Design: Prospective study and questionnaire development.

Setting: Faculty Hospital.

Participants: 100 adult stroke patients (64±15 years old). The delay since stroke ranged from 1 to 260 weeks.

Intervention: A preliminary questionnaire included 43 items representing a large sample of locomotion activities. This questionnaire was tested on the 100 stroke patients and their responses were analyzed using the Rasch model (RUMM 2020 software®) to select items that had an ordered rating scale and fitted a unidimensional model.

Main outcome measures: the questionnaire ABILOCO.

Results: The retained items resulted in a 13-item questionnaire, which includes a wide range of locomotion abilities well targeted to the sample population, leading to good reliability (R=0.93). The item calibration was independent of age, sex, time since stroke, and affected side. The concurrent validity of ABILOCO was also investigated by comparing it with well-known, gold-standard scales (Functional Walking Category, Functional Ambulation Categories, the 12th item of the Functional Independence Measure evaluating walking ability) and the walking speed measured with the 10-meter Walking Test.

Conclusion: The ABILOCO questionnaire presents good psychometric qualities to measure locomotion ability in adult stroke patients. Its range and measurement precision make it attractive for clinical use throughout the rehabilitation process and for clinical research.

Published as:

2.1.1. Introduction

Post-stroke neurological impairment is a major cause of permanent disability among adults. This impairment frequently limits walking ability, which is an activity essential for daily life activities and social participation. Walking is also considered to be the most important activity of daily living by stroke patients (Chiou and Burnett, 1985). The assessment of locomotion ability is therefore fundamental in neurological rehabilitation so as to follow the patient’s improvement in clinical practice and to analyze the therapeutics’ efficacy in clinical research. The World Health Organization International Classification of Functioning (ICF) (World Health Organization, 2001) is recommended as the framework to assess rehabilitation. The ICF defines locomotion or mobility as the individual’s ability to move about effectively in his environment (World Health Organization, 2001) and classifies locomotion in the Activity domain.

The functional assessment of a stroke patient can concern several aspects of mobility. In the first ICF domain (Body structures and functions), neurological impairment secondary to stroke can be assessed by, for instance, using the NIHSS (Roth et al., 1998), the SIAS (Chino et al., 1996) or the Fugl-Meyer assessment (Duncan et al., 1983). The gait pattern can be assessed, for instance, by visual assessment with the Physician Rating Scale (Pirpiris et al., 2001), the Observational Gait Scale (Mackey et al., 2003), the Observation-Based Clinical Gait Assessment Tool (Toro et al., 2007) or the Rivermead Visual Gait Assessment (Lord et al., 1998). The gait pattern can also be quantitatively analyzed in a gait laboratory, which provides detailed quantification of kinematic, kinetic, energetic and electromyographic data during walking. These data are useful for treatment planning and clinical research, but might not be related to the patient’s walking ability during daily life in his environment.

In the second ICF domain (Activity), the locomotion ability can be assessed by several scales: the Functional Walking Category (FWC) (Perry et al., 1995), the Functional Ambulation Categories (FAC) (Brun et al., 2000), the 12th item of the Functional Independence Measure evaluating walking ability (FIMw) (Granger et al., 1993), the Rivermead Mobility Index (RMI) (Collen et al., 1991), the Mobility Milestones (Baer et al., 2003), the Modified Emory Functional Ambulation Profile (Baer et al., 2001) or the New Mobility Scale (Stanko et al., 2001). Unfortunately, these scales present some
limitations in the measurement of walking ability. Indeed, these tools (with the exception of the mEFAP) are ordinal scales that permit only limited computation and low power non-parametric statistics (Merbitz et al., 1989; Wright and Linacre, 1989). Some of these tools may not have the capacity to assess patients throughout their rehabilitation. For instance, the FWC was developed to assess the patient during his outpatient rehabilitation; whereas the FIMw and FAC seem more appropriate during inpatient rehabilitation. Tests that measure walking speed [the 10-meter, the 6-minute Walking Test (Dobkin, 2006)] are useful (simple, quick, inexpensive) and well validated. However, these tests describe a subject’s performance in an artificial and motivating environment that might not be related to the patient’s walking capacity during his daily life.

The Rasch model was developed in the 1960s in educational and psychological measurement (Andrich, 2004) and, thereafter, extended to measurement in health sciences (Conrad and Smith, 2004) to overcome the limitation of the traditional psychometrics method (Hobart, 2002). This model allows the measurement of a latent variable that cannot be quantified by a measuring device. For instance, dexterity can be quantified by a tool like the Purdue Pegboard or the Box and Block Test. But the measure of manual ability, a latent variable defined as “the capacity to manage daily life activities requiring the use of the upper limbs, whatever the strategies involved.” (Penta et al., 2001), required the development of the ABILHAND questionnaire (Penta et al., 2001), a Rasch-built interval scale. The process of establishing a new measure starts with the definition of the variable to be measured. Next, a large bank of items concerning this variable is created to build a preliminary questionnaire to be submitted to a representative population. A Rasch analysis is then applied to the subjects’ responses to select the items fitting the model and respecting the principles of linearity, unidimensionality and invariance. None of the existing scales available to assess locomotion ability were developed following the Rasch model.

The purpose of this study was to develop a new questionnaire (ABILOCO) assessing the walking ability of adult stroke patients focusing on the Activity domain of the ICF. The psychometric qualities of the ABILOCO were assessed using the Rasch probabilistic model (Rasch, 1992; Wright, 1982). This scale would be able to assess the locomotion ability of the stroke patient throughout his rehabilitation process (in a
hospital setting, at home and in the community) and be suitable for clinical practice and research.

2.1.2. Patients and methods

2.1.2.1. Patients

A one hundred sample of convenience of adult stroke patients (60 men and 40 women) were recruited from our inpatient and outpatient rehabilitation departments. Characteristics of the sample population are shown in Table 1. Patients had a stroke (World Health Organization, 1973) that occurred at least one week before the study with no major cognitive deficit that would prevent them from completing the questionnaire. Their neurological impairments induced gait disturbances and walking disability noticeable by visual observation. Patients unable to perform any walking rehabilitation because of neurological impairments or other medical conditions were excluded. Patients confined to bed or wheelchair, or patients who recovered a normal gait without any noticeable disturbances were also excluded. Patients participated freely in the study, which was approved by the local ethics committee.

Table 1. Sample characteristics (n=100)

<table>
<thead>
<tr>
<th><strong>Age (years)</strong></th>
<th>64 ± 15 (30-89)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>60</td>
</tr>
<tr>
<td>Female</td>
<td>40</td>
</tr>
<tr>
<td><strong>Site of lesion</strong></td>
<td></td>
</tr>
<tr>
<td>Right cerebral lesion with hemineglect</td>
<td>15</td>
</tr>
<tr>
<td>Right cerebral lesion without hemineglect</td>
<td>25</td>
</tr>
<tr>
<td>Left cerebral lesion with aphasia</td>
<td>26</td>
</tr>
<tr>
<td>Left cerebral lesion without aphasia</td>
<td>13</td>
</tr>
<tr>
<td>Cerebral trunk lesion</td>
<td>8</td>
</tr>
<tr>
<td>Cerebellar lesion</td>
<td>5</td>
</tr>
<tr>
<td>Many-sided lesions</td>
<td>8</td>
</tr>
<tr>
<td><strong>Delay since stroke (weeks)</strong></td>
<td>30 ± 42 (1-260)</td>
</tr>
</tbody>
</table>

* mean ± SD (range)
2.1.2.2. Questionnaire development

The preliminary questionnaire included a large sample of activities corresponding to the ICF definition of locomotion (World Health Organization, 2001): the individual’s ability to move about effectively in their environment classified in the Activity domain. Item selection was also based on a review of existing scales [FWC, FAC, FIMw and the Gillette Functional Assessment Questionnaire (Novacheck at al., 2000)] and on the clinical experience of our rehabilitation team (physical therapists, physical medicine and rehabilitation specialists). The first version of ABILOCO included a pool of 43 items.

2.1.2.3. Procedure

The 43-item questionnaire was completed by the 100 stroke patients using an interview technique (Penta et al., 2001). The ability of the patients to participate in the study was established by the rehabilitation team taking care of the patient on a daily basis. These rehabilitation professionals were familiar with the ability of the patient to understand and fill out the questionnaire. The assessors always checked the consistency of the answers. For each question, patients were asked to estimate, using a three-level rating scale (0 = impossible, 1 = difficult and 2 = easy), their perceived difficulty in performing that locomotion activity. Activities not attempted since the stroke were not scored and were encoded as missing responses. However, when an activity was never attempted because it was impossible, it was scored as « impossible ». The activities in the questionnaire were presented in a random order to avoid any systematic effect. Ten different random orders of presentation were used.

2.1.2.4. Data Analysis

Patients’ responses were analyzed using the Rasch Unidimensional Measurement Models computer program (RUMM2020, RUMM Laboratory Pty Ltd, Perth, Western Australia). The Rasch model (Rasch, 1992) allows the raw total scores to be converted into linear measures. This model requires that only item difficulty and patient ability
determine the probabilities of endorsing any given category. Measurement units are expressed in logits (log-odds units), a probability unit that expresses the natural logarithm of the odds of success. At any given ability level, one logit difference between two patients indicates that their odds of successfully achieving any activity are 2.7:1 ($e^{1}$). The logit metric provides a linear unit, representing a fixed increment along the entire scale of the explored variable.

### 2.1.2.5. Item selection

Results from successive analyses were used to select the 13 items that constituted the final ABILOCO scale. Items that did not meet any of the following criteria were eliminated.

The first selection criterion was the frequency of missing values. Only items with a response rate higher than 50%, indicating that they were commonly attempted by the patients in our sample, were retained.

The second criterion was the order of thresholds between response categories (ordered rating scale). If the anticipated order of response categories was correct, subjects with greater locomotion ability should select a higher response for any given item and subjects selecting a higher response for a given item should have greater locomotion ability. When these conditions were not met, the order of thresholds between successive response categories was skewed, indicating that the rating scale was not being used as anticipated for that particular item (Andrich, 1978). Only items with thresholds in the anticipated order were retained.

The third criterion was the unidimensionality. The subject’s responses to each item had to depend only on locomotion ability and not on other patient or item characteristics. Based on the estimated ability of the patient and the difficulty of the item, the expected response of a subject to an item can be computed by the model. The similarity between the observed and expected responses to any item is reported by the software, through a Chi-square fit statistic (Andrich and Sheridan, 2005). The Chi-square fit statistic cumulates the deviations from the model’s expectations. A test of significance is then applied to determine whether the Chi-square is too high to be
Chapter 2. The ABILOCO questionnaire

attributed to random variations. If the p-value was less than 0.05, the item did not fit the unidimensionality criterion and was eliminated (Penta et al., 2001).

The fourth criterion was the Differential Item Functioning (DIF) test. The lack of variance in the item difficulty hierarchy among patient subgroups was tested. Four DIF tests were performed on the basis of the following criteria: sex (male versus female), age (< 60 versus ≥ 60 years), delay since stroke (< 3 versus ≥ 3 months), and affected side (right versus left hemiparesis).

The fifth selection criterion was the redundancy. If two items had the same level of difficulty and were therefore redundant, the activity with the best fit unidimensionality criterion (lowest item Chi-square) was retained.

2.1.2.6. Scale reliability

In Rasch theory, error measure variance is directly computed from the measurement error accompanying each patient’s ability and item difficulty estimates (Wright and Linacre, 1989; Fisher, 1992). A person separation reliability coefficient was determined as the ratio between the true measure variance (as expressed by the standard deviation corrected for measurement error) and the observed (true + error) measure variance in the sample (Wright and Masters, 1982). Separation can be used to estimate the number of strata that are significantly distinguished within the range of observed patient abilities.

2.1.2.7. Concurrent validity

The ABILOCO measures were validated according to their relationship with raw scores of widely used existing scales (FWC, FAC, and FIMw) and the spontaneous walking speed (10-meter Walking Test). A Spearman correlation coefficient was computed for ordinal scales (FWC, FAC, and FIMw) and a Pearson correlation coefficient for spontaneous walking speed.
2.1.3. Results

Patients were unable to distinguish three levels of difficulty in locomotion activities; difficulty was perceived as either «impossible» or «easy» with an intermediate category «difficult» rarely observed. This indicated that patient perception was dichotomous, leading us to group the categories «difficult» and «easy» in a new category of «possible». Consequently, the three original categories were rescored as two categories «possible» or «impossible» with one threshold.

The item’s selection procedure excluded 30 items: 4 items were excluded since they had not been attempted since the stroke by more than 50% of the patients (cycling with a three-wheel bike); no item was eliminated for the second selection criterion (the 3 original categories were rescored in 2 categories with only one threshold); 7 items did not fit a unidimensional scale (e.g., getting the bus up and down, taking the train, running irrespective of the terrain); 17 items had a DIF (e.g., running correctly even if you have to turn, stepping up a curb, walking between parallel bars); and 1 item was redundant (going down stairs putting each foot on the next step, 0.61 logits). Furthermore, 1 item (running on flat and even ground) was eliminated because 74% of the patients rated it as «impossible»; this item was thus not relevant. The ABILOCO, therefore, became a 13-item questionnaire.

The perceived difficulties for the 13 activities are presented in Table 2. The items are listed in order of decreasing difficulty (range: +4.65 to −3.84 logits) from top to bottom, with higher logit values representing more difficult activities. This table also shows the standard error (SE) associated with each item difficulty (range: 0.38 to 0.58 logits) and the fit statistic computed as a Chi-square ($\chi^2$). A p-value greater than 0.05 indicates that all 13 items contributed to the definition of a unidimensional measure of locomotion ability in our sample.
Table 2. ABILOCO calibration for adult stroke patients

<table>
<thead>
<tr>
<th>Items</th>
<th>Difficulty (logits)</th>
<th>SE (logits)</th>
<th>Chi-square</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hopping on the healthy foot.</td>
<td>4.65</td>
<td>0.43</td>
<td>0.88</td>
<td>0.64</td>
</tr>
<tr>
<td>2. Going up an escalator alone.</td>
<td>2.77</td>
<td>0.41</td>
<td>1.21</td>
<td>0.55</td>
</tr>
<tr>
<td>3. Walking while holding a fragile object (such as a full glass).</td>
<td>1.65</td>
<td>0.38</td>
<td>1.50</td>
<td>0.47</td>
</tr>
<tr>
<td>4. Going up stairs putting each foot on the next step.</td>
<td>0.65</td>
<td>0.42</td>
<td>0.39</td>
<td>0.82</td>
</tr>
<tr>
<td>5. Walking backwards.</td>
<td>0.49</td>
<td>0.48</td>
<td>1.15</td>
<td>0.56</td>
</tr>
<tr>
<td>6. Walking more than five meters alone, indoors, on flat ground</td>
<td>0.19</td>
<td>0.43</td>
<td>0.97</td>
<td>0.62</td>
</tr>
<tr>
<td>without assistive device.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Striding over an object with the paretic foot first.</td>
<td>0.02</td>
<td>0.45</td>
<td>0.58</td>
<td>0.75</td>
</tr>
<tr>
<td>8. Striding over an object with the healthy foot first.</td>
<td>-0.74</td>
<td>0.46</td>
<td>0.29</td>
<td>0.87</td>
</tr>
<tr>
<td>9. Walking less than five meters alone without the help or supervision</td>
<td>-1.03</td>
<td>0.45</td>
<td>0.70</td>
<td>0.70</td>
</tr>
<tr>
<td>of a person.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Walking with the help of a person who guides but does not</td>
<td>-1.13</td>
<td>0.45</td>
<td>0.31</td>
<td>0.86</td>
</tr>
<tr>
<td>support.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Turning and walking in a narrow space.</td>
<td>-1.46</td>
<td>0.45</td>
<td>0.14</td>
<td>0.93</td>
</tr>
<tr>
<td>12. Walking less than five meters, indoors, holding onto pieces of</td>
<td>-2.23</td>
<td>0.47</td>
<td>0.93</td>
<td>0.63</td>
</tr>
<tr>
<td>furniture.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Walking less than five meters with the help of a person to support.</td>
<td>-3.84</td>
<td>0.58</td>
<td>0.50</td>
<td>0.78</td>
</tr>
</tbody>
</table>
The Table 3 shows the ABILOCO scale presented as a questionnaire. Patients were asked to estimate their ability to perform each activity as 'Impossible', or 'Possible'. Activities not attempted in the last 3 months were not scored and were entered as not applicable (question mark '?').

