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**THE DISCRIMINATIVE VALIDITY
OF THE
McGILL INGESTIVE SKILLS ASSESSMENT (MISA)**

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ABSTRACT

Introduction: Stroke is associated with a high prevalence of dysphagia in the elderly population. Hence, dysphagia evaluation and management are key issues in stroke rehabilitation. The McGill Ingestive Skills Assessment (MISA) is a recently developed mealtime observational tool aimed at evaluating the functional aspects of the oral phase of ingestion. **Objective:** To determine the discriminative validity of the MISA by assessing known/extreme groups of elderly individuals presenting with stroke, who have been admitted to an acute-care-hospital or a rehabilitation center. Participants were allocated to one of two groups: 1) individuals with stroke and no dysphagia, who are on a regular diet and 2) individuals with stroke and dysphagia, who are permitted only purees. **Methods:** Participants were evaluated with the MISA and a comprehensive chart review was conducted. **Analysis:** Groups were compared on socio-demographic and clinical characteristics. Univariate tests were performed to test the significance of between-group differences. **Conclusion and significance:** The results of the study are satisfactory, and enhance the clinical usefulness of the tool for dysphagia management. These results also support future studies addressing the responsiveness of the MISA.

ABRÉGÉ

L'accident vasculaire cérébral (AVC) est associé à une haute prédominance de la dysphagie chez la population âgée. Ainsi, l'évaluation et la gestion de la dysphagie sont des éléments clés dans la réhabilitation de l'AVC. L'Évaluation des Capacités d'Ingestion de McGill (ÉCIM) est un instrument d'observation (de repas) récemment développé qui permet d'évaluer les aspects fonctionnels de la phase orale d'ingestion. **Objectif:** Déterminer la validité discriminatoire de l'ÉCIM en évaluant des groupes connus/extrêmes d'individus âgés, qui présentent avec AVC et, qui ont été admis soit à un hôpital de soins aigus ou à un centre de réadaptation. Les participants ont été classés dans un des deux groupes, soit: 1) les individus avec AVC et sans dysphagie, sur diète régulier et 2) les individus avec AVC et dysphagie, à qui on permet uniquement des purées. **Méthodes:** Les participants ont subi l'ÉCIM ainsi qu'une évaluation complète de leur dossier médical. **Analyse:** Les groupes ont été comparés quant aux caractéristiques sociodémographiques et cliniques. Les analyses ont été exécutées afin d'évaluer la signification des différences entre-groupe. **Conclusion et signification :** Les résultats de cette étude sont satisfaisants et améliorent l'usage clinique de l'instrument pour la gestion de la dysphagie. Ces résultats soutiennent également des études futures en adressant la sensibilité de l'ÉCIM.

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GLOSSARY

1. **Dysphagia:** ‘Dysphagia’, according to its Latin roots, is a term used to describe ‘difficulty with swallowing’ (dys = difficult, phagia = swallow) or ‘impaired swallowing ability’.
2. **Ingestion:** Ingestion by definition (Merriam-Webster’s Collegiate Dictionary, 1993) refers to “the act of taking in (food and drink) for digestion”. It is this definition that will be employed for the purpose of this review.
3. **Texture (as in ‘solid texture’):** “The textural properties of a food are that group of physical characteristics that arise from the structural elements of the food, are sensed primarily by the feeling of touch, are related to the deformation, disintegration and flow of the food under a force, and are measured objectively by functions of mass, time and distance” (Bourne, 1994).
4. **Viscosity (as in ‘liquid viscosity’):** It is defined as the internal friction of a fluid or its tendency to resist flow.
5. **Silent aspiration:** Silent aspiration is defined as “foreign material entering the trachea or lungs without an outward sign of coughing or respiratory difficulty by the patient” (Boyce, Potter-Boyne, Dziobek, & Solomon, 1991).

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Chapter 1: LITERATURE REVIEW

1.1 Chapter overview

Chapter 1 is comprised of an introduction and a literature review. The introduction provides a brief review of the basic physiology of normal ingestion and dysphagia, in order to highlight the main differences between the two. It also explores the International Classification of Functioning, Disability and Health (ICF; WHO, 2001) and its clinical relevance with respect to the evaluation and management of dysphagia. The literature review is divided into two sections. The first section pertains to stroke research, such as the frequency of stroke, clinical features and functional recovery following stroke. Section two addresses the natural history, evaluation and management of dysphagia.

1.2 Introduction: Stroke and dysphagia

Dysphagia following an acute stroke is common and may affect approximately 28-65% of all patients with stroke (Barer, 1989; Gordon, Hower, & Wade, 1987; Hamdy et al., 1998; Lambert, Gisel, Groher, Abrahamowicz, & Wood-Dauphinee, 2005; Logemann, Veis, & Colangelo, 1999; Lugger, 1994; Mann, Hankey, & Cameron, 1999; Paciaroni et al., 2004; Park & O'Neil, 1994; Smithard et al., 1997; Smithard et al., 1996; Wiles, 1991). Some of the major complications associated with dysphagia include dehydration, aspiration, malnutrition, pneumonia, impaired cerebral perfusion and renal failure which significantly affect the level of morbidity and in severe cases even mortality (Barer, 1989; Finestone & Greene-Finestone, 2003; Gordon et al., 1987; Smithard et al., 1997). Secondary consequences of dysphagia include: social isolation (Layne, 1990), respiratory illness aggravated by aspiration (Feinberg, 1997), as well as depression of immune function, due to poor nutritional state (Pennington et al., 1996). Hence, stroke with dysphagia, has a major impact on an elderly individual's health status and function and makes an increased demand on resources in the health care system.

'Dysphagia', according to its Latin roots is a term used to describe 'difficulty with swallowing' (dys = difficult, phagia = swallow) or 'impaired swallowing ability'. The four phases associated with swallowing are the preparatory, oral, pharyngeal, and esophageal phases (Dodds, Stewart, & Logemann, 1990). Dysphagia research literature shows inconsistency in the use of the term 'dysphagia'. Although the term 'swallowing' most accurately refers to the reflex that occurs

in the pharyngeal phase of ingestion, ‘dysphagia’ (i.e., ‘swallowing difficulties’) is often used as a synonym for difficulties in any or all of the four phases. Faced with this predicament, Leopold and Kagel (1997) and Lambert, Gisel, Groher, Abrahamowicz and Wood-Dauphinee (2003) proposed the use of the term ‘ingestion’. Ingestion by definition (Merriam-Webster’s Collegiate Dictionary, 1993) refers to “the act of taking in (food and drink) for digestion”. It is this definition that will be employed for the purpose of this review.