Table 3. The ABILOCO questionnaire

<table>
<thead>
<tr>
<th>Could you estimate your ability to realize the following activities?</th>
<th>Impossible</th>
<th>Possible</th>
<th>?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Walking while holding a fragile object (such as a full glass).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Walking with the help of a person who guides but does not support.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Striding over an object with the paretic foot first.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Walking more than 5 meters alone, indoors, on flat ground without assistive device.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Turning and walking in a narrow space.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Striding over an object with the healthy foot first.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Walking less than 5 meters with the help of a person to support.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Walking backwards.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Walking less than 5 meters alone without the help or supervision of a person.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Going up stairs putting each foot on the next step.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Walking less than 5 meters, indoors, holding onto pieces of furniture.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Going up an escalator alone.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Hopping on the healthy foot.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The ABILOCO scale and patients’ locomotion abilities are shown in Figure 1. The distribution of the patients’ locomotion abilities is presented in the top panel, ranging from −4.80 to +6.17 logits. The measures of locomotion ability for the stroke patients are obtained by converting the ordinal total scores into linear scores. The bottom panel of Figure 1 illustrates the ogival relationship between the total raw score ranging from 0 to 13 and the measure of locomotion ability on the linear scale in logits. This relationship is approximately linear between total raw scores of 4 and 8. Outside this central range, however, a small increase in total raw score corresponds to a large increase in locomotion ability on the linear scale. This difference highlights the non-linearity of the total ordinal score.
Chapter 2. The ABILOCO questionnaire

The middle panel of Figure 1 shows the expected response to a given item as a function of the underlying locomotion ability. By comparing the locomotion ability of a given patient to the difficulty of each item, it is possible to determine the expected response of the patient to the item. A patient with an ability of 0 logit would be expected to be able to perform the 6 easiest activities and to fail to perform the 7 most difficult activities. According to the distribution of the subjects’ locomotion abilities, 23% of the patients in our sample should be able to successfully perform all the activities, and 5% should not be able to perform any of the 13 ABILOCO items. The 13 items explore a wide range of locomotion abilities well targeted to our sample. ABILOCO was elaborated from a representative sample of the stroke population since 80% have a right or left cerebral lesion, with 5% presenting a cerebellar lesion. These 5 patients fit the model and their locomotion abilities are distributed on our scale from −1.88 logits to +3.31 logits (mean: 0.98±2.27 logits). The patient reliability equals 0.93, indicating that 5.2 statistically different levels of ability can be distinguished in this sample (Fisher et al., 1992).
Figure 1: The top panel shows the distribution of patients’ perceived locomotion ability as assessed by ABILOCO. The middle panel presents the items by decreasing difficulty from top to bottom and illustrates the patients’ expected responses to each item as a function of the underlying measure of locomotion ability. The bottom panel presents the ogival relationship between the ABILOCO total raw score and the score expressed in logits on the linear scale.
The relationships between ABILOCO and the FWC, the FAC, the FIMw and the 10-meter Walking Test are presented in Figure 2. The ABILOCO results are highly correlated with the results obtained using the FWC ($\rho=0.81$, $p<0.001$), the FAC ($\rho=0.84$, $p<0.001$), and the FIMw ($\rho=0.81$, $p<0.001$). The ABILOCO results are also highly correlated with the walking speed measured by the 10-meter Walking Test ($r=0.83$, $p<0.001$).
Figure 2: Relationships between ABILOCO and the Functional Walking Category (panel A), the 12th item of the Functional Independence Measure evaluating the walking ability (panel B), the Functional Ambulation Categories (panel C), and the walking speed measured with the 10-meter Walking Test (panel D). Box plots (panels A, B, C) show the patient distributions in a given category: the box indicates the 25% and 75% limits and the vertical line inside the box indicates the median; vertical bars indicate the 10% and 90% limits; solid dots indicate the 5% and 95% outliers. The number of patients (n) in each category is indicated. The “ρ” values report the results of the Spearman correlation test. In panel D, each point shows the results obtained for one patient. The “r” value reports the results of the Pearson correlation test.
2.1.4. Discussion

According to the International Classification of Functioning of the World Health Organization, the main objective of rehabilitation after a stroke is to increase activity achievement and to promote the participation of the patient. The locomotion ability of a patient is critical to reach this objective (Chiou and Burnett, 1985). Stroke rehabilitation specialists have to assess the walking ability, at each stage of recovery, in clinical practice and in clinical research. Unfortunately, there is a lack of scales presenting good psychometric qualities. Therefore, the purpose of this study was to develop a new scale (ABILOCO) to measure the stroke patient’s walking ability in a hospital setting, at home and in the community. The major interest in this scale is that a Rasch analysis was applied in its developmental stages, demonstrating its unidimensionality, its invariance and its linearity.

In comparison with the existing scales, the final 13-item questionnaire (ABILOCO) presents several advantages. The first is linearity. By adding the score obtained at each question, the total raw score is obtained on an ordinal scale. The Rasch analysis then allows the conversion of this total raw score into a linear score expressed in logits on an interval scale. In contrast to the former, this latter score may be submitted to arithmetical computation and powerful parametric statistical analysis. The second advantage is unidimensionality, meaning that ABILOCO only measures locomotion ability and is not influenced by other patient characteristics. The unidimensionality of existing scales has never been tested. The third advantage is the invariance of ABILOCO across sex, age, and delay since stroke, and clinical presentation. Other scales may not be invariant. Indeed, several activities included in the FAC and the FWC scales (e.g., walking alone on any grounds or walking between parallel bars) presented a Differential Item Functioning (DIF) and were disregarded after the Rasch analysis. The invariance of ABILOCO for delay since stroke would permit its use to assess the stroke patient’s locomotion throughout his rehabilitation process. Other scales may not be adapted to the entire rehabilitation process. The FIM, the FAC and the Mobility Milestones seem more appropriate for patients with low locomotion ability at the inpatient rehabilitation stage. Conversely, the FWC and the New Mobility Scale assess the locomotion ability only at home and in the community.
Moreover, forty percent of our patients obtained the maximum FWC, FIM, and FAC scores, indicating a ceiling effect; whereas ABILOCO can discriminate between walking abilities from +3 to +6.17 logits among these patients. The invariance of ABILOCO among the different subgroups would confirm that the patients estimated correctly their walking capacity irrespective of their clinical presentation. The computation of the spontaneous walking speed over 10 meters is an easy and validated test (Dobkin, 2006) that provides continuous results. However, walking speed describes a subject’s performances under a particular set of circumstances and may not reflect locomotion ability under different conditions. On the one hand, patients walking at the same slow speed (< 0.5 m s⁻¹) present a wide range of locomotion ability from -5 to +3 logits (figure 2-D). On the other hand, patients with the same walking ability (around 4 logits) present a wide range of spontaneous walking speeds from 0.25 to 1.7 m s⁻¹ (figure 2-D). ABILOCO and the 10-meter Walking Test are therefore complementary. Both tests can be performed easily in only a few minutes; the ABILOCO can also be self-administered. The mEFAP comprises 5 individually timed tasks performed over different environmental terrains and provides clear functional information without apparent ceiling effect (Baer and Smith, 2001). Nevertheless, this timed tool is a performance, not necessarily reflecting the mobility within the individual’s usual environment.

The item hierarchy in ABILOCO corresponds to the experience of rehabilitation professionals and to the patients’ goals. The easiest item (13) «Walking less than five meters with the help of a person to support» is usually the first step in locomotion rehabilitation after stroke. The next item (12) «Walking less than five meters, indoors, holding onto pieces of furniture» allows the patient to walk in his bedroom and reach the bathroom. Walking without help or supervision (item 9) is more difficult than walking with help or supervision (item 10) and corresponds to the limit between dependence and independence. Item 3 «Walking while holding a fragile object (such a full glass)» requires the ability to perform two tasks at the same time (Bowen, 2001) and demands considerable concentration. This activity allows the patient to walk while holding an object, a task required in cooking, shopping or gardening. Items 1 and 2 require good balance and sufficient strength in both legs. These activities allow the patient to walk in the community for social participation. ABILOCO explores a
Chapter 2. The ABILOCO questionnaire

ABILOCO have the quality of a good measure of walking activity: reliable, accurate in measuring mobility, clinically practical and economical (Pearson et al., 2004). However, all the psychometric properties of a scale cannot be established in a single study (Hobart et al., 2003). In the future, it will be important to study the responsiveness of ABILOCO in a stroke population as a function of spontaneous recovery or after treatment with Botulinum toxin injections. ABILOCO could also be evaluated in other patients suffering from multiple sclerosis, Parkinson’s disease or amputation.

In conclusion, ABILOCO is a questionnaire that assesses the walking ability of adult stroke patients focusing on the ICF Activity domain. Elaborated following a Rasch analysis, this scale presents good psychometric qualities (reliability, linearity and unidimensionality) and can be used regardless of age, sex, affected side, and time since the stroke. For practical use of the ABILOCO, a website (http://www.rehab-scales.org) will be accessible shortly. The online analyses taking into account the missing values directly convert total scores into linear measures expressed in logits.
Chapter 2. The ABILOCO questionnaire

2.2. REPRODUCIBILITY OF THE ABILOCO QUESTIONNAIRE AND COMPARAISON BETWEEN SELF-REPORTED AND OBSERVED LOCOMOTION ABILITY IN ADULT PATIENTS WITH STROKE

Abstract

Objectives: To test the reproducibility of the ABILOCO questionnaire. To validate the patient self-reporting method and the third-party assessment of the stroke patients’ locomotion ability by a treating physical therapist. Design: Prospective study. Setting: University hospital. Participants: Adult stroke patients (N=28; 59±13y). The time since stroke ranged from 3 to 253 weeks. Intervention: Not applicable. Main Outcome Measure: The ABILOCO questionnaire. Results: The results of patient self-assessment and the results of the third-party assessments by the physiotherapists at a 2-week interval were highly correlated (intraclass correlation coefficient ICC=.77 and ICC=.89, respectively). The results of the patient self-assessment and the third-party assessment by the physical therapist were both well correlated to assessment by an independent medical examiner who observed the patient during the 13 ABILOCO activities (ICC=.69 and ICC=.87, respectively). Conclusion: The use of ABILOCO as a self-reporting questionnaire is a valid and reproducible method for assessing locomotion ability in patients with stroke in daily clinical practice and research.

Published as:

2.2.1. Introduction

The ABILOCO is a recently developed 13-item Rasch-built questionnaire (Caty et al., 2008) for evaluating locomotion ability in adult patients with stroke. The questionnaire’s linearity, unidimensionality, invariance, and concurrent validity have already been demonstrated (Caty et al., 2008). The objectives of the present study are 2-fold: first, to test the reproducibility of ABILOCO, and second, to validate (1) the patient self reporting method and (2) the third-party assessment by the treating physical therapist of the locomotion ability of the patient with stroke.

2.2.2. Methods

Participants were recruited in 3 physical medicine and rehabilitation services, where they were receiving rehabilitation care on an inpatient or an outpatient basis. They gave their written, informed consent for participation, and the study protocol was approved by the local ethics committee. Included patients (>20y) must have had a stroke at least 3 months previously to avoid a change in locomotion ability between assessments. Patients displaying other pathologies with potential effects on locomotion ability, patients confined to a bed or wheelchair, or patients who recovered a normal gait without any noticeable disturbances were excluded from the study. In contrast with the initial study (Caty et al., 2008), patients with aphasia or other cognitive disorders were not excluded.

The patients’ locomotion abilities were evaluated using the ABILOCO questionnaire. The patient’s ability to perform each of the 13 featured activities was rated as possible or impossible. The activity is rated not applicable if it was not performed in the 3 months prior to the assessment. The protocol included 2 interviews. At the first interview (t0), the patient’s personal data and clinical features (MMSE, date and type of stroke) were recorded. The patient and the treating physical therapist then filled out ABILOCO independently. If the patient presented cognitive disorders and had trouble filling out the questionnaire independently, the investigator helped the patient complete the questionnaire in the form of an interview. At the second interview performed 2 weeks later (t1), the patient and the physiotherapist filled out the ABILOCO again. A 2-week period was selected to
Chapter 2. The ABILOCO questionnaire

prevent the subject from remembering the responses. Next, 1 independent medical examiner (MD) asked the patient to perform each of the 13 activities and assessed whether the patient was capable or incapable of doing so. Each raw score was then converted into a linear measurement in logits using a Rasch analysis (Caty et al., 2008), taking into account the unperformed activities. In particular, the observation by the MD of the item “Going up an escalator alone” was not possible in 9 patients because of the lack of an escalator close to the assessment site. The reproducibility of the ABILOCO questionnaire was tested by comparing, on the one hand, the patient’s locomotion ability estimated at t0 and t1 by the patient, and, on the other hand, the ability estimated at t0 and t1 by the physical therapist. The validity of the self-assessment and third-party assessment was studied by comparing the locomotion ability assessed by the patient (self-assessment) and by the physical therapist (third-party assessment) with that evaluated by the MD. Correlations between the variables were measured using ICCs (Shrout et al., 1979; McGraw et al., 1996; Nickerson, 1997) (SPSS version 15.0). The ICC can consider the extent of the relative discrepancies between the evaluations and gives the proportion of variance attributable to between differences groups. The effect of aphasia, sensory neglect, and MMSE on the validity of ABILOCO self-assessment was studied using a 2-factor, repeated-measures analysis of variance.

2.2.3. Results

Twenty-eight patients with stroke (13 men, 15 women; mean age=59±13y; time since stroke, 33±58mo) participated in the study. Sixteen patients displayed left-side hemiplegia (of whom 4 had sensory neglect), and 12 displayed right-side hemiplegia (of whom 8 had aphasia). The median for the MMSE was 10.5 (range=6–30).

The correlation between the locomotion ability self-assessed by the patient at t0 and t1 is shown in figure 1A. The ICC was .77, and the Bland-Altman value (mean ± SD) was 0.2±3.5 logit. The correlation between the patient locomotion ability assessed by a physical therapist at t0 and t1 is shown in figure 1B. The ICC was .89, and the Bland-Altman value was .08±2 logit.

The correlation between the locomotion ability self-assessed by the patient and assessed by the MD is shown in
Chapter 2. The ABILOCO questionnaire

figure 1C. The ICC was .69, and the Bland-Altman value was .02±3.5 logit. The correlation between the patient locomotion ability assessed by a physical therapist and assessed by the MD is shown in figure 1D. The ICC was .87, and the Bland-Altman value was –.03±2.2 logit. Aphasia, sensory neglect, and MMSE did not have significant effects on the validity of the ABILOCO self-assessment ($P=.71$, $P=.57$, and $P=.47$, respectively).
Figure 1: The patients’ locomotion capacities evaluated using the ABILOCO questionnaire are expressed in logits. Each point represents the results obtained for one patient, with a linear regression adjusted to fit the data. Graph A shows the correlation between the locomotion ability self-assessed by the patient at $t_0$ and $t_1$. Graph B shows the correlation between the patient locomotion ability assessed by a physiotherapist at $t_0$ and $t_1$. Graph C shows the correlation between the locomotion ability self-assessed by the patient and assessed by the expert examiner. Graph D shows the correlation between the patient locomotion ability assessed by a physiotherapist and assessed by the expert examiner.
2.2.4. Discussion

This study validates the self-report method of the ABILOCO questionnaire and shows its reproducibility. Self-assessment questionnaires validated by Rasch analysis have several advantages relative to observational measurement and thus are increasingly used in a range of pathologies (Caty et al., 2008; Vandervelde et al., 2007; Durez et al., 2007). Such questionnaires (1) can be completed easily, quickly, and cheaply, (2) enable assessment of a patient’s activity and participation limitations in a real-life context, and (3) allow regular evaluation of a large number of subjects over the course of a rehabilitation program (whether on an inpatient or outpatient basis). In contrast, hospital-based performance tests evaluate the patient’s maximum capacity at a given moment in an artificial environment; the results of such tests depend on the patient’s motivation and may not always reflect the activities that the patient performs regularly in the personal environment (Caty et al., 2008). There are few literature data on patients’ self-assessment capacities; most work has sought to validate self-assessment and has looked at performance of activities of daily living, with variable results (Wijlhuizen et al., 1999; Owens et al., 2002; Sinoff et al., 1997).

Limited stroke-associated cognitive disorders (aphasia, sensory neglect) do not appear to have a significant impact on the validity of self-assessment with the ABILOCO questionnaire, but completing the questionnaire may require the aid of another person. When the severity of cognitive disorders precluded the self-assessment, the evaluation by the physical therapist was also valid. In the future, it would also be interesting to test the validity of assessment by a caregiver.

2.2.5. Conclusion

The use of ABILOCO as a self-reporting questionnaire is a valid and reproducible method for assessing locomotion ability in patients with stroke in daily clinical practice and research.
3. Chapter 3

Reliability of lower limb kinematics, mechanics and energetics during gait in patients after stroke

Abstract

Objective: To assess the reliability of kinematic, mechanical and energetic gait variables at short (1 day) and medium (1 month) intervals in adult patients after stroke. Design: Prospective study. Subjects: Ten patients with chronic post-stroke (mean age 53.5 years; age range 25–80 years). Methods: Three-dimensional gait analysis was performed 3 times in these subjects: at baseline (T0), after 1 day (T1) and after 1 month (T2). The reliability of the gait analysis was tested by comparing gait variables measured at T1 and T0 (1 day interval), at T2 and T0 (1 month interval). The intersession reliability of kinematic, mechanical and energetic variables was calculated by intra-class correlation coefficient (ICC). Results: The reliability of kinematic variables ranged from excellent to moderate (ICC≥0.51), except for the ankle position at heel strike (ICC=0.44). The reliability of mechanical and energetic variables ranged from excellent to good (ICC≥0.71). The most reliable variable was external mechanical work (ICC=0.96). The kinematic, mechanical and energetic variables did not change significantly between T0, T1 and T2 (repeated-measures analysis of variance). Conclusion: Kinematic, mechanical and energetic gait variables present good reliability when measured at 1 day and 1 month intervals in adult patients after stroke.

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Chapter 3. Reliability of lower limb kinematics, mechanics and energetics during gait in patients after stroke

3.1. INTRODUCTION

The gait laboratory can provide an objective assessment of walking using quantitative measurements of kinematic, mechanical and energetic variables. These variables are useful for treatment planning and clinical research. It is therefore important to know when a variation between measurements of these variables is the result of a gait modification and when it is related to the variability of the measurement used. The reliability of gait analysis to date has been considered largely in healthy subjects (Kadaba et al., 1989), with little exploration among patients with known gait impairments or disabilities. The reliability of spatio-temporal and kinematic gait parameters has been studied in subjects with idiopathic scoliosis (Fortin et al., 2008) and in children with cerebral palsy with hemiplegia (Mackey et al., 2005). In adult patients after stroke, Yavuzer et al. (2008) showed the short-term reliability of these variables during 2 sessions on the same day. Patients after stroke form a large population with gait disabilities. They often undergo movement analysis to study their gait disturbances, e.g. through daily clinical practice to plan surgery treatment or through clinical research studies. No study has yet evaluated the medium-term reliability of gait analysis among adult patients after stroke. This study aims to assess the reliability of kinematic, mechanical and energetic gait variables in patients after stroke at short (1 day) and medium (1 month) intervals.

3.2. MATERIALS AND METHODS

3.2.1. Study population

Ten patients with chronic post-stroke, 8 men and 2 women, were enrolled in the study. The inclusion criteria were: hemiparesis secondary to stroke, time since stroke greater than 6 months, and ability to walk independently without an assistive device on a treadmill for a sufficient time to complete a metabolic analysis (around 2 min). The median age was 53.5 years (range 25–80 years), median time since stroke was 22 months (range 6–125 months), and median Stroke Impairment Assessment Set (Chino et al., 1996) score was 57.5 (range 44–75). Other than an additional gait
assessment, this study made no changes to medical treatments being received by the subjects post-stroke. The study was approved by the local ethics committee and all patients provided written informed consent.

### 3.2.2. Instrumented gait analysis

Gait analysis was performed following the protocol described by Stoquart et al. (2008). Three-dimensional kinematic analysis, mechanical and energetic measurements were conducted as patients walked on a force-measuring treadmill (Mercury-LTmed, HP-Cosmos, Nussdorf-Traunstein, Germany). Segmental kinematics was measured using the Elite system (BTS, Milan, Italy). Six infrared cameras measured at 100 Hz the co-ordinates in the 3 spatial planes (frontal, sagittal and transverse) of 20 reflective markers positioned at specific anatomical landmarks (Davis et al., 1991). These measurements allowed for computation of the angular displacement of the hip, knee and ankle during the walking cycle. Ground reaction forces (GRF) were recorded by 4 strain gauges, located under each corner of the treadmill. The total positive mechanical work ($W_{tot}$) performed by muscles during walking was divided into 2 components: (i) the external work ($W_{ext}$) performed to move the centre of body mass (COMb) relative to the surroundings; and (ii) the internal work ($W_{int}$) performed to move body segments relative to COMb. The metabolic cost of walking was determined by the patient’s oxygen consumption and carbon dioxide production measured throughout the treadmill test. The energy expended above the resting value was divided by the walking speed to obtain the net energy cost of walking ($C$, J kg$^{-1}$ m$^{-1}$).

### 3.2.3. Protocol

The subjects were tested during 3 sessions: at baseline (T0), after 1 day (T1) and after 1 month (T2). The reliability of the gait analysis was tested by comparing gait variables measured at T1 and T0 (1 day interval), at T2 and T0 (1 month interval). Anthropometric measurements and data were collected by the same experienced physician. To reduce the variability of markers positioning, he placed the marker following anatomical landmarks. He then measured the distances required by the
model (Davis et al., 1991) and adapted the markers’ positioning to keep these distances constant across the 3 gait analyses. At T0, subjects were asked to walk on the treadmill at a self-selected, comfortable pace, which was then kept constant for the remaining 2 sessions (T1, T2). For each session, kinematic and mechanical data were recorded from 10 consecutive gait cycles and averaged. The mean values were used for statistical analysis. A set of kinematic data was selected during the gait cycle, as proposed by Benedetti (1998).

### 3.2.4. Statistics

The inter-session reliability of kinematic, mechanical and energetic variables was calculated by the one-way random intra-class correlation coefficient (ICC) using one-way analysis of variance (ANOVA) (Rankin et al., 1998). A one-way repeated-measures ANOVA was computed to study the effect of time (T0, T1, T2) on gait analysis variables.

### 3.3. RESULTS

The kinematic, mechanical and energetic variables did not change significantly between T0, T1 and T2. This confirms that the gait of our patients with chronic stroke was stable and did not change in the 1-month period between T0 and T2.

The reliability of kinematic variables (Table I) ranged from excellent [ICC values≥0.91 (Fermanian et al., 2005)] to moderate (ICC values≥0.51) except for the ankle position at heel strike (ICC=0.44). The most reliable variable was the maximum knee flexion in swing phase (ICC=0.93). The reliability of mechanical and energetic variables ranged from excellent to good (ICC values≥0.71). The most reliable variable was Wext (ICC=0.96). The short-term (1 day) and medium-term (1 month) reliability were similar (paired t-test, p>0.05). In order to assess the intra-subject reliability, the absolute differences between variables recorded at T0 and T2 were computed. The mean of these absolute differences for the kinematic variables ranged from 1° to 5°. The 95th percentile (p95) of these differences ranged from 4° to 14°. The mean of the absolute differences between T0 and T2 for the mechanic
and energetic variables ranged from 0.01 to 0.63 J kg$^{-1}$ m$^{-1}$. The Wext presented the lowest p95 (0.03 J kg$^{-1}$ m$^{-1}$).
Table I. Inter-session intra-class correlation coefficients (ICC), repeated-measures analysis of variance (ANOVA), mean absolute difference and 95th percentile of kinematic, mechanical and energetic variables.

<table>
<thead>
<tr>
<th>Variables</th>
<th>ICC T0-T1</th>
<th>ICC T0-T2</th>
<th>ANOVA p-value</th>
<th>Mean</th>
<th>p95</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kinematics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvic min sagittal position</td>
<td>0.70</td>
<td>0.74</td>
<td>0.91</td>
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<td>9</td>
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<tr>
<td>Pelvic max sagittal position</td>
<td>0.72</td>
<td>0.52</td>
<td>0.27</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>Hip flex at heel strike</td>
<td>0.86</td>
<td>0.84</td>
<td>0.47</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Hip max ext in stance phase</td>
<td>0.58</td>
<td>0.51</td>
<td>0.90</td>
<td>5</td>
<td>13</td>
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<tr>
<td>Knee flex at heel strike</td>
<td>0.71</td>
<td>0.60</td>
<td>0.31</td>
<td>4</td>
<td>10</td>
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<tr>
<td>Knee max flex at loading response</td>
<td>0.84</td>
<td>0.74</td>
<td>0.85</td>
<td>4</td>
<td>11</td>
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<tr>
<td>Knee max ext in stance phase</td>
<td>0.58</td>
<td>0.56</td>
<td>0.62</td>
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<td>14</td>
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<tr>
<td>Knee max flex in swing phase</td>
<td>0.94</td>
<td>0.93</td>
<td>0.52</td>
<td>4</td>
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<tr>
<td>Ankle flex at heel strike</td>
<td>0.64</td>
<td>0.44</td>
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<tr>
<td>Ankle max dorsiflex in stance</td>
<td>0.63</td>
<td>0.76</td>
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<tr>
<td>Ankle max dorsiflex in swing</td>
<td>0.84</td>
<td>0.67</td>
<td>0.37</td>
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<tr>
<td>Average frontal pelvic position</td>
<td>0.80</td>
<td>0.63</td>
<td>0.97</td>
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<tr>
<td>Average frontal hip position</td>
<td>0.69</td>
<td>0.80</td>
<td>0.31</td>
<td>2</td>
<td>5</td>
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<tr>
<td>Average transversal pelvic position</td>
<td>0.85</td>
<td>0.65</td>
<td>0.76</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Average transversal hip position</td>
<td>0.62</td>
<td>0.71</td>
<td>0.11</td>
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<tr>
<td>Average transversal ankle position</td>
<td>0.83</td>
<td>0.87</td>
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<td>Mechanics</td>
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<td></td>
</tr>
<tr>
<td>Wext</td>
<td>0.96</td>
<td>0.99</td>
<td>0.18</td>
<td>0.01</td>
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<tr>
<td>Wint</td>
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<tr>
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<td>0.84</td>
<td>0.23</td>
<td>0.08</td>
<td>0.35</td>
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<tr>
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<td></td>
</tr>
<tr>
<td>Cost</td>
<td>0.92</td>
<td>0.79</td>
<td>0.61</td>
<td>0.63</td>
<td>1.40</td>
</tr>
</tbody>
</table>

The difference of the kinematic variables is expressed in degree and the difference of the mechanical and energetic variables in J kg\(^{-1}\) m\(^{-1}\).

T0: at baseline; T1: after 1 day; T2: and after 1 month.

3.4. DISCUSSION

The present study revealed good reliability of kinematic, mechanical and energetic gait variables among adult stroke patients. The Wext is the most reliable variable. The p95 difference (0.03 J kg\(^{-1}\) m\(^{-1}\)) corresponds to only 7% of the mean Wext. This means that a difference greater than 7% between 2 successive measures in a single
subject is significant. This finding emphasizes the clinical importance of using Wext as an outcome variable. Regarding the energy cost of walking (C), a high ICC of 0.97 was previously reported in patients after stroke completing 2 trials on the same day (da Cunha-Filho et al., 2003). The good reliability of the C in the short and medium terms is confirmed in this study. However, C is less reliable than Wext. The average difference is 0.6 J kg$^{-1}$ m$^{-1}$, corresponding to 14% of the mean C and similar to values reported in children with cerebral palsy (Brehm et al., 2005). Yavuzer et al. (2008) reported a high ICC for kinematic variables (range 0.92–0.98) performed during 2 sessions on the same day. Similarly, our study demonstrated an excellent to moderate reliability of these variables at 1 month interval. This could be explained by the effort made to optimize the marker positioning: the same physician placed the marker keeping the distance between markers constant and performed anthropometric measurements at T0, T1 and T2. Indeed, proper marker positioning is fundamental to allow reliable and valid movement analysis (Gorton et al., 2009; Della Croce et al., 1999). This could also be related to the great number (n=10) of the gait cycles studied (Monaghan et al., 2007). However, the mean p95 difference for kinematic variables was 10°, meaning that a difference lower than 10° between 2 successive measurements in a single subject must be interpreted with caution. Finally, contrary to previous studies (Fortin et al., 2008; Mackey et al., 2005; Yavuzer et al., 2008), the results of this study showed the reliability of kinematic variables to be similar in the frontal, sagittal and transverse planes. The poor reliability for the ankle position at heel strike could be explained by the fact that this short multi-segment joint is determined by only 2 markers. In conclusion, kinematic, mechanical and energetic gait variables present good reliability when measured at 1 day and 1 month intervals in adult patients after stroke. The Wext is the most reliable variable.
Chapter 3. Reliability of lower limb kinematics, mechanics and energetics during gait in patients after stroke
4. Chapter 4

Effect of simultaneous Botulinum toxin injections into several muscles on impairment, activity, participation and quality of life among stroke patients presenting with a stiff-knee gait

Abstract

Background: Walking is an essential activity for daily life and social participation and is frequently limited after stroke (WHO-ICF). A lack of knee flexion during the swing phase (stiff-knee) is one of the impairments that restrict walking ability among hemiparetic spastic patients. Purpose: To study the effect of Botulinum toxin type A (BoNT A) injections in several spastic muscles on the impairment, activity, participation and quality of life of chronic stroke patients presenting with a stiff-knee gait. Methods: Twenty chronic hemiparetic post-stroke patients with stiff-knee gait and ability to walk on a treadmill were recruited. BoNT A was injected into several spastic muscles: the Rectus Femoris (RF, 200U), Semitendinosus (ST, 100U) and Triceps Surae (TS, 200U). Patients’ neurological impairments (Ashworth scale, Duncan-Ely test, SIAS and instrumented gait analysis), activity (ABILOCO and 10m walking test) and participation (SATIS-Stroke and SF36) were assessed before and 2 months after the injection. Results: BoNT A injection reduced the impairments. It improved Stroke Impairment Assessment Set (56.5 [48–63] to 56.5 [52.5 to 63]; p=0.001), reduced rectus femoris muscle tone (2 [1 to 2.5] to 0 [0 to 1]; p=0.001), and reduced semitendinosus muscle tone (1 [1 to 1.5] to 1 [0 to 1]; p=0.001). Gait analysis demonstrated increased knee flexion during the swing phase (22±19° to 27±16°; p=0.03), decreased external mechanical work (0.66±0.38 to 0.59±0.25 J kg⁻¹ m⁻¹; p=0.04), and demonstrated a lower energy cost (5.8±1.9 to 4.9±1.9 J kg⁻¹ m⁻¹; p=0.03). The patients’ locomotion ability (ABILOCO) was improved (2.2±1.9 to 3.2±2.1 logits; p=0.03). The participation and quality of life remained unchanged. Conclusions: BoNT A injections in several muscles improved the stiff-knee gait and the locomotion ability in adult stroke patients.

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4.1. INTRODUCTION

A third of the people who experience a stroke (Rowland, 2002) present with disorders in the three international classification of functioning (ICF) (World Health Organization, 2001) domains: permanent neurological impairment, activity limitation restraining their participation, and quality of life. Spastic hemiparesis is the classical clinical picture of neurological impairment that limits walking ability. Walking is essential for daily life activities and social participation and is therefore considered the most important activity of daily life by stroke patients (Chiu and Burnett, 1985). Stiff-knee gait is a common pattern of impaired kinematics in these patients; it is characterised by a lack of knee flexion during the swing phase of the gait cycle. The physiopathology and treatment of stiff-knee gait has not been clearly established. The overactivity of the Rectus Femoris (RF) is often cited (Riley and Kerrigan, 1998; Sung and Bang, 2000) but the altered activity of other muscles could also take place in the physiopathology (Goldberg et al., 2004).

In a previous study, Stoquart et al. (2008) demonstrated that 200 units of Botulinum toxin type A (BoNT A, Botox) injected into the Rectus Femoris (RF) was effective at improving knee movement and the energy cost of walking. These authors focused on gait analysis and explored only the first ICF domain. They demonstrated that RF chemodenervation was ineffective for patients with no knee flexion during the swing phase (<10°). This may be related to the involvement of other underactive (Iliopsoas) or overactive (Triceps Surae or Vasti) muscles in the stiff-knee physiopathology (Goldberg et al., 2004). In this case, simultaneous BoNT A injections into several spastic muscles could be an adequate treatment. To our knowledge, no previous study has evaluated BoNT A injections in multiple muscles for the treatment of stiff-knee gait.

Botulinum toxin type A (BoNT A) injections have been increasingly used to manage spasticity among hemiparetic stroke patients. Dose-related BoNT A injection efficacy was clearly demonstrated by a placebo-controlled RCT on muscle tone, commonly assessed by the Ashworth scale (Mancini et al., 2005; Pittock et al., 2003); specifically, the effects of BoNT A injection have only been shown to improve impairments. The impairment reduction may lead to a reduced burden of
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care, e.g., an increase in the passive range of motion facilitating dressing. The effect of BoNT A injection on patient activity and participation in social activities remains uncertain for two reasons (Francisco et al., 2007). First, the activity and participation are not systematically evaluated or assessed with an insensitive tool. For instance, locomotion activities are frequently measured by ordinal scales, and there is no standard method of appraising participation. Recently, new questionnaires were developed following Rasch analysis to assess locomotion ability (Caty et al., 2008) and social participation (Bouffioulx et al., 2008) in stroke patients. These linear, unidimensional scales should assess these domains with high sensitivity. Second, the relationship between impairment and disability is not straightforward in spastic patients. The disability may be more associated with negative upper motor syndrome signs (paresis and dexterity) than positive signs (spasticity and abnormal postures). A significant reduction in spasticity may not lead to a functional improvement in activity or participation. In some patients, the increased tone of spastic muscle may be useful, for instance, in spastic quadriceps femoris used for maintaining an upright position.

The main aim of this study was to investigate the efficacy of BoNT A injections in several muscles on stiff-knee gait in stroke patients following the ICF framework. The secondary aim was to analyse whether simultaneous BoNT A injections into several spastic muscles are more useful in the treatment of stiff-knee gait, as opposed to one single injection into the RF (Stoquart et al., 2008).