1.2.1 Physiology of Ingestion

Ingestion is comprised of four phases: preparatory, oral, pharyngeal, and esophageal (Dodds et al., 1990). The preparatory phase is a voluntary phase, which refers to the procurement of food and its delivery into the mouth (oral cavity). Mastication and bolus formation are the key elements of the oral phase and terminate with propulsion of the bolus from the oral cavity into the oropharynx (Hiimae & Palmer, 1999). The swallow is triggered voluntarily by pressure from the bolus (Logemann, 1983). The pharyngeal phase involves a rapid sequence of events: elevation of the soft palate, upward and forward movement of the hyoid bone and larynx, closure of the vocal folds and backward movement of the epiglottic fold to protect the airway. The tongue pushes backward and downward into the pharynx to propel the bolus downwards. The upper esophageal sphincter (UES) relaxes during this phase of ingestion and is opened by the forward movement of the hyoid bone and larynx (Dodds et al., 1990). The UES closes after passage of the food and the pharyngeal structures then return to their rest position. Contraction of the pharyngeal wall assists propulsion of the bolus into the esophagus. In the esophageal phase, the bolus is moved downward by peristalsis (alternating contraction and relaxation of the muscles lining the esophagus). The lower esophageal sphincter (LES) relaxes and the bolus is propelled into the stomach.

1.2.2 Physiology of Dysphagia (Ingestive Difficulties)

Dysphagia may be classified according to the ingestive phase that is affected. Disorders of the preparatory and oral phases of ingestion often result from poor oro-motor skills (decreased range of movement, strength and/or control). Individuals with difficulty in these phases frequently present with problems chewing solids and initiating swallows. With liquid boluses, these individuals have difficulty holding the liquid in the oral cavity before they swallow. As a result, liquid spills prematurely into the pharynx, and this often results in aspiration.

With dysfunction of the pharyngeal phase of swallowing, food transport to the esophagus may be impaired. As a result, food is retained in the pharynx after a swallow. In individuals with normal ingestive skills, small amounts of food are commonly retained in the valleculae or pyriform sinuses after swallowing (Palmer, Rudin, Lara & Crompton, 1992). With obstruction of the pharynx and weakness or decreased coordination of the pharyngeal muscles, patients may retain excessive amounts of food in the pharynx and experience overflow-aspiration just after swallowing (Dodds et al., 1990). If pharyngeal clearance is severely impaired, patients may be unable to ingest sufficient amounts of food and drink to sustain life. In addition, weakness of the soft palate and pharynx may lead to nasal regurgitation of food.

Impaired esophageal function can result in the retention of food and liquid in the esophagus after swallowing (Castell, 1990). This retention may occur because of mechanical obstruction, a motility disorder or impaired opening of the LES. Similar to the disorders of the pharyngeal phase, the esophagus may be obstructed, or the musculature may be weak or poorly coordinated. Although not a swallowing disorder per se, gastroesophageal reflux disease (GERD) is a closely related problem and may contribute to aspiration (Castell, 1990).

1.2.3 Theoretical Framework

The International Classification of Functioning, Disability, and Health (ICF) provides a conceptual framework for the interactions among the various factors that play a role in dysphagia evaluation and management. The ICF facilitates the organization of information about the different factors, such as the health condition (disorder/disease) and the contextual factors (personal and environmental), that affect/contribute to functioning and disability (activities and participation).

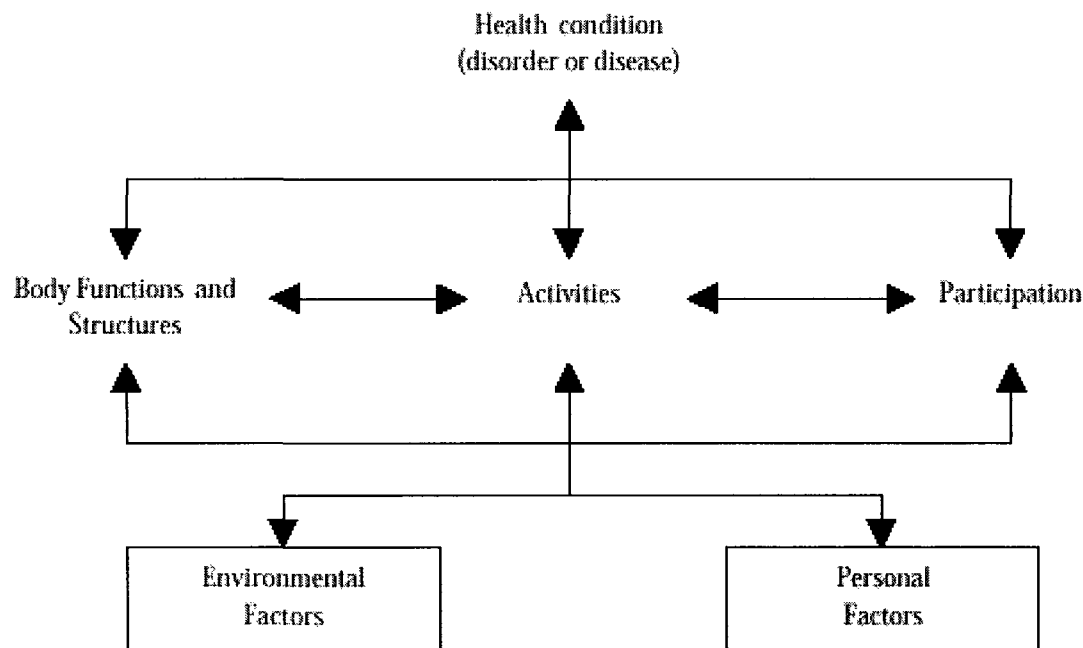


Fig. 1.2.3.1: International Classification of Functioning, Disability and Health (ICF) - Interaction of Concepts (ICF 2001)

The ICF model is relevant in our study for three main reasons: 1) with respect to dysphagia evaluation, the model may be used to classify the various assessments according to the domain(s) that they evaluate. 2) The McGill Ingestive Skills Assessment (MISA) was designed based on the ICF and 3) it offers a framework for complex, multi-faceted dysphagia management approaches.