4.2. PATIENTS AND METHODS

4.2.1. Subjects

Twenty chronic post-stroke patients, 15 males and 5 females, with spastic hemiparesis and stiff-knee gait are enrolled in the present study. The selection criteria are based on clinical examination and visual gait observation. The inclusion criteria are spastic hemiparesis secondary to stroke, longer than six months since stroke, lack of knee flexion during the swing phase and ability to walk independently without an assistive device. The exclusion criteria are inability to
walk on a treadmill for sufficient time to complete a metabolic analysis (around two minutes) and any cognitive deficit that would prevent the completion of the questionnaires. Their mean age is 52.3±16.1 years (range: 23-81), and the mean time since stroke is 45.9±32.9 months (range: 7-118). Ongoing treatments are kept unchanged (physical therapy and medication) throughout the study. This study is approved by the Local Ethics Committee and all patients provide written informed consent.

### 4.2.2. Body Function and Structure Assessment

Neurological impairments are assessed using the Stroke Impairment Assessment Set (SIAS) (Chino et al., 1996), which is a Rasch validated scale. The Duncan-Ely test (Marks et al., 2003) is used to quantify Rectus Femoris muscle tone, and the Ashworth Scale (Ashworth, 1964) is used to quantify Semitendinosus and Triceps Surae muscle tone.

Gait analysis is performed following the protocol described by Stoquart et al. (2008). Three-dimensional kinematic analysis and energetic measurements are conducted while patients walk on a force measuring treadmill (Mercury LTmed, HP Cosmos, Germany) (Dierick et al., 2004). Segmental kinematics is measured using the Elite system (BTS, Italy). At 100 Hz, six infrared cameras measure the three spatial coordinates of 20 reflective markers positioned on specific anatomical landmarks. These measurements allow computation of the angular displacement of the hip, knee and ankle during the walking cycle (Davis et al., 1991). The amplitude of knee flexion ($d_3$) is computed as the difference between the minimum knee flexion at the end of the stance phase ($d_1$) and the maximum knee flexion during the swing ($d_2$). Ground Reaction Forces (GRF) are recorded by four strain gauges located under each corner of the treadmill (Dierick et al., 2004). The total positive mechanical work ($W_{\text{tot}}$) performed by muscles during walking is divided into the external work ($W_{\text{ext}}$) performed to move the center of body mass (COM$_b$) relative to the surroundings and the internal work ($W_{\text{int}}$) performed to move body segments relative to the COM$_b$ (Willems et al., 1995). The $W_{\text{ext}}$ and $W_{\text{int}}$ are computed following the method described by Detrembleur et al. (2003). The metabolic cost of walking is determined by the patient's oxygen consumption ($\dot{V}O_2$) and carbon
dioxide production ($\dot{V}CO_2$) measured throughout the treadmill test. The energy expended above the resting value (standing subtracted from walking consumption) is divided by the walking speed to obtain the net energy cost of walking ($C, J kg^{-1} m^{-1}$).

### 4.2.3. Activity Assessment

Locomotion ability is assessed using ABILoco (Caty et al., 2008). This 13-item questionnaire, validated by Rasch analysis, is a linear interval, unidimensional and invariant scale assessing locomotion ability in adult stroke patients and can be used regardless of age, sex, cerebral lesion type, and time since the stroke occurred. Walking ability is also assessed by standard ordinal scales: the Functional Walking Category (FWC) (Perry et al., 1995), the Functional Ambulation Categories (FAC) (Brun et al., 2000) and the 12th item of the Functional Independence Measure (Granger et al., 1993) evaluating walking ability (FIMw). The patients’ spontaneous walking speed is measured using the 10-meter Walk Test.

### 4.2.4. Participation and Quality of Life Assessment

Patient participation is assessed with the SATIS-Stroke questionnaire (Bouffioulx et al., 2008), and the quality of life is assessed with the 36-item Short Form Health Survey (SF-36) (Ware, 1993). SATIS-Stroke, validated by Rasch analysis, is a linear, unidimensional scale assessing the stroke patient satisfaction in participation.

### 4.2.5. BoNT A Treatment

Selection of muscles to be injected is based on clinical assessment and gait analysis. All the BoNT A injections are performed by the same experienced physician (C.B.) with EMG guidance or electrostimulation. BoNT A (100 U Botox in 1mL saline, Allergan®) is injected into the Rectus Femoris (RF, 200 U, six sites), the Semitendinosus (ST, 100 U, four sites) and the Triceps Surae (TS, 200 U, six sites), including the Gastrocnemius Medialis (GM), the Gastrocnemius Lateralis (GL), and the Soleus (S). The total BoNT A dose for a patient ranges from 300 to 500 U.
Indeed, seven patients underwent a selective tibial neurotomy to treat a spastic equinus foot. Their TS is no longer spastic and is not injected. Table 1 shows the BoNT A dose for each patient. Note that a BoNT A injection (100 U) into the Flexor Digitorum Longus (FDL) is performed in two patients to treat spastic toes.
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Table 1. Patient' description, BoNT A dosage and muscles injected

<table>
<thead>
<tr>
<th>Patient</th>
<th>pre-BoNT A SIAS</th>
<th>BoNT A dosage (U Botox)</th>
<th>Muscles injected</th>
<th>pre-BoNT A $d_3$ (degrees)</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>1'</td>
<td>57</td>
<td>300</td>
<td>RF (2), ST (1)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>49</td>
<td>500</td>
<td>RF (2), GM-GL-S (4), ST (1)</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>47</td>
<td>500</td>
<td>RF (3), GM-GL-S (2), ST (1)</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>55</td>
<td>500</td>
<td>RF (3), GM-GL-S (3), ST (1)</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>5*</td>
<td>41</td>
<td>300</td>
<td>RF (3), ST (1)</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>6*</td>
<td>52</td>
<td>400</td>
<td>RF (1), ST (1), FDL</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>7*</td>
<td>36</td>
<td>300</td>
<td>RF (3), ST (1)</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>8*</td>
<td>65</td>
<td>300</td>
<td>RF (2), ST (2)</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>61</td>
<td>500</td>
<td>RF (1), GM-GL-S (3), ST (1)</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>10</td>
<td>43</td>
<td>300</td>
<td>RF (2), ST (2)</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>11</td>
<td>51</td>
<td>500</td>
<td>RF (2), GM-GL-S (4), ST (1), FDL</td>
<td>16</td>
<td>2</td>
</tr>
<tr>
<td>12</td>
<td>56</td>
<td>500</td>
<td>RF (1), GM-GL-S (3), ST (1)</td>
<td>21</td>
<td>2</td>
</tr>
<tr>
<td>13</td>
<td>71</td>
<td>500</td>
<td>RF (1), GM-GL-S (3), ST (1)</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>14</td>
<td>42</td>
<td>500</td>
<td>RF (1), GM-GL-S (3), ST (1)</td>
<td>30</td>
<td>2</td>
</tr>
<tr>
<td>15*</td>
<td>59</td>
<td>300</td>
<td>RF (3), ST (2)</td>
<td>35</td>
<td>2</td>
</tr>
<tr>
<td>16*</td>
<td>66</td>
<td>300</td>
<td>RF (1), ST (1)</td>
<td>44</td>
<td>2</td>
</tr>
<tr>
<td>17</td>
<td>64</td>
<td>500</td>
<td>RF (1), GM-GL-S (3), ST (1)</td>
<td>44</td>
<td>2</td>
</tr>
<tr>
<td>18</td>
<td>61</td>
<td>500</td>
<td>RF (1), GM-GL-S (3), ST (1)</td>
<td>46</td>
<td>2</td>
</tr>
<tr>
<td>19</td>
<td>63</td>
<td>500</td>
<td>RF (1), GM-GL-S (1), ST (1)</td>
<td>53</td>
<td>2</td>
</tr>
<tr>
<td>20</td>
<td>63</td>
<td>500</td>
<td>RF (2), GM-GL-S (3), ST (2)</td>
<td>62</td>
<td>2</td>
</tr>
</tbody>
</table>

*patients with a history of selective tibial neurotomy.

RF = Rectus Femoris, GM = Gastrocnemius Medialis, GL = Gastrocnemius Lateralis, S = Soleus, ST = Semitendinosus, FDL = Flexor Digitorum Longus.

( ) = spasticity of RF (Duncan-Ely test), GM-GL-S (Ashworth Scale) and ST (Ashworth Scale).

$d_3$ = amplitude of knee flexion during the swing phase.

4.2.6. Study Protocol

The same physician (G.C.) performs all clinical examinations, tests and analyses. Each subject is assessed before and two months after BoNT A treatment. The walking speed on the treadmill is determined before BoNT A treatment as the most comfortable speed and is similar for both gait analyses. The patients walk on the treadmill at 62.5 to 100 % of their spontaneous walking speed as measured at the 10-meter Walk Test.
4.2.7. Statistics

In a previous study, Stoquart et al. (2008) showed that the benefit of RF BoNT A injection is influenced by knee flexion amplitude. For this reason, the patients are divided into two groups as a function of \(d_3\), the pre-BoNT A amplitude of knee flexion during swing (Table 1): group I (\(n=8\)) includes patients with pre-BoNT A knee flexion less than 10° (5\(\pm\)2°), and group II (\(n=12\)) includes patients with pre-BoNT A knee flexion higher than 10° (33\(\pm\)16°). A two-way repeated-measures ANOVA is computed to study the effects of BoNT A treatment and groups on parametric data (mean\(\pm\)sd). A Signed Rank Test (Wilcoxon) is used to compare the non-parametric data after BoNT A treatment (median [range]) for twenty patients and in each group.

4.3. Results

The results will be presented successively for each ICF domain. The treatment is well tolerated, and no side effects are reported.

4.3.1. Body Function and Structure-Neurological impairments

BoNT A injection reduces neurological impairments (Table 2). Despite the fact that the SIAS median value has not changed, the neurological impairments are significantly improved, as evidenced by the increase in the lowest values (56.5 [48-63] to 56.5 [52.5-63], \(p<0.001\)). BoNT A injections have beneficial effects on spasticity, leading to a decreased muscle tone of the RF, ST and TS. The median Duncan-Ely score decreases from 2 [1-2.5] to 0 [0-1] (\(p<0.001\)), and the median and range for the ST Ashworth Scale remains and decreases, respectively, from 1 [1-1.5] to 1 [0-1] (\(p<0.001\)). The median TS Ashworth Scale tends to decrease from 3 [0-3] to 0 [0-3] (\(p=0.06\)).
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Table 2. Functional assessment pre- and post-BoNT A treatment

<table>
<thead>
<tr>
<th>Body Function and Structure</th>
<th>GROUP I</th>
<th>GROUP II</th>
<th>p-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-BoNT A</td>
<td>Post-BoNT A</td>
<td>Pre-BoNT A</td>
<td>Post-BoNT A</td>
</tr>
<tr>
<td>ASAS (logits)</td>
<td>5.5 [4.4-6.6]</td>
<td>5.4 [4.8-5.8]</td>
<td>6.1 [5.3-6.5]</td>
<td>6.5 [5.4-6.4]</td>
</tr>
<tr>
<td>Ely Test</td>
<td>2.5 [1.3-3.2]</td>
<td>1.0 [0.3-2.0]</td>
<td>1.0 [1.3-2.0]</td>
<td>0.0 [0.1-0.3]</td>
</tr>
<tr>
<td>Semitendinosus AS (degrees)</td>
<td>1 [0-1]</td>
<td>0.5 [0.2-1.3]</td>
<td>1 [0-1]</td>
<td>0.5 [0-1]</td>
</tr>
<tr>
<td>Triceps Surae AS</td>
<td>1 [0.3]</td>
<td>0.5 [0-0.5]</td>
<td>3 [0-1]</td>
<td>0 [0-0.5]</td>
</tr>
<tr>
<td>d3 = amplitude of knee flexion during the swing phase</td>
<td>5.1±2.6</td>
<td>12.3±6.9</td>
<td>33.3±66.6</td>
<td>37.2±12.9</td>
</tr>
<tr>
<td>Wint = internal mechanical work</td>
<td>0.9±0.45</td>
<td>0.7±0.32</td>
<td>0.4±0.15</td>
<td>0.5±0.18</td>
</tr>
<tr>
<td>Wtot = total mechanical work</td>
<td>0.3±0.13</td>
<td>0.27±0.9</td>
<td>0.25±0.06</td>
<td>0.24±0.07</td>
</tr>
<tr>
<td>C (J/kg m(^{-3}))</td>
<td>0.7±1.0</td>
<td>5.6±2.2</td>
<td>5.3±2.0</td>
<td>4.4±1.7</td>
</tr>
</tbody>
</table>

Activity

| FAC                        | 4.3±3.5 | 4.3±3.9 | 4.3±4.5 | 4.3±4.9 | 0.5 | NA          |
| WFC                       | 5.3±5.6 | 5.5±5.6 | 5.5±4.4 | 5.6±5.6 | 0.125 | NA          |
| ABILICO (logits)           | 2.3±1.2 | 3.6±1.2 | 2.1±2.2 | 2.6±2.3 | 0.026 | 0.433          |
| 10 m Walk Test (ms\(^{-1}\)) | 0.5±0.23 | 0.5±0.24 | 0.7±0.31 | 0.7±0.32 | 0.209 | 0.061          |

Participation

| SF 36                      | 99.0±100.5 | 90.5 [45.5-96.3] | 94 [49.3-96.3] | 95.5 [60.9-96.8] | 0.362 | NA          |

AS = Ashworth Scale, d3 = amplitude of knee flexion during the swing phase, Wint = internal mechanical work, Wtot = total mechanical work, C = energy cost. NA = Not Available.

4.3.2. Body Function and Structure-Gait analysis

Figure 1 presents the knee angular displacement during stride in the sagittal plane. In healthy subjects (dotted line), a first slight knee flexion occurs during the loading phase at the beginning of the stance phase. A second large knee flexion occurs during the swing phase to allow for foot clearance. Typical traces of knee angular displacement are presented for both groups. In patient #2, before BoNT A (grey line), the knee is permanently flexed around 15°, and no additional knee flexion occurs during the swing phase (d3=3°). This patient belongs to group I. After BoNT A (dark line), knee flexion is normalized around 45° during the swing phase (d3=25°). In patient #16, before BoNT A, the amplitude of knee flexion is reduced during the swing phase (d3=44°). Moreover, the shape of the curve is abnormal. Knee flexion stops at the beginning of the swing phase, and the curve presents a characteristic double bump shape. This patient belongs to group II. After BoNT A, knee flexion increases, and this double bump disappears. Before BoNT A, d3 is
markedly reduced in both groups: $5.1\pm2.6^\circ$ in group I corresponding to 10% of the normal value and $33.3\pm16.6^\circ$ in group II corresponding to 66% of the normal value. The treatment improves the knee flexion movement ($p=0.029$, Table 2, Figure 2). In group I, the mean $d_1$ increases by 2.4 times from $5^\circ\pm2^\circ$ to $12^\circ\pm7^\circ$; in group II, the mean $d_1$ increases by 1.12 times from $33^\circ\pm17^\circ$ to $37^\circ\pm13^\circ$.

Figure 1: Typical traces of knee angular displacement during the stride of a patient (#2) of group I (left panel) and of a patient (#16) of group II (right panel). The dotted lines represent values of healthy subjects. The grey lines and dark lines represent respectively pre- and post-BoNT A data of the patients. The amplitude of knee flexion ($d_3$) is computed as the difference between the minimum knee flexion at the end of stance phase ($d_1$) and the maximum knee flexion during the swing ($d_2$).

Figure 2 characterizes the energetic of walking for all patients. The mechanical work done by the muscles during walking is markedly increased in all patients. Before BoNT A, the external mechanical work ($W_{ext}$) is on average two times greater than in healthy subjects. After treatment, mean $W_{ext}$ decreases 0.9 times from $0.66\pm0.38$ to $0.59\pm0.25$ J kg$^{-1}$ m$^{-1}$ ($p=0.04$, Table 2, Figure 2). Before BoNT A, the internal mechanical work ($W_{int}$) is on average 1.5 times greater than in healthy subjects. After treatment, $W_{int}$ does not change ($0.28\pm0.09$ to $0.26\pm0.07$ J kg$^{-1}$ m$^{-1}$, $p=0.3$, Table 2). Before BoNT A, the total mechanical work ($W_{tot}$) is on average 2 times greater than in healthy subjects. After treatment, $W_{tot}$ decreases from $0.94\pm0.44$ to $0.86\pm0.3$ J kg$^{-1}$ m$^{-1}$ ($p=0.06$, Table 2). Because of the high mechanical work done by
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the muscles during walking, the energy cost (C) is markedly increased before BoNT A and is on average 2.2 times greater than in healthy subjects. After treatment, C decreases 0.85 times from 5.8±1.9 to 4.9±1.9 J kg⁻¹ m⁻¹ (p=0.03, Table 2, Figure 2).

The treatment effect on the mechanical work is more important for group I than group II. In group I, Wext decreases from 0.93±0.45 to 0.7±0.32 J kg⁻¹ m⁻¹ (p=0.007, Table 2), and Wtot decreases 0.8 times from 1.23±0.56 to 0.96±0.39 J kg⁻¹ m⁻¹ (p=0.03, Table 2).

Figure 2

**Figure 2:** Impact of the BoNT A treatment on the Body Function and Structure (amplitude of the knee flexion, mechanical work and energy cost), the Activity (locomotion ability) and the Participation (SATIS-Stroke measure) ICF domains. The grey box and dark box represent, respectively, pre- and post-BoNT A data. Each bar corresponds to standard deviations. The asterisk (*) indicates the data significantly improved after BoNT A treatment.

### 4.3.3. Activity

The inclusion criterion (ability to walk independently at any speed and without an assistive device) explains the high score on the FIMw, FWC and FAC scales. No significant changes between pre- and post-BoNT A treatment are detected on the FIMw, FWC and FAC (Table 2) In contrast, the ABILOCO score increases from
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2.2±1.9 to 3.2±2.1 logits, p=0.03 (Figure 2). This corresponds to a 1.12 time increase in the range of locomotion ability explored by ABILOCO.

The patients’ spontaneous walking speed measured with the 10-meter Walk Test is initially low and remains unchanged after BoNT A treatment (0.63±0.29 to 0.66±0.30 m s\(^{-1}\), p=0.19).

4.3.4. Participation and Quality of life

The treatment has no effect on the quality of life as measured by the SF-36 questionnaire (92 [86.5-96.8] to 94 [90.3-98], p=0.35) or on the participation satisfaction assessed by the SATIS-Stroke (0.39±0.85 to 0.21±1.26 logits, p=0.4) (Figure 2).

4.4. DISCUSSION

This study demonstrates the beneficial effects of simultaneous Botulinum toxin injections into several spastic muscles for stiff-knee gait among adult chronic stroke patients. BoNT A treatment significantly reduces muscle tone, improves knee kinematics, decreases energy cost (Body Function and Structure ICF domain), and improves locomotion ability (Activity ICF domain); however, the treatment has no impact on satisfaction with respect to participation and quality of life (Participation ICF domain).

4.4.1. Body Function and Structure

The decrease in RF, ST and TS muscle tone after BoNT A injection in the present study is expected and corresponds to the well-known chemodenervation effect of the BoNT A injection (Mancini et al., 2005 and Pittock et al., 2003).

The gait analysis demonstrates that BoNT A injection improves knee flexion during the swing phase: disappearance of the double bump shape and increase of approximately 5° in knee flexion amplitude. Stoquart et al. (2008) found similar results after 200 U BoNT A injection in the RF, and Sung et al. (2000) found similar results after phenol injection of the RF motor branch. The improvement in knee movement reduces the energy cost of walking, similar to that observed by Stoquart
et al. (2008). However, these authors reported an improvement of C only in patients who flexed their knee more than 10° before the injection (group II). In the present study, C is improved in all patients irrespective of their group. The BoNT A injection program should be adapted for each patient depending on the clinical examination and walking pattern. In group I patients, only 200 U BoNT A injected in the RF are ineffective; however, 500 U BoNT A injected into several spastic muscles are effective at improving gait analysis variables, which supports the hypothesis that the stiff-knee gait physiopathology is variable and several muscles may be involved (Goldberg et al., 2004). In group I, stiff-knee would be related to the overactivity of several muscles (RF, ST, TS), while in group II, it seems to be mainly related to RF overactivity. The patients in group I have more severe neurological impairment (median SIAS 50.5) than group II (median SIAS 61) patients. In group II patients, a 500 U BoNT A injection in several muscles is not more effective than one single 200 U BoNT A injection in the RF. Given the high cost of Botulinum toxins and the risk of a paresis induced by excessive BoNT A dosage, the BoNT A injection should be as focused as possible.

### 4.4.2. Activity

The locomotion ability, assessed by the FWC, FAC and FIMw scales, are not modified by the treatment. This may be related to a ceiling effect; indeed, the pre-BoNT A FWC, FAC and FIMw scores are high because of the inclusion criterion, i.e., the subjects have to be able to walk independently. This may also be related to a lack of sensibility to change (responsiveness) of these ordinal scales. In contrast, ABILOCO detects a functional improvement in walking ability. This scale was developed following Rasch analysis to measure walking ability (Activity ICF domain) and presents the fundamental properties, such as linearity, unidimensionality and invariance (Caty et al., 2008). ABILOCO can assess walking abilities among stroke patients with a wide range of locomotion capacities. The ABILOCO results can be submitted to arithmetic and parametric statistics (Caty et al., 2008). These results and their relation to gait analysis illustrate the responsiveness of ABILOCO and support its use in clinical practice and research. It also underlines the interest of Rasch-built questionnaires for the outcome assessment
Chapter 4: Effect of simultaneous Botulinum toxin injections into several muscles on impairment, activity, participation and quality of life among stroke patient presenting with a stiff-knee gait

of neurological rehabilitation (Arnould et al., 2004; Vandervelde et al., 2007; Hsieh et al., 2007).

In a recent review, Francisco (2007) stated that until recently “… studies have not demonstrated unequivocally that Botulinum toxin injection is effective in improving function…” The present study is the first to report a functional improvement induced by BoNT A injections. The increased amplitude of knee flexion during the swing phase and the decreased energetic cost can explain the improvement in locomotion ability. Some locomotion activities assessed by ABILICO become feasible after BoNT A: «Going up an escalator alone» and «Going up stairs putting each foot on the next step». A 1 logit increase means that, on average, the patients are able to perform three more locomotion ABILICO items as a result of treatment.

4.4.3. Participation and Quality of life

The BoNT A treatment has no impact on subject participation and quality of life. Several hypotheses can be advanced to explain this phenomenon. First, participation is the most difficult ICF domain to tackle, and there is no gold standard methodology to assess it. SF36 (Ware, 1993) is a generic questionnaire to assess the health related quality of life and may lack specificity to evaluate stroke patients. SATIS-Stroke (Bouffioulx et al., 2008) is specifically dedicated to stroke patients. However, some SATIS-Stroke items, such as «Using knife, fork and spoon in all circumstance» and «Reading and understanding a document in all circumstance», bear no relationship to locomotion. Second, the power of the treatment may be below patient expectations: the physician’s goal is an improvement, whereas the patient’s hope is often complete recovery, even months after the stroke. The improvement in walking ability may be insufficient to improve patient quality of life or to reach the level of participation improvement they hope for. Third, the two-month delay in assessing the outcome may be insufficient to obtain a modification of participation and quality of life. Repeated BoNT A injections could be necessary to allow the patient to modify his social life. Fourth, participation is also dependent on contextual factors that can not be modified by the treatment.
Chapter 4: Effect of simultaneous Botulinum toxin injections into several muscles on impairment, activity, participation and quality of life among stroke patient presenting with a stiff-knee gait

4.4.4. Conclusion

This study demonstrates that BoNT A injections are effective for a stiff-knee gait among stroke patients. For the first time, a functional improvement in walking is demonstrated after a reduction in impairment induced by BoNT A.
Chapter 4: Effect of simultaneous Botulinum toxin injections into several muscles on impairment, activity, participation and quality of life among stroke patient presenting with a stiff-knee gait
5. Chapter 5

Effect of upper limb Botulinum toxin injections on impairment, activity, participation and quality of life among stroke patients

Abstract

Background and Purpose: The purpose of this study was to study the effect of Botulinum toxin type A (BoNT A) injections in spastic upper limb muscles on impairment, activity, participation and quality of life in chronic stroke patients.

Methods: BoNT A (Dysport) was injected into several upper limb spastic muscles in a group of 20 patients. Neurological impairment (muscle tone and strength, dexterity, SIAS), activity (ABILHAND), participation (SATIS-Stroke), and quality of life (SF36) were assessed before and 2 months after the injections. Results: BoNT A injections improved muscle tone, but had no impact on dexterity, manual ability, social participation, and quality of life. Conclusions: In this study, BoNT A injections in spastic upper limbs significantly reduced neurological impairments, but had no functional impact.

Published as:

5.1. INTRODUCTION

Many stroke patients present with hand disability secondary to spastic hemiparesis. This activity limitation can reduce their social participation and quality of life. Botulinum toxin type A (BoNT A) injections are increasingly used to manage spasticity among stroke patients. Systematic reviews (Simpson et al., 2008) have shown that these injections effectively reduce neurological impairment. However, the functional consequences of these reductions on activity and participation remain unclear, despite the fact that functional issues are often a major focus of rehabilitation programs (Elovic et al., 2008). Upper limb abilities (ICF activity domain) presented by hemiparetic patients can be divided into passive and active function. Passive functions relate to the tasks performed by the nonaffected arm or by a caregiver, whereas active functions include tasks that the subject performs with the affected limb. Even though the relationship between impairment and activity is not clear in hemiparetic spastic patients, we would logically hypothesize that a reduction in spasticity might lead to an improvement in patient activity and to a reduction in burden of care. Very few studies (Elovic et al., 2008; Brashear et al., 2002) have examined the effects of managing poststroke upper limb spasticity on activity, and to date no studies have comprehensively assessed active function. Consequently, Francisco (2007) recently stated that, to date, “. . . studies have not demonstrated unequivocally that Botulinum toxin injection is effective in improving function . . .” Additionally, no study has specifically addressed the effect of upper limb BoNT A injections on social participation. Therefore, our aim with this stroke patient study was to investigate the effects on impairment, activity (particularly active function), and participation of BoNT A injections in spastic upper limb muscles.

5.2. PATIENTS AND METHODS

Twenty stroke patients were enrolled in our study, which was approved by the Local Ethics Committee. All subjects provided written informed consent. Inclusion criteria were spastic arm paresis, minimal manual dexterity (Box and Block test score ≤ 1),
and a period of greater than 6 months since the patient’s most recent stroke. Exclusion criteria included BoNT A injection within the past 6 months, other pathologies with potential effects on manual ability, and any cognitive deficit that would prevent the completion of questionnaires. The mean subject age was 58.9 ± 18.1 years (range: 20 to 82), and interval since stroke was 45.9 ± 57.7 months (range: 7 to 252). Ongoing treatments (physical therapy and medication) remained unchanged throughout the study.

BoNT A (500U Dysport/1 mL saline, Ipsen) was injected with EMG guidance and electrostimulation in several spastic arm muscles (Table 1). The total BoNT A dose for each patient ranged from 400 to 1000U. Each subject was assessed by the same evaluator before and 2 months after BoNT A injection. The ICF-based assessment set is presented in Table 2. A paired t test was used to analyze the modification of the parametric data and a Wilcoxon Test to analyze the modification of non-parametric data.

### Table 1. Patient descriptions and muscles injected

<table>
<thead>
<tr>
<th>Patient</th>
<th>pre-BoNT A SIAS</th>
<th>BoNT A dosage (U Dysport)</th>
<th>Muscles injected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>56</td>
<td>900</td>
<td>BB (1+), B (1+), FCR (3), PT (1), FDP (1+)</td>
</tr>
<tr>
<td>2</td>
<td>59</td>
<td>900</td>
<td>BB (1), B (1), FCR (3), PT (1), FDP (1)</td>
</tr>
<tr>
<td>3</td>
<td>58</td>
<td>750</td>
<td>BB (2), B (2), FCR (1+), PT (1+)</td>
</tr>
<tr>
<td>4</td>
<td>58</td>
<td>400</td>
<td>FCR (2), FDP (3), FPL (1)</td>
</tr>
<tr>
<td>5</td>
<td>60</td>
<td>800</td>
<td>BB (1+), B (1+), PT (1), FDP (1)</td>
</tr>
<tr>
<td>6</td>
<td>65</td>
<td>950</td>
<td>BB (1), B (1), FCR (1), PT (2), FDP (1)</td>
</tr>
<tr>
<td>7</td>
<td>54</td>
<td>1000</td>
<td>BB (3), B (3), FCR (1), PT (2), FDP (2), FPL (2)</td>
</tr>
<tr>
<td>8</td>
<td>59</td>
<td>550</td>
<td>FCR (2), PT (1), FDP (3), FPL (2)</td>
</tr>
<tr>
<td>9</td>
<td>59</td>
<td>800</td>
<td>BB (1), B (1), PT (2), FDP (2)</td>
</tr>
<tr>
<td>10</td>
<td>66</td>
<td>950</td>
<td>BB (3), B (3), FCR (2), PT (2), FDP (2)</td>
</tr>
<tr>
<td>11</td>
<td>55</td>
<td>500</td>
<td>FCR (1+), PT (1), FDP (1)</td>
</tr>
<tr>
<td>12</td>
<td>67</td>
<td>800</td>
<td>BB (2), B (2), FCR (1), FDP (1)</td>
</tr>
<tr>
<td>13</td>
<td>51</td>
<td>1000</td>
<td>BB (2), B (2), FCR (1+), PT (1), FDP (2), FPL (1+)</td>
</tr>
<tr>
<td>14</td>
<td>65</td>
<td>950</td>
<td>BB (1), B (1), FCR (3), PT (1), FDP (3)</td>
</tr>
<tr>
<td>15</td>
<td>49</td>
<td>950</td>
<td>BB (3), B (3), FCR (3), PT (2), FDP (2)</td>
</tr>
<tr>
<td>16</td>
<td>57</td>
<td>550</td>
<td>FCR (2), PT (2), FDP (2), FPL (2)</td>
</tr>
<tr>
<td>17</td>
<td>51</td>
<td>800</td>
<td>BB (1+), B (1+), FCR (1), FDP (1+)</td>
</tr>
<tr>
<td>18</td>
<td>50</td>
<td>950</td>
<td>BB (1+), B (1+), FCR (4), PT (4), FDP (4)</td>
</tr>
<tr>
<td>19</td>
<td>63</td>
<td>800</td>
<td>BB (1), B (1), FCR (3), FDP (1)</td>
</tr>
<tr>
<td>20</td>
<td>59</td>
<td>400</td>
<td>FCR (1), FDP (1), FPL (1+)</td>
</tr>
</tbody>
</table>

BB, Biceps Brachii (250U); B, Brachialis (200U); FCR, Flexor Carpi Radialis (150U); PT, Pronator Teres (150U); FDP, Flexor Digitorum Profondu (200U); FPL, Flexor Pollicis Longus (50U). Numbers in parentheses indicate spasticity level of BB, B, FCR, PT, FDP and FPL (modified Ashworth scale).
Table 2. ICF-based assessment set

<table>
<thead>
<tr>
<th>Body Function and Structure</th>
<th>Activity</th>
<th>Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke Impairment Assessment Set</td>
<td>ABILHAND†</td>
<td>SATIS-Stroke</td>
</tr>
<tr>
<td>Modified Ashworth scale</td>
<td></td>
<td>36-item Short Form Health Survey</td>
</tr>
<tr>
<td>Medical Research Council</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximal grip strength (Jamar dynamometer)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximal key pinch strength (Pinch gauge)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual dexterity (Box and Block test)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digital dexterity (Purdue Pegboard test)*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*, indicates active function; †, active and passive function

5.3. RESULTS

BoNT A treatment, which was well tolerated, reduced neurological impairment, as evidenced by the increase in SIAS values and the decrease in muscle tone (Table 3). Maximal voluntary grip and key pinch strengths did not change. The MRC grade was significantly reduced for the elbow and thumb flexors but not for other muscles. The active function of the affected arm (Box and Block and Purdue Pegboard tests), manual ability, satisfaction with social participation, and quality of life all remained unchanged.
Table 3. Results

<table>
<thead>
<tr>
<th>Body Function and Structure</th>
<th>Before BoNT-A</th>
<th>After BoNT-A</th>
<th>P Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIAS</td>
<td>59 [55.5-64]</td>
<td>59.5 [56.5-63.5]</td>
<td>0.011</td>
</tr>
<tr>
<td>Elbow flexor MAS</td>
<td>1.5 [1-2]</td>
<td>1 [0-1.25]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Wrist flexor MAS</td>
<td>2 [1-3]</td>
<td>1 [0-2]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fingers flexor MAS</td>
<td>1.8 [1-2]</td>
<td>1 [0-1]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Thumb flexor MAS</td>
<td>0 [0-1]</td>
<td>0 [0-0]</td>
<td>0.156</td>
</tr>
<tr>
<td>Wrist pronator MAS</td>
<td>1 [0-2]</td>
<td>0 [0-1]</td>
<td>0.002</td>
</tr>
<tr>
<td>Elbow flexor MRC grading</td>
<td>4 [4-4]</td>
<td>4 [3-4]</td>
<td>0.031</td>
</tr>
<tr>
<td>Thumb flexor MRC grading</td>
<td>4 [3-4]</td>
<td>4 [1-4]</td>
<td>0.016</td>
</tr>
<tr>
<td>Maximal grip strength</td>
<td>9.1±6.7</td>
<td>8.2±4.9</td>
<td>0.439</td>
</tr>
<tr>
<td>Maximal key pinch strength</td>
<td>3.9±2.1</td>
<td>3.6±1.6</td>
<td>0.404</td>
</tr>
<tr>
<td>Manual dexterity (Box and Block test, #)</td>
<td>15.2±10.3</td>
<td>15.3±9.3</td>
<td>0.97</td>
</tr>
<tr>
<td>Digital dexterity (Purdue Pegboard test, ##)</td>
<td>1.4±1.7</td>
<td>1.1±1.6</td>
<td>0.222</td>
</tr>
</tbody>
</table>