The five scales of the MISA (self-feeding, texture management, solid ingestion, liquid ingestion and positioning) address different aspects of the ICF to varying degrees. For example, ‘self-feeding’ contributes mainly to the ‘participation’ component of the ICF as well as the ‘activities’ component, however it also makes a contribution to ‘body functions and structures’ with respect to the movement and coordination required. Under ‘activities’ we have the solid ingestion, liquid ingestion, and texture management scales, which also overlap with the ‘body functions and structures’ component, in terms of the associated sensory stimulation and motor functions. The positioning scale may be influenced by all three levels of the classification, in that the environment (physical and social) impacts on an individual’s posture during the meal – whether by the use of positioning devices or verbal cueing from care-givers, etc.

For research outcomes to be translated into holistic, person-centered clinical practice, a non-linear approach is imperative. Due to its multidimensional nature, the ICF model fits well into the conceptual framework of dysphagia evaluation and management and hence, will be used for the purpose of our research study.

The ICF model places equal emphasis on the influence of personal and environmental elements on a person's overall health and well-being. The MISA addresses this by way of evaluating individuals in their regular mealtime environment. The ICF also acknowledges that the context in which people live plays a central role in the expression of their capacity to function. In the context of feeding difficulties, this may mean environmental adaptations, such as decreased distractions during feeding and/or the use of adapted utensils, which may enhance functional abilities. Furthermore, the social and cultural environment must be considered during assessment and intervention, since we know that people's attitudes, values and beliefs affect their participation in daily activities (Law, King, & Russell, 2001).

1.3.1 Frequency of stroke

According to Canadian Statistics (Health Canada, 2008), stroke is the fourth leading cause of death. There are over 50,000 strokes each year and about 300,000 Canadians are living with the effects of stroke (Heart and Stroke Foundation, 2008). Due to the demographic shift and increasing life expectancy, there continues to be a dramatic increase in the size of the elderly population. This is significant because evidence suggests that the stroke rate more than doubles in individuals aged 55 years and over (Brown, Whisnant, Sicks, O'Fallon & Wiebers, 1996; Wolfe et al., 1992). As well, individuals who have had a stroke have a 20% chance of having another stroke within 2 years (Heart and Stroke Foundation, 2008).

1.3.2 Clinical features of stroke

The symptoms and neurological consequences of a stroke depend on the type of stroke, the area of the brain that is affected and the severity of brain damage. About 80% of all strokes are caused by primary cerebral ischemia resulting in infarction; whereas, the remaining 20% are caused by cerebral hemorrhage (Capildeo, Haberman & Rose, 1978; Foulkes, Wolf, Price, Mohr & Hier, 1988). Ischemic strokes include embolic, thrombotic and lacunar infarcts. Infarcts of unknown etiology account for approximately 30% of ischemic strokes. Hemorrhagic strokes are further classified into intra-cerebral or subarachnoid hemorrhagic strokes (Sarner & Rose, 1967).

Ischemic stroke is usually associated with insidious onset of symptoms; however signs of hemorrhagic stroke usually develop gradually. Stroke is a clinical diagnosis, but brain imaging using Computer Tomography (CT) and/or Magnetic Resonance Imaging (MRI) scans is required to distinguish between ischemic strokes and intra-cerebral hemorrhagic strokes. In contrast, subarachnoid hemorrhage is usually easily distinguished by its presentation with sudden-onset (“thunderclap”) headache and signs of meningism (meningeal irritation associated with acute febrile illness or dehydration) and neck stiffness (Bamford, Sandercock, Dennis, Burn & Warlow, 1991).

Strokes may also be classified anatomically (Capildeo, Haberman & Rose, 1978). The brain is divided into four primary anatomic regions: the right hemisphere, the left hemisphere, the cerebellum and the brain stem.

In strokes affecting the right hemisphere of the brain, which controls the movement of the left side of the body and analytical and perceptual tasks, patients often experience left hemiplegia and may also have problems with their spatial and perceptual abilities, such as left-sided hemi-neglect. These individuals may also present with impaired judgment, increased impulsivity and decreased short-term memory.

Left-hemispheric strokes are characterized by right hemiplegia and are often associated with aphasia. Individuals with strokes of the left-hemisphere present with diminished executive cognitive functioning and have difficulty learning new information or conceptualizing and generalizing skills and tasks.

The cerebellum controls many of our reflexes and much of our balance and coordination. A stroke that takes place in the cerebellum can cause abnormal reflexes of the head and trunk, decreased coordination and balance, dizziness, nausea and vomiting.

Brain stem strokes are especially debilitating as the brainstem controls involuntary functions, such as breathing rate, blood pressure and heartbeat. The brain stem also controls eye movements, hearing, speech and swallowing. Since the nerve impulses that elicit upper and lower extremity movement and coordination, are generated in the hemispheres and then

conducted through the brain stem to the extremities, patients with a brain stem stroke may also develop paralysis in one or both sides of the body.

1.3.3 Pathophysiology of stroke and functional recovery

In the early phase following stroke, there is prompt initial improvement in function as the pathologic processes associated with the ischemic metabolic injury or hemorrhage resolve. This is referred to as natural spontaneous neurological recovery, and it may be facilitated by pharmacological intervention, such as tissue plasminogen activator (tPA) administration (National Institute of Neurological Disorders and Stroke, NINDS; 1995). The time frame for recovery of function in the reversibly injured neurons is relatively short, accounting for improvement in the first several weeks (Duncan & Lai, 1997). The ongoing improvement in neurological function occurs by a different set of mechanisms that allow for structural and functional reorganization within the brain. The processes involved in this cortical reorganization represent neuroplasticity and may continue for many months following the stroke. The mechanisms of neuroplasticity include restitution of partially damaged pathways, by collateral sprouting from intact cells to the denervated region and expansion of representational brain, by recruitment of neurons that are not usually designated for that activity and play an important role in stroke recovery (Saper, Iverson & Frackowiak, 2000; Cauraugh and Kim, 2003).

The prognosis for functional recovery in stroke is influenced by neurological, functional, and psychosocial factors (Duncan et al., 1992; Hosek et al., 1986; Alexander 1994; Heinemann et al., 1994; Hyman, 1972). The most significant neurological and functional post-stroke recovery occurs within the first six months following a stroke, although as many as 5% of individuals continue to show measurable progress up to 12 months, especially with respect to language and visuo-spatial functions (Bader & Palmer, 2006; Kalra & Langhorne, 2007; Duncan & Lai, 1997; Kelly-Hayes, Wolf, Kase et al., 1989; Skilbeck, Wade, Hewer et al., 1983). Mobility impairments and partial to total dependence in activities of daily living (ADL) are common during the acute post-stroke period. However, most patients demonstrate higher levels of independence within a year (Dombovy, 1993; Ahlsio, Britton, Murray & Theorell, 1984; Dombovy, Basford, Whisnant, & Bergstralh, 1987; Wade & Hewer, 1987; Cohen & Hallett, 2003).