Activity

| Activity | ABILHAND (logit) | 0.77±1.37 | 0.91±1.26 | 0.492 |

Participation

<table>
<thead>
<tr>
<th>Participation</th>
<th>SF36</th>
<th>58 [44.5-66.5]</th>
<th>59 [47.5-74]</th>
<th>0.114</th>
</tr>
</thead>
<tbody>
<tr>
<td>SATIS-Stroke</td>
<td>logit</td>
<td>1.03±1.03</td>
<td>0.81±1.04</td>
<td>0.101</td>
</tr>
</tbody>
</table>

MAS indicates modified Ashworth scale; MRC, Medical Research Council; #, number of blocks; ##, number of metal rods

5.4. DISCUSSION

This study confirms the efficacy of BoNT A injections in reducing spasticity and neurological impairment among stroke patients. However, these injections did not improve activity or participation, which is consistent with a recent systematic review (Simpson et al., 2008). Certain studies claim to identify functional effects of BoNT A injections with the Frenchay Arm Test (Lagalla et al., 2000) or the Disability Assessment Scale (DAS) (Elovic et al., 2008; Brashear et al., 2002) and have shown variable results (Slawek et al., 2005). However, such instruments do not focus on activity and certain domains measured by the DAS (eg, pain and palmar infection) refer to impairment and not to functional upper limb abilities. The study by Brashear (2002) was criticized (Slawek et al., 2005; Dobkin, 2003) because of its lack of
clarity regarding the term “functional disability”, and because of the limited improvement recorded in a subjective and narrow band of patient disabilities. In contrast, the ABILHAND questionnaire (Penta et al., 2001) assesses unimanual and bimanual daily life activities, and all functional upper limb ability (ie, both passive and active function). Another particularity of the present study is that we also include patients who exhibit minimal manual dexterity, namely subjects who should be more prone to functional improvement. Despite this inclusion criterion, no significant effect was present at the group level. It was also impossible to identify a subgroup of patients that demonstrated a positive effect in terms of functional outcome by studying the relationship between their initial impairments, activity assessments, or clinical characteristics (ANOVA and correlation analysis). This lack of functional improvement suggests that spasticity does not necessarily contribute to limitations in respect of upper limb function. Disability may be more directly related to negative upper motor syndrome signs (eg, paresis). The BoNT A treatment had no impact on subject participation (SATIS-Stroke, Bouffioulx et al., 2008) or on quality of life (SF36). Potential explanations for this phenomenon include a lack of improvement in the activity domain, a treatment effect that failed to meet patient expectations, a relatively short interval (2 months) between evaluations, and the fact that participation may depend on contextual factors that cannot be modified by treatment. A specific goal should be set for each patient before BoNT A injection. Goals targeted toward improving the impairment should be realistically attainable. Such goals could include pain relief, healing of palmar ulcerations, or limb positioning improvements. A goal related to activity is far more difficult to achieve. Indeed, the present study, along with other publications (Simpson et al., 2008), has failed to demonstrate active functional improvement at the group level. However, based on our clinical experiences, some patients actually improve their upper limb function. Unfortunately, no known patient characteristics allow us to identify those patients that are most likely to benefit in this way. A short-term anesthetic nerve blockade can be useful in predicting the effectiveness of BoNT A (Kamper et al., 2003). The first BoNT A injection may then be considered a trial, and should be repeated only if a careful assessment confirms a functional improvement. The
Chapter 5: Effect of upper limb Botulinum toxin injections on impairment, activity, participation and quality of life among stroke patients

spasticity treatment should be included in a more global goal-oriented rehabilitation plan that is specifically adapted to each patient.
Chapter 5: Effect of upper limb Botulinum toxin injections on impairment, activity, participation and quality of life among stroke patients
Chapter 6. Discussion

6.1. ICF AND REHABILITATION

The International Classification of Functioning, Disability and Health (ICF) provides universal common language for understanding and studying functioning, disability and health (Snögren and Sunnerhagen, 2009). The ICF also allows the characterization of specific functional problems of individuals (Hinsch and Zick, 2010). Of course information on functioning and disability is essential for everyday clinical care, including diagnosis, intervention management, and evaluation of treatment outcomes (Stucki et al., 2005). The ICF is of prime importance in research since it allows rehabilitation professionals to describe and categorize functioning and disability in a standardized way. Uniform language should result in avoidance of some errors in functional assessment. For example, certain studies, such as the one published in a famous journal by Brashear et al. in 2002, claimed to identify functional effects of BoNT A injections in upper limb spasticity treatment whereas the improvement concerned for the most part the impairment. The mix-up owed to a lack of clarity of terms used, notably “functional disability”.

Before the ICF concept was established (World Health Organization, 2001), the consequences of stroke were identified with many different clinical measurement tools, each with their specific conceptual framework, content, wording of items and response options. To facilitate the comparability of research findings and to improve stroke care, some consensus became progressively established across the different national and international guidelines regarding stroke patients’ problems and instruments to be used to manage stroke disability. In 2004 (Geyh et al.), a formal consensus process integrating evidence and expert opinion based on the ICF framework and classification led to the definition of the ICF Core Sets for stroke (including both the Comprehensive ICF Core Set and the Brief ICF Core Set). Now, with the ICF Core Sets we have a globally normalized framework and classification system to define the spectrum of problems in the functioning of stroke patients.
Chapter 6. Discussion

These Core Sets include several categories in connection with the three ICF domains. Limitations and restrictions in activities and participation appear to be most relevant to patients with stroke. All aspects of patients’ everyday activities and involvement in life situations are represented. These show that stroke has an overall effect on patients’ lives. The activity of daily life considered most important by stroke patients is walking (Chiou and Burnett, 1985) and its assessment is, therefore, fundamental in neurological rehabilitation. In 2007, Mudge and Stott performed a systematic review of the literature and identified sixty-one different outcome measures assessing walking ability following stroke (six of the outcome measures reflected impairment and 52 reflected limitations of activity and participation). The most frequently used outcome measures classified, according to the ICF, are presented in Table 1. However, the majority of these scales assess one ICF subcategory of walking ability (e.g., walking short distances). These authors conclude that there is a need to develop outcome measures that capture a greater range of walking ability, particularly in the community (like walking around obstacles and over uneven ground). These conclusions still reinforce the need to develop an appropriate tool to assess walking ability.
Table 1. Most frequently used outcome measures classified according to the ICF (Mudge and Stott, 2007).

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>ICF domain reflected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gait speed (self-paced)</td>
<td>activity and participation</td>
</tr>
<tr>
<td>2. Spatiotemporal parameters</td>
<td>impairment</td>
</tr>
<tr>
<td>3. Gait speed (fast)</td>
<td>activity and participation</td>
</tr>
<tr>
<td>4. Barthel Index</td>
<td>activity and participation</td>
</tr>
<tr>
<td>5. Kinematics</td>
<td>impairment</td>
</tr>
<tr>
<td>6. Functional Ambulation Categories</td>
<td>activity and participation</td>
</tr>
<tr>
<td>7. Kinetics</td>
<td>impairment</td>
</tr>
<tr>
<td>8. 6 minute walk test</td>
<td>activity and participation</td>
</tr>
<tr>
<td>9. Timed Up and Go</td>
<td>activity and participation</td>
</tr>
<tr>
<td>10. Electromyography</td>
<td>impairment</td>
</tr>
<tr>
<td>11. Motor Assessment Scale</td>
<td>activity and participation</td>
</tr>
<tr>
<td>12. Rivermead Mobility Index</td>
<td>activity and participation</td>
</tr>
<tr>
<td>13. Rivermead Motor Assessment</td>
<td>activity and participation</td>
</tr>
<tr>
<td>14. 36 Item Short Form Health Survey (SF-36)</td>
<td>activity and participation</td>
</tr>
<tr>
<td>15. Frenchay Activities Index</td>
<td>activity and participation</td>
</tr>
<tr>
<td>16. Scandinavian Stroke Scale</td>
<td>activity and participation</td>
</tr>
<tr>
<td>17. Nottingham Extended Activities of Daily Living Index</td>
<td>activity and participation</td>
</tr>
</tbody>
</table>

Stucki et al. (2007) defines rehabilitation as “a health strategy that aims to enable people experiencing or likely to experience disability to achieve and maintain optimal functioning in interaction with the environment”. Consequently, the assessment of patient’s functioning is the starting point of the goal-oriented rehabilitation process. To this end, appropriate ICF tools are actually developed to describe a functioning state, to illustrate the patient's experience of functioning and the relation between rehabilitation goals and appropriate intervention targets, and finally, the changes in functioning states following rehabilitative interventions (Rauch et al., 2008). Currently we have scales showing good psychometric properties and focusing on a specific function. One way of developing instruments with high psychometric qualities is to elaborate them using the principles of the Rasch model.
6.2. RASCH IN REHABILITATION

Rehabilitation medicine aims to restore behaviours and perceptions present in an individual such as independence, pain and fatigue (Tesio, 2003). Obviously, these variables can not be measured directly and are usually assessed by measuring related behaviours, defined by sets of standardized items. In 1960 Georg Rasch proposed a unitary and statistical approach to the study of these person’s behaviours and perceptions. Thanks to the appropriate metric properties established by this model, it has become increasingly applied to rehabilitation medicine and research. A brief review of the literature by searching in PubMed with the keywords Rasch and rehabilitation shows a yearly increase in use of the Rasch model in rehabilitation medicine (1990-2009) (Figure 1).

**Figure 1**

![Graph showing the increase in Rasch articles from 1990 to 2009](graph.png)

*Figure 1* presents the number of Rasch articles in relation with the rehabilitation domain cited in PubMed from 1990 to 2009. Each point shows the results obtained for each year.
Chapter 6. Discussion

It is important to remember that the basic psychometric qualities of a relevant and useful measurement instrument include reliability, validity, responsiveness, invariance, unidimensionality, and linearity. Reliability is a property that describes how consistent the instrument is (Frisbie, 1989) and how reproducible the scores are. We must distinguish between the inter-rater, intra-rater and test-retest reliability. Validity is defined as the ability of an instrument to actually measure what it purports to measure (Messick, 1989). Herein, we can also differentiate the content, concurrent and construct validity. The responsiveness is defined as the ability of an instrument to detect important changes over time (De Bruin et al., 1997). The invariance is the maintenance of item or person estimates across different subgroups of persons or items respectively or across testing occasions. Finally, an instrument is unidimensional when it measures only one variable without being influenced by other factors and is linear when the measurement unit is constant throughout the scale, so that intervals between two graduations represent the same amount of a variable (Wright and Linacre, 1989).

The main advantage of the Rasch model concerns its ability to elaborate questionnaires respecting the principles of unidimensionality, linearity, and invariance. The preservation of these principles is essential to obtain the objective measures desired in the physical sciences (Wright and Linacre, 1989; Hobart, 2002; Andrich, 2004).

Some Rasch-built scales, as ABILHAND (Penta et al., 2001) or ACTIVLIM (Vandervelde et al., 2007) (accessible on our website http://www.rehab-scales.org), were elaborated in our lab READ. Some of these questionnaires are now used in foreign rehabilitation team for other pathologies. For example Burger et al. (2009) have validated ABILHAND for measuring manual ability in adults with unilateral upper limb amputation.

However, the Rasch model has other measurement applications in health and human sciences. It can be useful for adjusting or optimizing well validated and largely used scales in terms of category functioning or item unidimensionality, or for validating scales across different cultures. For example, Hsieh et al. (2007) simplified the 50-
items Fugl-Meyer motor scale (FM) after a Rasch analysis to a short form of the FM (the S-FM). The S-FM contains only 12 items, making it a very efficient measure for assessing the motor function of stroke patients in both clinical and research settings. In the same way, the Gross Motor Function Measure, a widely used scale for children with cerebral palsy, was also simplified from 88 to 66 items, focused on improving psychometric qualities (Avery et al., 2003). Lundgren-Nilssonthe et al. (2005) have analyzed the cross-cultural validity of the Functional Independence Measure (FIM) in stroke patients using the Rasch model and demonstrated that Differential Item Functioning was found by country. As a result, clinically collected data from FIM for stroke patients cannot be compared across countries.

The interest of Rasch-built questionnaires for the outcome assessment of neurological rehabilitation is particularly well demonstrated in our work on BoNT A treatment of lower limb spasticity. Indeed, ABILOCO has allowed the detection of a functional improvement in walking ability contrary to other standard ordinal scales used in this study. Also, it shows the sensibility to change (responsiveness) of our questionnaire after treatment with Botulinum toxin injections.

6.3. MANAGEMENT OF SPASTICITY IN STROKE REHABILITATION

To answer to the main question of the Introduction “Are Botulinum toxin type A injections effective in improving function in the lower and upper limb spasticity treatment?”, we have investigated its efficacy within the ICF framework. The original feature of these studies is that activity and participation were assessed with Rasch-built questionnaires (ABILOCO, ABILHAND, SATIS-Stroke). Importantly, these studies have confirmed the efficacy of BoNT A treatment on impairment in terms of decrease in muscle tone, improvement of knee kinematics and decrease in walking energy cost for lower limb spasticity. For the first time a functional improvement induced by BoNT A treatment has been reported. We have demonstrated that this therapy improves locomotion ability as measured by ABILOCO. In contrast, the locomotion ability, assessed by the Functional Walking Category (FWC) (Perry et al., 1995), the Functional Ambulation Categories (FAC)
(Brun et al., 2000), the 12th item of the Functional Independence Measure evaluating walking ability (FIMw), are not modified by the treatment. This may be related to a ceiling effect; indeed, the pre-treatment FWC, FAC and FIMw scores are high because of the inclusion criterion, i.e., the subjects have to be able to walk independently. This may also be related to a lack of sensibility to change (responsiveness) of these ordinal scales. ABILOCO can assess walking abilities among stroke patients with a wide range of locomotion capacities. The ABILOCO results and their relation to gait analysis illustrate the responsiveness of ABILOCO and support its use in clinical practice and research. Also, it highlights the relation between ICF domains. The increased amplitude of knee flexion detected by gait analysis (Body Structures and Functions domain) can explain that some locomotion activities assessed by ABILOCO, such as «Going up stairs» (Activity domain), become more feasible after BoNT A.

On the other hand, BoNT A injections in spastic upper limb muscles do not lead to a functional improvement which is consistent with a systematic review published in 2009 (Elia et al.). The lack of functional improvement in this study suggests that disability resulting from stroke may be more associated with negative upper motor syndrome signs than positive signs, and that in some patients, increased tone of spastic muscle may be useful. Two recent studies (Chang et al., 2009; Meythaler et al., 2009) claim to identify functional effects after BoNT A injections in spastic upper limb muscles using the Motor Activity Log (MAL). However, this scale assesses the quality of movement and the amount of use of the patients’ impaired arm to accomplish daily tasks (Uswatte et al., 2005) but does not measure the person's ability to manage these activities. In contrast, the ABILHAND questionnaire (Penta et al., 2001) assesses bimanual daily life activities, and all functional upper limb ability (i.e., both passive and active function). Another particularity of the present study is that we also include patients who exhibit minimal manual dexterity, namely subjects who should be more prone to functional improvement. Despite this inclusion criterion, no significant effect was present at the group level. It was also impossible to identify a subgroup of patients that demonstrated a positive effect in terms of functional outcome by studying the relationship between their initial impairments, activity assessments, or clinical characteristics. A specific goal should be set for each patient before BoNT A...
Chapter 6. Discussion

injection. Goals targeted toward improving the impairment should be realistically attainable. Such goals could include pain relief, healing of palmar ulcerations, or limb positioning improvements. A goal related to activity is far more difficult to achieve. Indeed, the present study, along with other publications (Simpson et al., 2008), has failed to demonstrate active functional improvement at the group level (for reminder, active function includes tasks that the subject performs with the affected limb). However, based on our clinical experiences, some patients actually improve their upper limb function. Unfortunately, no known patient characteristics allow us to identify those patients that are most likely to benefit in this way. A short-term anesthetic nerve blockade can be useful in predicting the effectiveness of BoNT A (Kamper et al., 2003). The first BoNT A injection may then be considered a trial, and should be repeated only if a careful assessment confirms a functional improvement. The spasticity treatment should be included in a more global goal-oriented rehabilitation plan that is specifically adapted to each patient.

Finally, the BoNT A injections in lower as well as in upper limb spasticity has no impact on participation and quality of life. Several hypotheses can be advanced to explain this phenomenon. First, participation is the most difficult ICF domain to tackle, and there is no gold standard methodology to assess it. SF36 (Ware, 1993) is a generic questionnaire to assess the health related quality of life and may lack specificity to evaluate stroke patients. Second, the power of the treatment may be below patient expectations: the physician’s goal is an improvement, whereas the patient’s hope is often complete recovery, even months after the stroke. The improvement in walking or manual ability may be insufficient to improve patient quality of life or to reach the level of participation improvement they hope for. Third, the two-month delay in assessing the outcome may be insufficient to obtain a modification of participation and quality of life. Repeated BoNT A injections could be necessary to allow the patient to modify his social life. Fourth, participation is also dependent on contextual factors that can not be modified by the treatment.