1.4.1 Dysphagia - Natural History

Only a few studies address the natural history of dysphagia following an acute stroke. Gordon et al. (1987) conducted a prospective study to define the incidence, duration, and consequences of dysphagia in the acute stroke phase. They reported that spontaneous recovery occurred within 8 days in 37% of the patients and within 14 days in 86% of patients. A slightly higher percentage of recovery was reported by Barer (1989). His study showed that 50% of patients with dysphagia following stroke recovered by day seven and at the end of four weeks 98% of the patients had recovered (Barer, 1989). Similar results were obtained by Smithard et al. (1997) and Hamdy et al. (1998). Results by Smithard et al. (1997) indicated that the majority of individuals (63% of 121 patients) recovered spontaneously in the first few weeks in the acute, post-stroke phase. Hamdy et al. (1998) reported that at presentation, 71% of patients with stroke had dysphagia. Of the total group of patients who recovered swallowing function spontaneously, 75% did so in the first month and the rest in the third month post stroke. All patients with persistent dysphagia had moderate to severe dysphagia, which is consistent with earlier findings.

One of the main problems in studying the natural history of dysphagia is the lack of consensus with respect to the most appropriate and psychometrically sound diagnostic tool. The studies by Gordon et al. (1987) and Barer (1989) relied solely on bedside clinical examination to diagnose dysphagia. The studies by Hamdy et al. (1998) and Smithard et al. (1997) used Video Fluoroscopy (VF) in addition to a standardized bedside clinical assessment. From the literature, it is evident that only a minority (approximately 2%) of patients with dysphagia following stroke do not recover spontaneously and are severely affected. These individuals have a higher risk of pulmonary infection, malnutrition, prolonged hospital stay and in severe cases even mortality (Barer, 1989; Gordon et al., 1987; Holas, DePippo, & Reding, 1994; Nilsson, Ekberg, & Olsson, 1996; Smithard et al., 1997). Hence, early and accurate diagnosis of dysphagia is crucial for these individuals.

1.4.2 Dysphagia Assessment

The two main categories of dysphagia assessments are bedside assessments and instrumental evaluations. Bedside evaluation of dysphagia aims at identifying possible causes, establishing a baseline and the severity, investigating the most appropriate feeding options and determining the need for an instrumental evaluation. Instrumental evaluation of dysphagia

contributes to the accuracy of defining the physiological aspects of ingestive difficulties. In elderly individuals, instrumental evaluation of dysphagia raises a number of issues with respect to the appropriateness, practicality and feasibility.

1.4.3 Bedside Assessment of Dysphagia

Over the years, several types of bedside ‘swallow’ assessments have been used to evaluate patients with dysphagia following an acute stroke. Many researchers have assessed difficulty in drinking small volumes of water (Barer, 1989; Gordon et al., 1987; Gottlieb, Kipnis, Sister, Vardi, & Brill, 1996). Timed tests of swallow capacity have noted the time and number of swallows required to swallow 150 ml of water and have shown that delayed swallowing, coughing, or dysphonia indicated swallowing problems (Hinds & Wiles, 1998). DePippo, Holas and Reding (1992) compared a 3-oz water swallow test with VF, showing that patients who coughed during or after swallowing or those who developed a wet or hoarse voice were at risk of aspiration. Daniels, McAdam and Foundas (1997) performed an oropharyngeal examination and a clinical swallowing assessment using different volumes of water. The presence of two or more of the following features: dysphonia, dysarthria, abnormal volitional cough, abnormal gag reflex, voice change after swallow and cough after swallow, predicted greater dysphagia severity on VF. McCullough, Wertz and Rosenbek (2001) used a similar assessment and found ‘cough during swallowing’ and ‘clinical estimate of the presence of aspiration’ to be reliable items for detection of aspiration. Smithard et al. (1998) used 5 ml of liquid and then a larger volume (60 ml), to assess laryngeal movement, cough, dysphonia, and the time taken to finish the drink. Teramoto and Fukuchi (2000) studied patients with aspiration pneumonia and non-acute stroke. They developed a 2-step swallowing provocation test that involved injecting boluses (0.4 and 2 ml) of water into the suprapharynx of a supine patient and noting the latency time for swallowing. The test identified patients with aspiration pneumonia, but sample sizes were small. The results of these studies seem to strongly suggest and support the use of the water swallow tests for detecting aspiration. However, it is important to note that although the presence of an abnormal, volitional cough (Daniels et al., 1998; Gordon et al., 1987; Horner, Brazer, & Massey, 1993; Horner & Massey, 1988) and the absence of a pharyngeal gag reflex (Daniels et al., 1998; Gordon et al., 1987; Horner & Massey, 1988; Linden & Siebens, 1983; Logemann et al., 1999) have been identified by some researchers as signs of aspiration in patients with stroke, others have found no significant relationship between an

abnormal, volitional cough or the lack of a pharyngeal gag reflex and aspiration (Linden, Kuhlemeier, & Patterson, 1993).

Splaingard, Hutchins, Sulton and Chaudhuri (1988) monitored swallowing of various volumes and consistencies of food while watching for respiratory distress and compared the results with VF findings. Horner and colleagues (1988, 1993) used similar methods of evaluation as Splaingard et al. (1988) in a small sample of patients and found that a weak cough and dysphonia correlated with aspiration on VF. Once again, the significance of these findings may be refuted in light of the results of the studies by Linden et al. (1993).

Linden and Siebens (1983) performed a sensorimotor examination, observed swallowing and related movements, and found a high incidence of impaired pharyngeal gag and dysphonia in patients exhibiting laryngeal penetration. Linden et al. (1993) used the Dysarthria/Dysphagia Battery - a clinical battery of questions about respiration, anatomy, drooling, and parenteral feeding. Factors predictive of sub-glottic penetration on VF included recumbent posture, abnormal phonation, abnormal laryngeal elevation, abnormal palatal gag, wet spontaneous cough, and impaired swallowing of secretions. Addington, Stephens and Gilliland (1999) used a reflex cough test. A weak or absent cough was regarded as predictive of aspiration risk. An absent gag reflex has been suggested as predictive of aspiration in some studies (Daniels et al., 1998; Horner et al., 1993; Linden et al., 1993; Linden & Siebens, 1983) but has been refuted in others (Horner & Massey, 1988; McCullough, Wertz, & Rosenbek, 2001; Smithard et al., 1998; Stanners, Chapman, & Bamford, 1993). Davies, Kidd, Stone and MacMahon (1995) have demonstrated that up to 30% of healthy younger adults and 44% of healthy older adults may have unilateral or bilateral absent gag reflexes. Absent pharyngeal sensation is rare in normal patients. However, in studies by Davies et al. (1995) and Kidd, Lawson, Nesbitt and MacMahon (1993), abnormal pharyngeal sensation was noted in all patients with stroke who aspirated on VF. Aviv et al. (1998) developed a method of testing laryngopharyngeal sensation by stimulating the mucosa endoscopically with air pulses and determining sensory discrimination thresholds. Most patients with a diagnosis of dysphagia, secondary to stroke or chronic neurological disease, showed sensory deficits when tested. Aspiration or penetration was more common in those with severe deficits. Sensory deficits were also demonstrated in patients with acute stroke without clinical dysphagia (Aviv, 1997). It has also been suggested that silent sensory deficits may predispose individuals to silent aspiration (Aviv,

1997). Silent aspiration is defined as “foreign material entering the trachea or lungs without an outward sign of coughing or respiratory difficulty by the patient” (Boyce, et al., 1991).

The validity of most ‘swallow’ tests has been determined by comparison with VF. Detection of aspiration by bedside testing has been variable, with sensitivities between 42% and 92% and specificities between 59% and 91% (Daniels, McAdam, & Foundas, 1997; DePippo, Holas, & Reding, 1992; Smithard et al., 1998; Splaingard, Hutchins, Sulton, & Chaudhuri, 1988). Positive predictive values for testing of bedside swallow range from 50% to 75%; negative predictive values range from 70% to 90% (Smith, Lee, O’Neil, & Connolly, 2000; Smithard et al., 1998; Splaingard et al., 1988), suggesting that further investigation of psychometric properties of tests and/or development of new tests are required.

Inter-rater and intra-rater reliability levels for clinical examination vary considerably between studies (32% to 91%), as reported by Ellul and Barer (1996), Mann, Hankey and Cameron (2000), McCullough et al. (2001) and Smithard et al. (1998). The latter calculated values for inter-rater agreement on diagnosis of ‘dysphagia or aspiration’ respectively, by 2 speech pathologists and found that agreement for the clinical diagnosis of a swallowing disorder ($k: 0.82 \pm 0.09$) and aspiration ($k: 0.75 \pm 0.09$) was ‘good’ and the inter-rater agreement between a speech pathologist and radiologist for the videofluoroscopic diagnosis of a swallowing disorder ($k: 0.75 \pm 0.09$) and aspiration ($k: 0.41 \pm 0.09$), was ‘good’ and ‘fair’ respectively – which supports their statement regarding the differences in levels of reliability (Smithard et al., 1998). These differences may be reflective of differences in the focus of dysphagia assessments that may exist among the various health care professions. The study by Smithard et al. (1998) found better agreement between assessments by speech therapists ($k=0.79$; 95% CI, 0.55 to 1.0) than between doctors ($k=0.5$; 95% CI, 0.26 to 0.73). Values for agreement between a doctor and a therapist were ‘moderate’ to ‘substantial’ ($k>0.5$). Ellul and Barer (1996) looked at inter-rater reliability of a bedside swallow assessment performed predominantly by nursing staff and found highly variable values, ranging from $k=0.19$ to 1.0. McCullough et al. (2000) studied reliability between speech pathologists performing a clinical swallow examination and also found wide-ranging values for both inter-rater and intra-rater reliability for the measures studied. These wide-ranging values of inter- and intra-rater reliability have a great impact on the diagnosis of dysphagia and the variation in dysphagia management strategies employed. Hence, the use of a standardized clinical evaluation would be highly beneficial.

Traditional functional feeding bedside assessments include Evaluation of Oral Function in Feeding (Stratton, 1981) and the Functional Feeding Assessment (FFA), which is a sub-scale of the Multidisciplinary Feeding Profile developed by Kenny et al. (1989). The Evaluation of Oral Function in Feeding (Stratton, 1981) has no published psychometric information regarding the validity of the assessment and there has also been no reported use of the assessment with a geriatric population. With respect to the FFA, although validity of the tool for use with children was established (Gisel & Alphonse, 1995), its use with an elderly population is limited (Lambert & Gisel, 1994). More recently, a bedside screening assessment of swallowing which focuses on the physiological aspects of swallowing (during the pharyngeal phase) was developed by Mann (2002). In the same year, Martino, Pron and Diamant (2004) developed a tool for the screening of oro-pharyngeal dysphagia and for predicting the need for an instrumental evaluation. Both these tools, like most of the tools traditionally used for the evaluation of dysphagia focus on the “physiology” of swallowing. In contrast, the McGill Ingestive Skills Assessment (MISA) is a diagnostic tool, designed as a functional feeding assessment of the oral phase of ingestion in elderly patients. The MISA is comprised of 43 items divided into 5 scales: Positioning, Self-feeding, Solid ingestion, Liquid ingestion, and Texture management. Each item on the MISA is scored on a 3–point, ordinal scale. Studies have established the psychometric properties of the MISA (Lambert et al., 2003, 2004, 2005, 2006).

1.4.4 Instrumental Assessment of Dysphagia

Several instrumental assessments of swallowing exist to provide objective information about swallowing function and safety. These include, but are not limited to VF, Fiberoptic Endoscopy, Pharyngeal Manometry, the Exeter Dysphagia Assessment Technique, Cervical Auscultation, Scintigraphy and Timed Drinking Tests. The major critique with respect to these assessment tools is that there are a limited number of published studies to document their psychometric properties and poor evidence for reliability and validity. VF was identified as the most frequently used instrumental method of assessment of the oropharyngeal phase of ingestion. However, because the evaluation occurs under conditions of optimal positioning, this test may not be representative of the individual’s actual position at mealtimes (Drinka & Voeks, 1993). The individual’s swallowing performance may further be influenced by the specific testing environment, which is not familiar to the individual. The fact that individuals need to be