Another special feature of our work presented in Chapter 4 is that we have improved our knowledge of stiff-knee gait physiopathology and treatment. Stiff-knee gait,
characterized by a lack of knee flexion during the swing phase of the gait cycle, is a common pattern of impaired kinematics in stroke patients with a walking disability. The role of the Rectus Femoris (RF) is often cited (Riley and Kerrigan, 1998; Sung and Bang, 2000) in stiff-knee gait physiopathology and is confirmed by Stoquart et al. (2008) who have demonstrated that 200 units of BoNT A (Botox) injected into this muscle is effective at improving knee movement and the energy cost of walking. However, they also demonstrated that RF chemodenervation is ineffective for patients with no knee flexion during the swing phase (<10°) suggesting the role of other muscles in this physiopathology. Our study is the first to evaluate BoNT A injections in multiple muscles [Rectus Femoris, Semitendinosus (ST), Triceps Surae (TS)] for the treatment of stiff-knee gait.

We have demonstrated that 500 units of BoNT A (Botox) injected into several spastic muscles are effective at improving gait analysis variables in all patients, but it is not more effective than one single 200 U BoNT A injection in the RF of patients with knee flexion more than 10°. However, in patients with knee flexion less than 10°, 500 units of BoNT A injected in several muscles (RF, ST, TS) are necessary, which supports the hypothesis that stiff-knee gait physiopathology is variable and several muscles may be involved (Goldberg et al., 2004). Therefore, the BoNT A injection program in stiff-knee gait treatment should be adapted for each patient depending on the clinical examination and walking pattern. A short-term anesthetic nerve blockade in the Rectus Femoris (Stoquart et al., 2008; Robertson et al., 2009) can be useful for the clinician in his BoNT A injection program.

6.4. CONCLUSION AND PERSPECTIVES

The aim of this thesis was to assess the efficacy of a spasticity treatment in stroke patients within the ICF framework. Particularly, we have investigated the effects on impairment, activity, and participation of BoNT A injections in spastic lower and upper limb muscles. Activity and participation were assessed with Rasch-built questionnaires (ABILOCO, ABILHAND, SATIS-Stroke).

BoNT A injections reduced neurological impairments in lower and upper spasticity. For the first time, a functional improvement in walking is demonstrated after BoNT
A treatment. On contrary, this treatment didn’t improve manual ability and had no impact on social participation.

The questionnaire ABILOCO was elaborated to overcome the limitations of the existing walking scales (e.g., ordinal scales or presenting a ceiling effect) assessing locomotion ability (ICF Activity domain). Before the development of ABILOCO, none of the existing scales available to assess walking were developed following the Rasch model. To our knowledge, there is currently no other questionnaire incorporating all of these essential psychometric properties (unidimensionality, linearity, invariance, reliable, validity and reproducibility).

In the future, it will be important to study the responsiveness of ABILOCO in a stroke population using the most frequently cited indices in responsiveness studies (Middel and van Sonderen, 2002). In the same way, Vandervelde et al. (2009) have investigated the sensitivity to change of their ACTIVILIM questionnaire with these responsiveness indices. ABILOCO could also be calibrated and used for other patients suffering from amputation, Parkinson’s disease or rheumatoid arthritis. We know that our questionnaire was translated from English into other language like Korean and is beginning to be used in foreign universities, such as those in New Zealand. ABILOCO was also cited in a systematic review (Tyson and Connell, 2009) about measures of walking and mobility in neurological conditions.

Recently, Belvedere and de Morton (2010) demonstrated that application of Rasch analysis is now increasing in mobility instruments and presented ABILOCO (and ABILOCO-Kids) as an example.
Chapter 7. References


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8. Appendix

ABILOCO-Kids: A Rasch-built 10-item questionnaire for assessing locomotion ability in children with cerebral palsy

Abstract
Objective: To develop a questionnaire (ABILOCO-Kids), based on the Rasch measurement model that assesses locomotion ability in children with cerebral palsy (CP). Design: Prospective study and questionnaire development. Participants: 113 children with CP (10±2.5 years old). Methods A 41-item questionnaire was developed based on existing scales and on the clinical experience of professionals in the field of rehabilitation. This questionnaire was tested separately on the 113 children with CP and their parents. Their responses were analysed using the Rasch model (RUMM-2020®) to select items that had an ordered rating scale and that fit a unidimensional model. Results: The final ABILOCO-kids scale consisted of 10 locomotion activities of which difficulty was rated by the parents. The parents gave a more precise assessment of their children’s ability than the children themselves, leading to a wider range of measurement that was well-targeted on the sample population and that had good reliability (R=0.97) and reproducibility (ICC=0.96). Item calibration did not vary with age, sex or clinical presentation (hemiplegia, diplegia, quadriplegia). The concurrent validity of the ABILOCO-Kids questionnaire was also shown by its correlation with the Gross Motor Function Classification System. Conclusion: The ABILOCO-Kids questionnaire has good psychometric qualities for measuring a wide range of locomotion abilities in children with CP.

Published as:

8.1. INTRODUCTION

Cerebral palsy (CP) is the leading cause of physical disability among children (Rosenbaum, 2003). The neurological impairments in children with CP frequently limit walking ability, which is an activity essential for daily life activities and social participation (ICF model World Health Organization, 2001). New therapeutic approaches are continuously being developed for the management of locomotor impairment in individuals with CP (Patrick et al., 2001). Some of these new strategies are intended to reduce spasticity (Gormley et al., 2001) (e.g., intramuscular botulinum toxin, intrathecal baclofen administration or dorsal rhizotomy), while others aim to improve locomotion ability using sophisticated orthoses (Butler et al., 1992) or multilevel surgery (Nene et al., 1993). The efficacy of these treatments on locomotion activity should be appraised using appropriate clinical assessment tools. In addition, the ability of children to walk may change during growth (Kuban et al., 1994) and needs to be assessed over time (Young et al., 1995).

Several scales are available to assess locomotion ability in the Activity domain of the ICF (World Health Organization, 2001) among children with CP: the Gross Motor Function Measure (Russell et al. 1989) (GMFM) and the Gross Motor Function Classification System (GMFCS) (Palisano et al., 1997), the Pediatric Evaluation of Disability Inventory (PEDI) (Haley et al., 1992), the Activities Scale for Kids (ASK) (Young et al., 2000), the Functional Independence Measure for Children (WeeFIM) (Ottenbacher et al., 2000), the Functional Mobility Scale (FMS) (Graham et al., 2004) and the Gillette Functional Assessment Questionnaire (FAQ) (Novacheck et al., 2000). These validated and reliable scales are widely used in the assessment of children with CP (Table I). Unfortunately, these tools present some limitations in the measurement of walking ability. Indeed, they are not specific for walking ability; the GMFM, the PEDI and the ASK measure the physical disability as a whole and the WeeFIM measures a child's functional performance in daily life activities (e.g., self care, social function, and mobility). These four scales require 15 to 45 minutes to be administered by skilled staff. On the contrary, the FMS and the
FAQ are focused on walking ability and are easily and quickly administered. The psychometric properties (unidimensionality and linearity) of the GMFM-66, the PEDI, the ASK and the WeeFIM have been proven by Rasch analysis (Rasch, 1992; Wright and Masters, 1982). The latent variable measured by these scales is the global physical ability. The WeeFIM is invariant across age and the GMFM-66 is invariant across age and disability. The FAQ and the FMS have not been submitted to Rasch analysis. These two tools are ordinal scales that permit only limited computation and low power, non-parametric statistical analysis (Merbitz, 1989; Wright and Linacre, 1989).

In addition to these scales, there are gait laboratories that can perform extensive locomotion analyses that are especially useful for treatment planning. For instance, the results of these analyses can be used to select overactive muscles for chemodenervation or to choose an appropriate surgical approach (DeLuca et al., 1997). However, the artificial and highly motivating clinical environment of the gait laboratory may poorly reflect a child’s walking ability during daily life activities. The effect of treatment should not be limited to gait analysis but should also include an assessment of walking ability in the community.

The purpose of this study was to develop a questionnaire (ABILOCO-Kids) assessing the walking ability of children with CP focusing on the Activity domain of the ICF. A Rasch analysis (Rasch, 1992; Wright and Masters, 1982) was applied to select items respecting the principles of linearity, unidimensionality and invariance. Locomotion ability can be inferred from a patient’s or proxy reporter’s perception of the difficulty of performing locomotion activities. The use of parents as proxy reporters is advised for very young children and for teenagers (Vogels et al., 1998). The preliminary questionnaire was, therefore, given to children and to their parents in order to compare the reliability of the reported perceptions.
### Appendix. ABILOCO-kids

**Table I.**

<table>
<thead>
<tr>
<th>Test</th>
<th>Reliability &amp; Validity &amp; Inter-examiner reproducibility</th>
<th>Structure and domains</th>
<th>Time of administration</th>
<th>Linearity</th>
<th>Interval scale</th>
<th>Latent variable unidimensionality</th>
<th>Invariance DIF test</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEDI</td>
<td>Reliability @ Validity @ Inter-examiner reproducibility @</td>
<td>237 items / 3 domains</td>
<td>45 minutes</td>
<td>Yes</td>
<td>Physical disability</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>ASK</td>
<td>Reliability @ Validity @ Responsiveness @</td>
<td>30 items / 9 domains</td>
<td>30 minutes</td>
<td>Yes</td>
<td>Physical disability</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>WeeFIM</td>
<td>Reliability @ Validity @ Inter-examiner reproducibility @</td>
<td>18 items / 6 domains</td>
<td>15 minutes</td>
<td>Yes</td>
<td>Functional performance</td>
<td>Yes (age)</td>
<td></td>
</tr>
<tr>
<td>GMFM- 66</td>
<td>Reliability @ Validity @ Responsiveness @</td>
<td>66 items / 5 domains</td>
<td>45 minutes</td>
<td>Yes</td>
<td>Gross motor ability</td>
<td>Yes (ability)</td>
<td></td>
</tr>
<tr>
<td>GMFCS</td>
<td>Reliability @ Validity @ Inter-examiner reproducibility @</td>
<td>A 5-level ordinal grading classification focusing on mobility</td>
<td>A few minutes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FAQ</td>
<td>Validity @ Inter-examiner reproducibility @</td>
<td>A 10-level ordinal scale focusing on functional mobility</td>
<td>A few minutes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMS</td>
<td>Reliability @ Validity @</td>
<td>A 6-level ordinal scale focusing on functional mobility</td>
<td>A few minutes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8.2. PATIENTS AND METHODS

8.2.1. Patients

The definition adopted for CP was « all non-progressive but often changing motor impairment syndromes secondary to lesions or anomalies of the brain arising in the early stages of its development » (Mutch, 1992). One hundred and thirteen children were recruited from seven centres involved in the care of children with CP (Table II). Because ABILOCO-Kids was designed as an interview-based questionnaire, children with a major intellectual deficit (IQ<60) or who were younger than six years of age were excluded. Unfortunately, five parents did not complete the questionnaire. The final sample was thus made up of 113 children and 108 parents. The study was approved by the ethics committee of our Medical School.
8.2.2. Questionnaire development

The preliminary questionnaire included a large sample of activities corresponding to the ICF definition of locomotion (World Health Organization, 2001): the individual’s ability to move about effectively in their environment, as classified in the Activity domain. Item selection was also based on a review of existing scales (GMFM, PEDI, ASK, WeeFIM and FAQ) and on the experience of our
rehabilitation team. The first version of ABILOCO-Kids included a pool of 41 items (Table III).

Table III. The 41-item preliminary questionnaire

1. Running on all types of surfaces.
2. Walking between parallel bars.
3. Walking alone outside on all types of surfaces.
4. Taking the train or the underground railway.
5. Walking while holding a fragile object (such as a full glass).
6. Kicking a ball with the paretic foot.
7. Walking several minutes at the same speed as a healthy child.
8. Going up stairs putting both feet on each step.
9. Stepping up a curb alone.
10. Running correctly even if you have to turn.
11. Walking few steps with the help of a person.
12. Walking more than five meters with a rollator.
13. Walking with the help of a person who guides but doesn’t support.
14. Walking more than five meters with a crutch.
15. Walking more than five meters alone, indoors, on flat ground without an assistive device.
16. Jumping the height of one step of stairs.
17. Hopping on the healthy foot.
18. Going down stairs putting both feet on each step.
19. Turning and walking in a narrow place.
20. Walking less than five meters, indoors, holding onto pieces of furniture.
22. Taking the bus alone.
23. Running on regular and flat ground.
24. Walking less than five meters alone without the help of a person.
25. Going up and down stairs without holding onto the banisters.
26. Running with a tricycle.
27. Kicking a ball with the healthy foot.
28. Skipping rope.
29. Going down stairs putting each foot on the next step.
30. Hopping on the affected foot.
31. Striding over an object with the paretic foot first.
32. Walking more than five meters, alone, outside on flat ground.
33. Walking with the help of two persons who support.
34. Striding over an object with the healthy foot first.
35. Running with a bike.
36. Going up an escalator alone.
37. Going up and down stairs with the help of a handrail.
38. Walking backwards.
39. Going up stairs putting each foot on the next step.
40. Running with a bike with a stabilizer.
41. Walking while holding an object.
8.2.3. Procedure

The 41-item questionnaire was administered separately to the children and to their parents in order to compare the reliability of the reported perceptions. The activities were presented in a random order to avoid any systematic effect. Ten different random orders of presentation were used. Each item was presented verbally to the child by the examiner, while the parents completed the questionnaire by themselves in another room. For each question, the children and their parents were asked to estimate, using a three-level rating scale (0=impossible, 1=difficult, and 2=easy), their perceived difficulty in performing that locomotion activity. Activities not attempted in the last 3 months or those for which they could not estimate the difficulty, were not scored and were encoded as missing responses. However, when an activity was never attempted because it was impossible, it was scored as «impossible».

8.2.4. Data Analysis

The responses from the children and those from their parents were analysed separately (RUMM2020 software, RUMM Laboratory Pty Ltd, Perth, Western Australia). The Rasch model (Rasch, 1992) allows the total raw scores to be converted into linear measures. This model requires that only the item difficulty, the patient’s ability and the threshold difficulties determine the probabilities of endorsing any given category. Measurement units are expressed in logits (log-odds units), a probability unit that expresses the natural logarithm of the odds of success (i.e., the pass to fail probability ratio). At any given ability level, one logit difference between two patients indicates that their odds of successful achievement of any activity are 2.7:1 (i.e., $e^{1}:1$). The logit metric provides a linear unit, representing a fixed increment along the whole scale of the explored variable. Analyses were performed with the rating scale and partial credit models (Andrich, 1996).
Appendix. ABILOCO-kids

8.2.5. Item selection

Successive analyses were used to select the items that constituted the final ABILOCO-Kids scale. Items that did not meet any of the following criteria were eliminated.

The first selection criterion was the frequency of missing values. Only items with a response rate higher than 90%, indicating that the children in our sample commonly attempted them and that these activities are relevant to measure their locomotion ability, were retained.

The second criterion was the order of thresholds between successive response categories (ordered scale). The thresholds of each item correspond to the locomotion ability levels required to have an equal probability of endorsing one response rather than the previous one. If the anticipated order of response categories was verified, subjects with greater locomotion ability should have selected a higher response for any given item and subjects selecting a higher response for a given item should have had greater locomotion ability. When these conditions were not met, the order of thresholds between successive response categories was skewed, indicating that the rating scale was not being used as anticipated for that particular item (Andrich, 1996). Only items with thresholds in the anticipated order were retained.

The third criterion was unidimensionality. The subject’s responses to each item depended only on locomotion ability and not on other patient or item characteristics. Based on the estimated ability of the patient and the estimated difficulty of the item, the expected response of a subject to an item can be computed by the model. The software, through a Chi-square fit statistic (Andrich and Sheridan, 2005), reports the similarity between the observed and the expected responses to any item. The Chi-square fit statistic cumulates the deviations from the model’s expectations. A test of significance is then applied to determine whether the Chi-square is too high to be attributed to random variations. If the p-value was less than 0.05, the item did not fit the unidimensionality criterion and was eliminated (Smith et al., 1998).

The fourth criterion was the Differential Item Functioning (DIF) test (Holland and Wainer, 1993). This allows verification of the invariance of the scale across different subgroups of children with CP. The score observed for an item should not be
influenced by other demographic (e.g., age and sex) or clinical (e.g., type of CP) factors. Hence, children having the same locomotion ability are supposed to obtain the same score on any item, regardless of the other variables. If this is not the case, the item presents a differential functioning.

Three DIF tests were performed on the basis of the following criteria: sex (male versus female), age (≤ 10 versus > 10 years-old) and clinical presentation (hemiplegia, diplegia and quadriplegia [Stanley et al., 2000]).