transported to and from the hospital might also affect their performance, because elderly individuals may be frail and may not respond well to environmental changes (Groher, 1994). Hence, VF may not be suitable for the elderly in the acute post-stroke phase (Warlow et al., 2000). Fiberoptic Endoscopy (Kidder, Langmore, & Martin, 1994) and Pharyngeal Manometry (Dejaeger, Pelemans, Bibau, & Ponette, 1994; Elidan, Shochina, Gonen, & Gay, 1990; McConnel, Cerenko, Jackson, & Hersh, 1998) are two other methods for evaluating the pharyngeal stage of swallowing. However, these methods do not allow for visualization of the entire anatomy of the oral or pharyngeal stages. The lack of studies to support the reliability of these tools and their invasive nature has been reported as a limitation for their use as tools of evaluation (Lambert & Gisel, 1996). The Exeter Dysphagia Assessment Technique (Selley, Flack, Ellis, Phil, & Brooks, 1990) and Cervical Auscultation (Bosma, 1992; Heinz, Vice, & Bosma, 1994) make use of the sounds produced during swallowing to assess the pharyngeal stage of swallowing. However, there are serious limitations of these two tests. With respect to cervical auscultation, it is difficult to identify the source of the sounds that are being measured (Logemann, 1998). It could be a combination of heart beat, muscle noise, and swallowing. In Manometry, there are pressure changes without anatomical landmarks, which limit the usefulness of information obtained (Feussner, Kauer, & Siewert, 1993). Scintigraphy is a diagnostic test in which radioisotopes are administered to a patient to obtain a two-dimensional picture of a body structure (Smart & Butler, 1994). This method has been used for detecting aspiration and has been shown to provide useful information when positive. However, there is a highly significant false-negative rate - i.e., the individual may present with dysphagia and silent aspiration, but the results of the test are negative. Decisions made on the basis of a negative test need to be made with caution, because undiagnosed and unmanaged dysphagia can lead to various complications (Nathadwarala, McGroary, & Wiles, 1994). Hence, insufficient studies on the psychometric properties of these assessments are a definite limitation. Another major limitation with respect to the use of instrumental evaluations for a geriatric population, is that it is neither practical nor appropriate for these elderly individuals to be transported back and forth from their residences to evaluation sites, or for them to undergo invasive assessment procedures (Kuhlemeier, 1994) and not all patients with dysphagia are evaluated using instrumental methods of evaluation. Hence, for this population, a psychometrically sound bedside assessment tool would be more appropriate.

1.5 Dysphagia Management

The goals of dysphagia management are to reduce a patient's risk of aspiration, to improve their ability to eat and swallow, and to optimize their nutritional status. The type of management strategy and its efficacy is also largely dependent on the type and location of the stroke, which affect the patient's clinical profile.

Conservative management of dysphagia includes postural changes, exercises to strengthen oro-pharyngeal musculature, sensory stimulation, compensatory strategies and grading of bolus size and texture. The precise form of dysphagia management required will depend on the nature of the problem. The two most frequently employed conservative management strategies are postural modifications and grading of food textures (Logemann, 1995; McCullough, Pelletier, & Steele, 2003).

Postural changes are often the first interventions aimed at improving the 'direction of food flow and dimensions of the pharynx' (Logemann, 1995). Patients with dysphagia can also be taught compensatory swallowing strategies (Logemann, 1995; McCullough et al., 2003). These techniques, combined with sensory stimulation and other therapeutic strategies, often provide immediate resolution of the problems (Ali, Wallace, & Schwartz, 1996; Logemann, Kahrilas, Kobara, & Vakil, 1989; Palmer & DuChane, 1991, 1994).

McCullough et al. (2003) reported that modification of textures is one of the most common strategies used for the management of dysphagia. Most patients with significant dysphagia are unable to eat regular textures and require a mechanically altered diet (soft, minced or pureed), which is recommended by the dysphagia clinician (Logemann, 1983; O'Sullivan-Maillet, Fixelle, & Thornton, 1997; Rubin-Terrado & Linkenheld, 1997). The rationale for altering the consistency of foods is to minimize feeding effort and to alter the rate at which food passes through the mouth and pharynx, to assist the patient in swallowing and to reduce the risk of aspiration (Curran & Groher, 1990). Depending on the classification used, there are three to five different diet texture levels from pureed (level 1) up through modified solid foods (level 5; McCullough et al., 2003). Due to the fact that there was no uniformity for modification of diet texture, the National Dysphagia Diet Task Force (NDDTF), a group of Registered Dietitians (RD), Speech Language Pathologists, researchers, and industry leaders, was organized to develop a nationally standardized definition for food textures and liquid consistencies for the management of dysphagia. This classification is referred to as the National Dysphagia Diet. According to this classification, there

are four dysphagia diets consisting of pureed, minced, soft and regular solid textures (McCullough, et al., 2003). Similarly, for liquids there are different viscosities ranging from thin liquids (such as water) to honey-consistency liquids. However, there is limited research evidence supporting this classification of liquid viscosities, except that radiological findings indicate decreased aspiration of food/drink with modified textures and viscosities (Ekberg & Nylander, 1982).

Current practice guidelines established by the American Occupational Therapy Association (2003), the Canadian Association of Speech-Language Pathologists and Audiologists (1995) and the Canadian Stroke Network (2003), recommend that modification of textures be preceded by a modified barium swallow exam (Logemann, 1995). However in cases where this is not possible, clinicians rely on their professional experience and clinical judgment to guide their decisions for modification of food textures and liquid consistencies. From a perspective of safety, patients may be advanced too quickly to the next higher texture because of poor clinical judgment, which can be dangerous to the individual because of the risk of choking and aspiration (Langmore, et al., 1998). On the contrary, patients may be prescribed or maintained on a low-textured diet, when unnecessary. The disadvantage and hazards associated with these will be discussed in the following paragraph. This problem causes considerable concern with respect to standardization of dysphagia management, and leads to an important question:

What is the importance of accurate patient progression to higher textures? This question may be answered from the patient's perspective and from a physiological perspective. To understand the importance of patient progression to higher food textures, we need to take a closer look at the principal factors influencing the appeal of food for the patient; namely, appearance of food, flavor, texture and nutritional content (Bourne, 1982). Texture, is the component that we wish to focus on. Bourne (1982) defined texture as: *"... the response of the tactile senses to physical stimuli that result from contact between some part of the body and the food. The tactile sense (touch) is the primary method for sensing texture, but kinesthetic (sense of movement and position) and sometimes sight and auditory components (degree of slump and sound, associated with crisp, crunchy and crackly textures) are also used to evaluate texture."* This is extremely important, because of the pleasures associated with eating (Bourne, 1982). An early study by Cabanac (1979) on hedonism and ingestive behavior showed that sensory pleasure is an important component for the motivation of individuals to eat. This is clearly evident in the clinical environment with elderly individuals in long term care settings who have decreased motivation for

eating when offered purees. The importance of food textures was also documented by Schiffman, Musante and Conger (1978). Subjects were blindfolded and introduced to pureed foods. Results indicated that most subjects had difficulty identifying pureed foods in comparison to identification of regular textured foods. Being on pureed diets also has social implications, in that individuals on this diet often have considerable difficulty dining outside their usual meal environment because of their need for a mechanically altered diet. As well, in the case of elderly individuals on modified food textures, they may feel uncomfortable eating with others who do not have modified textures because of 'societal acceptance'. Studies by Lichtenberger and Johnson (1974) indicate changes from a physiological perspective, when the digestive system is not stimulated by roughage, as is the case with pureed diets. Due to decreased mechanical stimulation, the villi in the digestive system atrophy (Lichtenberger and Johnson, 1974). When an individual continues on a pureed diet, when no longer necessary, there may also be 'deconditioning' associated with ingestive skills and it takes 3 to 4 days for the villi to regain their 'normal' structure and functions. Since most individuals who have sustained a stroke are elderly, this recovery may take longer and may be more difficult.

Thus, we see the significant impact of ingestive difficulties on patients with dysphagia and recognize the need for early and accurate identification of the nature and extent of the problems. Hence standardization of clinical practice with respect to dysphagia evaluation and management is of utmost importance. To do so, clinical assessments for the diagnostic evaluation of dysphagia in patients who have sustained a stroke must be psychometrically sound.

1.6 Summary of Literature Review

From the above literature review, we conclude that that stroke is especially common in the elderly and makes significant demands on the health care system (Health Canada, 2008). Depending on the clinical characteristics of the patient, and the localization, type and severity of the stroke, there is a wide array of symptoms and neurological consequences.

Studies indicate that dysphagia following an acute stroke is common and may affect approximately 28-65% of all patients with stroke (Barer, 1989; Gordon et al., 1987; Hamdy et al., 1998; Logemann et al., 1999; Lugger, 1994; Mann et al., 1999; Paciaroni et al., 2004; Park & O'Neil, 1994; Smithard et al., 1997; Smithard et al., 1996; Wiles, 1991). The study by Barer (1989) showed that 50 - 98% of patients with dysphagia following stroke recovered spontaneously within

four weeks. Similar results were obtained by Smithard et al. (1997) and Hamdy et al. (1998). Some of the major complications associated with dysphagia include dehydration, aspiration, malnutrition, pneumonia, impaired cerebral perfusion, and renal failure which significantly affect the level of morbidity and in severe cases even mortality (Barer, 1989; Finestone & Greene-Finestone, 2003; Gordon et al., 1987; Smithard et al., 1997). Hence, especially for the minority of individuals who do not recover spontaneously, one of the main areas of concern is accurate diagnostic evaluation of dysphagia, as unsubstantiated evaluation methods may have serious consequences for dysphagia management.

The two main categories of dysphagia assessments are bedside assessments and instrumental evaluations. A number of bedside swallow tests are currently available, which are considered safe, repeatable, and relatively straightforward to administer. However, reliabilities of these tests have a wide range (from 'fair' to 'good') and the sensitivities and specificities are highly variable with many methods unable to detect silent aspiration. Instrumental evaluation of dysphagia in elderly individuals raises a number of issues with respect to their appropriateness, practicality, and feasibility. It is also important to note that upon review of this body of work, pertaining to dysphagia assessment, it is unclear whether the available measurement tools are for screening or diagnostic purposes. In fact, the same question arises in clinical practice. Dysphagia research and literature are not unique with respect to this problem. For example, the Mini-Mental State Examination (MMSE; Folstein, Folstein & McHugh, 1975) was developed as a screening tool but is being used as a formal assessment in numerous studies.

Management of dysphagia is largely dependent on early and accurate identification of patients with ingestive difficulties. Conservative management of dysphagia includes postural changes, exercises to strengthen the oropharyngeal musculature, sensory stimulation, and compensatory strategies such as grading of bolus size and texture (Logemann, 1983). Standardization of clinical practice with respect to dysphagia evaluation and management is of utmost importance. In order to meet this goal of standardization of clinical practice, clinical assessments for the diagnostic evaluation of dysphagia in patients who have sustained a stroke must be psychometrically sound and sensitive enough to discriminate between different ingestive abilities. This leads to the consideration of the rationale of this study.

Chapter 2: RATIONALE, MEASUREMENT AND PILOT STUDY

2.1 Chapter overview

This chapter addresses the underlying rationale for the study. It also includes a description of the McGill Ingestive Skills Assessment (MISA) and a synopsis of the pilot study, preliminary results obtained and limitations encountered with respect to the logistics of the main study.

2.2 Rationale for the study

When a person with stroke has dysphagia, appropriate progression to higher food textures is necessary to optimize the recovery process in the acute post stroke phase. The natural history of dysphagia recovery shows that spontaneous recovery often occurs within the first four weeks post-stroke (Hamdy et al., 1998; Smithard et al., 1997). However, for a small minority of individuals (~2%) who do not recover spontaneously, the consequences of dysphagia are severe. Hence, diagnostic evaluation for detection of dysphagia is a fundamental aspect of acute stroke management (Ramsey, Smithard, & Kalra, 2003).

The key elements of diagnostic evaluation are the selection of the most appropriate tool and its psychometric properties. The value of any measurement tool depends on its scientific integrity and its usefulness in the clinical environment. “A clinically useful tool is one that is acceptable to patients and health care professionals, practical to administer and cost effective. Such an instrument should also be sound in terms of the three basic psychometric properties: reliability, validity and responsiveness” (Streiner & Norman, 1995). Clinicians need to use measures with sound psychometric properties, to facilitate the standardization of clinical practice.

“Psychometric properties are those aspects of test development and evaluation that are essential to ensure that an assessment is appropriate for a particular client group, provides reliable and valid information, and is administered and interpreted in a consistent and ethical manner” (Nunnally & Bernstein, 1994). The two best known psychometric properties are reliability and validity. Reliability is a “measure of the stability and reproducibility of a test score” (Streiner & Norman, 1995). It provides an estimate of the true score and sources of error that contribute to that score. Validity is an accumulation of evidence that supports the “appropriateness, meaningfulness, and usefulness of inferences and actions that are based on test scores” (Messick, 1995). The primary considerations are that the assessment items adequately measure what they claim to

measure. There must be evidence for validity of the use of the test for the intended population and purpose. The principle of discriminative construct validity, as its name suggests, is based on the ability of the instrument to discriminate between two or more groups (Streiner & Norman, 1995). A frequently used approach to determine discriminative validity is by comparison of ‘known’ or ‘extreme’ groups. Comparison by extreme groups typically involves comparison of two groups that are expected to have distinctly varied outcomes.