The fifth selection criterion was redundancy. If two items had the same level of difficulty and were therefore redundant, the activity with the best fit to the unidimensionality criterion (the item with the lowest Chi-square) was retained.

8.2.6. Scale reliability

In Rasch theory, the error measure variance is directly computed from the measurement error accompanying each patient’s ability and item difficulty estimates (Wright and Masters, 1982; Fisher, 1992). A person separation reliability coefficient was determined to be the ratio between the true measure variance (as expressed by the standard deviation corrected for measurement error) and the observed (true + error) measure variance in the sample (Wright and Masters, 1982). Separation can be used to estimate the number of strata that are significantly distinguished within the range of observed patient abilities.

From the 108 children that this study included, 73 participated in a second assessment one month later. The test-retest reliability of the parents’ responses was determined by the intraclass correlation coefficient (ICC) (Shrout and Fleis, 1979). A DIF test was carried out to verify the reproducibility of item hierarchy between the first and the second assessment.

8.2.7. Concurrent validity

The ABILOCO-Kids measures were validated by assessing their relationship with raw scores of the GMFCS using a Spearman correlation coefficient.
8.3. RESULTS

The analysis of the children’s responses resulted in a five-item questionnaire: 10 items were excluded as more than 90% of the children were not able to estimate their difficulty or had not performed that activity in the last three months (e.g., Going up an escalator alone; taking the train or the underground railway); 18 items showed a disordered rating scale (e.g., Striding over an object with the paretic foot first; stepping up a curb alone); three items did not fit a unidimensional scale (e.g., Going up stairs putting each foot on the next step; kicking in a ball with the paretic foot); three items had a DIF (e.g., Going up and down stairs without holding onto the banisters; running on regular and flat ground); and one item was redundant (Running on all types of surfaces). Furthermore, one item was eliminated because most of the children rated it « easy » and this item was, therefore, not relevant. The large number of items showing a disordered rating scale indicated that their perception was more dichotomous. Having difficulty with locomotion activities was perceived by the children as either « impossible » or « easy », with the intermediate category of « difficult » rarely observed.

The analysis of the parents’ responses resulted in a 10-item questionnaire: seven items were excluded according to the first selection criterion (e.g., Taking the train or the underground railway; ice-skating, skate-boarding, roller-skating); eight items showed a disordered rating scale (e.g., Going up and down stairs holding onto the banisters; walking more than five meters alone, indoors, on flat ground without an assistive device); eight items did not fit a unidimensional scale (e.g., Kicking in a ball with the paretic foot; running with a bike with a stabilizer); seven items had a DIF (e.g., Running on all types of surfaces; striding over an object with the paretic foot first); and one item was redundant. The partial credit model was retained because it allowed us to maintain more items and to discriminate the locomotion ability with a greater resolution than the rating scale model.

The subjects’ measures and the item threshold distributions for both the parents’ and the children’s scales are presented in Figure 1. The items are well-targeted on the subjects in both scales. Both scales have a comparable floor effect, but the children’s scale has a greater ceiling effect. Forty-two children with CP considered themselves
able to perform all the locomotion activities easily. The parents’ scale covers a wider range of measurements than the children’s scale, indicating a more precise perception of item difficulties. Subjects’ measures are estimated over a range of 9.03 logits by the parents while they cover 5.70 logits according to the children’s perceptions. Consequently, locomotion ability can be discriminated with a 27 times greater resolution than when using the parents’ perception rather than the children’s.

Figure 1

![Figure 1](image)

**Figure 1**: Locomotion ability scales as perceived by the parents (10 items, 20 thresholds, left panel) and by the children (5 items, 10 thresholds, right panel) and the corresponding distribution of the subjects (top panels). The item threshold locations are well-targeted on the subject measures on both scales. The floor and the ceiling effects are denoted by the number of children (C) with extreme scores (minimum or maximum) as indicated in the upper corner of the top panels.

Because it allowed a greater discrimination of the three-level rating scale and a wider range of measurement, the final version of the ABILOCO-Kids questionnaire was built exclusively on the parents’ perceptions.
The calibration of the final 10-item ABILOCO-Kids scale is presented in Table IV A. The items are listed, from top to bottom, in order of decreasing difficulty (range: +2.29 to -4.07 logits). Higher logit values represent more difficult activities that require a greater locomotion ability to be performed successfully. This table also shows the standard error (SE) associated with each item difficulty (range: 0.23 to 0.37 logits; mean: 0.27 logits) and the fit statistic computed as a Chi-square ($\chi^2$). A p-value greater than 0.05 indicates that all 10 items contributed to the definition of a unidimensional measure of locomotion ability in our sample. The calibration of the final five-item ABILOCO-Kids scale, elaborated following the children’s perception, is presented in Table IV B.

The ABILOCO-Kids scale and the children’s locomotion abilities are shown in Figure 2. The distribution of the children’s locomotion abilities is presented in the top panel, ranging from -4.71 to +4.31 logits. This illustrates the wide range of locomotion abilities encountered in this study and explored by the ABILOCO-Kids questionnaire.

The bottom panel of the Figure 2 illustrates the ogival relationship between the total raw scores ranging from 0 to 20 and the measures of locomotion ability on the linear scale in logits. The middle panel shows the expected response to a given item as a function of the underlying locomotion ability. By comparing the locomotion ability of a given child to the difficulty of each item, it is possible to determine the expected response of the patient to the item. According to the parents’ perceptions, a child with an ability of -1 logit would be able to perform the tenth activity easily, to perform the middle activities (items 4 to 9) with some difficulty, and would be unable to perform the first three items. According to the distribution of the subjects’ locomotion abilities, 19% of the children in our sample were able to perform all the activities easily and 15% were not able to perform any of the 10 ABILOCO-Kids items. The 10 items explore a wide range of locomotion abilities that are well-targeted to our sample. The patient reliability equals 0.97, indicating that 5.7 statistically different levels of ability can be distinguished in this sample (Fisher, 1992).
Figure 2: Top panel: Distribution of locomotion ability measures of children with CP as perceived by their parents. Twenty-five children with extreme scores cannot be measured by the scale because all activities were either impossible (16C) or easy (9C). Middle panel: A child’s expected response to each item as a function of the underlying measure of locomotion ability. A locomotion ability of zero is by convention set at the average item difficulty. Bottom panel: Ogival relationship between the ABILOCO-Kids total raw score and the locomotion ability measures expressed in logits on the linear scale.

The relationship between ABILOCO-Kids measures and the GMFCS is presented in Figure 3. The ABILOCO-Kids scores correlated well with the results obtained using the GMFCS ($\rho=0.88$, $p<0.001$). On the contrary, the ABILOCO-Kids measures based on children’s perception is not correlated with the GMFCS levels ($\rho=0.393$, $p=0.142$). This supports the selection of the parents’ perceptions. A DIF analysis
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between the children’s and the parents’ perceptions was performed on 10 items from the ABILOCO-Kids questionnaire. Two items presented a DIF between children and parents: “Running correctly even if you have to turn” and “Walking while holding a fragile object (such as a full glass)”.

Figure 3

The test-retest reliability (delay: 25±13 days) of the children’s measures is shown in Figure 4 (right panel). Children’s locomotion abilities measured at the first and second assessment are highly correlated (intraclass correlation coefficient=0.96, p<0.001). 92% of the measures lie inside the 95% CI of the identity line, indicating that parents consistently estimate their child’s ability. The left panel shows the DIF
plot of the item difficulty hierarchy between the first and the second assessment. The ICC is equal to 0.97 (p<0.001), indicating a very good reproducibility of the item hierarchy. Nine of the 10 items lie inside the 95% CI of the identity line.

**Figure 4**

*Figure 4*: Left panel: Differential item functioning plot of the item difficulty perceived by the children’s parents at the first and the second assessment (delay: 25±13 days) and the 95% confidence interval (solid line) of the ideal invariance. Nine of the 10 items lie inside the 95% confidence interval. Right panel: relationship between the children’s locomotion abilities measured at the first and second assessment and the 95% confidence interval (solid line) of the ideal invariance. Measures (dots) lying within the control lines have the same estimated ability at both the first and the second assessments.

In addition, five experts on children with CP were asked to order the 10 items according to difficulty. The similarity in how the items were ordered by the ABILOCO-Kids and by the experts was good (Spearman correlation coefficient=0.78, p<0.01).
8.4. DISCUSSION

This study presents ABILOCO-Kids, a new scale used to measure the walking ability of children with CP that focuses on the ICF Activity domain. A Rasch analysis selected 10 items respecting the principles of linearity, unidimensionality and invariance. The 10 items show a continuous progression in difficulty, are well targeted to our sample and cover a wide range of functional states. Moreover, the parents evaluate their children consistently after about one month.

The 10-item ABILOCO-Kids questionnaire was exclusively built on parents’ perceptions of their children’s abilities. Indeed, the children’s locomotion ability was better discriminated by the parents than by the children themselves. The questionnaire based on children’s perception presents a great ceiling effect, indicating that the children tended to overestimate their ability. The children also seem to poorly estimate their locomotion ability as indicated by the absence of a correlation with their GMFCS levels. In addition, the children perceived the activities as either “impossible” or “easy” with very rare intermediate responses. This rather dichotomous perception is consistent with the Piagetian theory in which young children engage in dichotomous thinking (Chambers and Johnston, 2002). The polychotomous perception of the parents provides a more accurate source of information about locomotion ability than the children’s dichotomous perception. Arnould et al. (2004) obtained similar results when they developed the ABILHAND-Kids questionnaire to assess manual ability in children with CP. The difference in discrimination between parents and children must be interpreted with some caution, given that a face-to-face interview was used for the children and a written self-report for the parents (Arnould et al., 2004). A written self-administered report is more appropriate for a routine clinical use than a face-to-face interview, which may be influenced by the personality and the style of the interviewer and his/her relationship with the subject (Verrips et al., 2001). Moreover, using the parents’ perception should enable locomotion ability to be assessed in all patients with CP, including very young children and those with mental or communicative disorders.
In comparison with the existing scales, the final 10-item questionnaire (ABILOCO-Kids) presents several advantages. The first is linearity. The Rasch analysis allows the conversion of a total raw score into a linear score that may be submitted to arithmetical computation and parametric statistical analysis. In contrast, the FMS and the FAQ are only ordinal scales that provide a total raw score allowing limited computation. The second advantage is unidimensionality, meaning that ABILOCO-Kids only measures locomotion ability and is not influenced by other child characteristics. The GMFM, the PEDI and the ASK have been analysed following the Rasch model, and therefore respect the concepts of linearity and unidimensionality. However their latent variable is physical disability and they do not focus on walking ability. Our preliminary questionnaire specifically explored locomotion and included a large number of locomotion activities that a healthy child realizes during his daily life activity and social participation. The third advantage is the invariance of ABILOCO-Kids across sex, age, and clinical presentation. The WeeFIM is invariant across age in children older than three years of age and the GMFM-66 is invariant across age and disability. Other scales could not be invariant. Indeed, several activities included in the GMFM and the PEDI scales (e.g., stepping up a curb alone, striding over an object) presented a DIF and were disregarded after the Rasch analysis. ABILOCO-Kids also provides good test-retest reliability. Finally, ABILOCO-kids can be easily incorporated into clinical practice. The parents can fill out the questionnaire in the waiting room in just a few minutes. Other questionnaires (PEDI, ASK, WeeFIM and GMFM-66) require a greater amount of time and a skilled staff.

The concurrent validity of ABILOCO-Kids is supported by the correlation between the ABILOCO-Kids results and the GMFCS classification. However, the ABILOCO-Kids questionnaire is more precise. Indeed, 45% of our patients obtained the maximum GMFCS score (Level I), indicating a ceiling effect. Among these patients, the ABILOCO-Kids questionnaire can discriminate a wide range of locomotion ability from 1.07 to 5.22 logits.
The item hierarchy corresponds to the rehabilitation staff experience. The item «walking less than five meters, indoors, holding onto pieces of furniture» is the easiest activity (item 10) corresponding to the locomotion activity usually acquired first by children (Woollacott et al., 2004). Going up and down stairs without holding onto the banister (item 1) requires good balance and sufficient strength in both legs, and is naturally more difficult than going down or up stairs putting each foot on the next step (item 7-8). Running (item 2) requires more stamina and muscular strength than walking. Item 4 «walking while holding a fragile object» requires the ability to perform dual tasks at the same time (Bowen, 2001) and requires considerable concentration. The item hierarchy is also related to the clinical presentation. The locomotion ability of the quadriplegic children is distributed from -5.71 to +3.04 logits (mean: -3.54±2.84), of the diplegic children from -4.72 to +4.31 logits (mean: 0.48±3.13), and of the hemiplegic children from -5.71 to +5.22 logits (mean: 2.69±2.35). Thus, on average, the hemiplegic children have greater locomotion ability than the diplegic children, and diplegic children have greater locomotion ability than the quadriplegic children. Furthermore, according to their parents, 15% of the children with CP were not able to perform at least one item, and 94% of these children are quadriplegic. Similarly, the 19% of the children with CP who were able to perform all items easily are all hemiplegic or diplegic.

Tests measuring walking speed in a hospital environment are useful and well validated (Mc Dowell et al., 2005). These tests provide continuous results that can be submitted to parametric statistics, and they have a greater responsiveness than ordinal scales. However, this walking speed test describes a child’s performance under a particular set of circumstances and may not reflect locomotion ability under different conditions. The ABILOCO-Kids is, therefore, complementary to the walking test. Both tests can be performed easily in only a few minutes; the ABILOCO-Kids can also be self-administered. Our questionnaire is also complementary to instrumented gait analysis.

Initially, we hoped to develop a questionnaire that was adapted to assess locomotion ability among children and adults with brain lesions. This is why we selected both adult and children’s activities. The preliminary questionnaire was submitted to 113
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CP children and to 100 adult stroke patients. Rasch analysis revealed different item selection, calibration and item functioning between adults and children. It was then impossible to build a similar scale adapted to both adult stroke patients and to children with CP. The 13-item questionnaire assessing locomotion ability in stroke patients is presented as ABILOCO (Caty et al., 2008).

From a practical point of view, whenever a clinician wants to assess the locomotion ability of a child with CP, he asks the parents to complete the ABILOCO-Kids questionnaire. The parents are asked to estimate the child’s ability to perform each of the 10 ABILOCO-Kids activities as «Impossible», «Difficult» or «Easy». The activities not attempted by the child within the last 3 months are not scored and are considered as not applicable. The activities that the child does not perform because they are too difficult are scored as «Impossible». This assessment can be done during a regular consultation to assess the evolution of the child’s locomotion ability as a function of growth. This can also be done before and after a therapeutic intervention (e.g. orthopaedic surgery, Botulinum toxin injection or orthosis), in clinical practice or in a research protocol. A website (www.rehab-scales.org) is accessible to perform online analyses to convert total raw scores into linear measures expressed in logits.

In conclusion, ABILOCO-Kids is a questionnaire that assesses the walking ability of children with CP, focusing on the ICF Activity domain. Elaborated following a Rasch analysis, this scale presents good psychometric qualities (reliability, linearity, unidimensionality, invariance and reproducibility). Its responsiveness should be tested in the future.
9. Annexe

The 43-item preliminary ABILOCO questionnaire

1. Running on all types of surfaces.
2. Walking between parallel bars.
3. Walking alone outside on all types of surfaces.
4. Taking the train or the underground railway.
5. Walking while holding a fragile object (such as a full glass).
6. Kicking a ball with the paretic foot.
7. Walking several minutes at the same speed as a healthy child.
8. Going up stairs putting both feet on each step.
9. Stepping up a curb alone.
10. Running correctly even if you have to turn.
11. Walking few steps with the help of a person.
12. Walking more than five meters with a rollator.
13. Walking with the help of a person who guides but doesn’t support.
14. Walking more than five meters with a crutch.
15. Walking more than five meters alone, indoors, on flat ground without an assistive device.
16. Jumping the height of one step of stairs.
17. Hopping on the healthy foot.
18. Going down stairs putting both feet on each step.
19. Turning and walking in a narrow place.
20. Walking less than five meters, indoors, holding onto pieces of furniture.
21. Ice-skating.
22. Taking the bus alone.
23. Running on regular and flat ground.
24. Walking less than five meters alone without the help of a person.
25. Going up and down stairs without holding onto the banisters.
26. Running with a tricycle.
27. Kicking a ball with the healthy foot.
28. Skipping rope.
29. Going down stairs putting each foot on the next step.
30. Hopping on the affected foot.
31. Striding over an object with the paretic foot first.
32. Walking more than five meters, alone, outside on flat ground.
33. Walking with the help of two persons who support.
34. Striding over an object with the healthy foot first.
35. Running with a bike.
36. Going up an escalator alone.
37. Going up and down stairs with the help of a handrail.
38. Walking backwards.
39. Going up stairs putting each foot on the next step.
40. Running with a bike with a stabilizer.
41. Walking while holding an object.
42. Skate boarding.
43. Roller-skating.