Clinical utility of a tool refers to the “ease and efficiency of use of an assessment, and the clinical relevance and meaningfulness of the information that it provides” (Law et al., 2001; Letts et al., 1999). Some aspects of clinical utility include: the availability and ease of use, administration time, qualifications needed to administer the tool, set-up required and relevance of the information obtained. Thus far in the field of dysphagia research, one identifiable bedside assessment for diagnostic evaluation of ingestive skills that has demonstrated significant reliability and validity for use as a diagnostic tool in the geriatric population is the MISA (Lambert, Gisell, Groher, Abrahamowicz, & Wood-Dauphinee, 2003).

2.3 The McGill Ingestive Skills Assessment (MISA)

The MISA (Lambert, 2002) is a recently developed observational tool, which unlike traditional tools for the evaluation of dysphagia (based primarily on the ‘physiological’ aspects of swallowing) aims at evaluating the functional aspects of the oral phase of ingestion. The fact that the MISA evaluates individuals in their regular mealtime environment by observation alone and not by direct therapist intervention makes it ideal for use with an elderly population in the acute post-stroke phase.

The MISA is comprised of 43 items, organized into 5 scales: Positioning, Self-feeding, Solid-ingestion, Liquid ingestion and Texture management. The positioning scale addresses issues such as posture and symmetry. The self-feeding scale includes items evaluating the patient’s physical and cognitive ability to feed and drink independently (by using utensils appropriately, grading bolus size, focusing and tolerating the physical effort required during feeding). The solid and liquid ingestion scales rate the patient’s oro-motor skills such as lip closure, mastication and transport of bolus and airway clearance, during solid and liquid intake respectively. The texture management scale corresponds to solid textures and liquid viscosities tolerated by the patient. Each

item of the MISA is scored on a scale ranging from 1 to 3, allowing a total score range from 43 to 129. A low score on the MISA is indicative of poor ingestive performance.

Psychometric studies by Lambert et al. to establish the primary psychometric properties of the MISA, such as adequacy of the scoring mechanism, item and scale selection, as well as reliability and validity revealed excellent results for clinical use (Lambert, 2002; Lambert et al. 2003, 2004, 2005, 2006). The MISA has demonstrated satisfactory face and content validity. It also has an inter-rater agreement of above 0.9 on all scales and similarly high measures of other aspects of reliability and convergent and predictive validity (Lambert et al., 2003, 2004, 2005, 2006).

Once satisfactory results have been obtained from the initial studies assessing the psychometric properties of a measurement tool, the next step is an analysis of the clinical utility of the tool. This in turn provides justification for our study aimed at determining the discriminative validity of the MISA in order to promote its clinical utility in the diagnosis and management of dysphagia (to be used with or without an adjunct instrumental evaluation). Discriminative validity is one type of construct validity. “A construct is a collection of related behaviors that are associated in a meaningful way,” (Nunnally & Bernstein, 1994). Construct validity examines the relationships between constructs i.e., it examines the extent to which an assessment measures the construct (e.g., ingestive skills) which the test purports to measure. The three types of construct validity are: convergent validity, discriminant validity, and discriminative (or known groups) validity. Our study aims to address the discriminative validity of the MISA. “Discriminative validity refers to the ability of the tool to differentiate between different groups, or within individuals,” (Campbell & Fiske, 1959). Determining the discriminative validity is the first step towards ascertaining if a tool will be responsive to change in patient status over time. To examine discriminative validity, we need to demonstrate that the MISA can identify and measure the difference between two known/extreme groups of individuals as proposed in our hypotheses.

In an effort to maximize research quality and efficiency, a pilot study (n=5) was conducted to test the study logistics and gather preliminary data for sample size calculations.

2.4 Pilot study objectives and methodology

The primary objective of the pilot study was to determine the extent to which the MISA can discriminate within-individual differences for patients able to tolerate different solid textures

and liquid viscosities. A secondary objective was to validate and refine the methodology for a future study with a larger sample.

The initial methodology of the pilot study outlined four subgroups, categorized with respect to solid and liquid ingestion:

Group 1:

- i) Individuals with stroke and without dysphagia who are on a regular diet and
- ii) Those with stroke and dysphagia, who are on a pureed diet (irrespective of liquid intake)

Group 2:

- i) Individuals with stroke and without dysphagia, who drink clear liquids and
- ii) Those with stroke and dysphagia who are permitted only honey-viscosity liquids.

Figure 2.4.1 Possible permutations for subject recruitment (based on the above categorization):

	Regular solids	Regular liquids	Pureed solids	Nectar-viscosity liquids	Honey-viscosity liquids
Group 1 i)	√	√		√	√
Group 1 ii)		√	√	√	√
Group 2 i)	√	√			
Group 2 ii)			√		√

As seen in Figure 2.4.1, there was significant overlap between Group 1i) and Group 2i), hence, to eliminate redundancy, these two groups were collapsed into one (seen in figure 2.4.2), to include all patients without dysphagia, who were able to tolerate regular solids and regular liquids.

Figure 2.4.2 – Regular solids and liquids vs. Pureed solids and varied liquid viscosities:

	Regular solids	Pureed solids	Regular liquids	Nectar-viscosity liquids	Honey-viscosity liquids
Group 1	√		√	√	√
Group 2i)		√	√		
Group 2ii)		√		√	
Group 2iii)		√			√

Another logistic limitation of the above grouping was that two of the recruiting institutions only offered either modified regular or honey-viscosity liquids. Hence essentially, this would only allow for three groups:

Group 1: Individuals with stroke and without dysphagia who are able to tolerate regular solids and regular liquids

Group 2: Those with stroke and dysphagia, who are able to tolerate purees and regular liquids

Group 3: Those with stroke and dysphagia who are able to tolerate purees and honey-viscosity liquids.

After consultation with dysphagia clinicians at the respective centers, it was concluded that an analysis of the differences between patients able to tolerate purees and minced solids would be more informative. Hence the following repeated measures design was implemented for the pilot study:

Figure 2.4.3 Pilot study patient allocation:

	Pureed solids	Minced solids	Regular liquids	Honey-viscosity liquids
Time 1	√		√	√
Time 2		√	√	√

Five consecutive patients aged 65 years and over were sampled from in-patient stroke units at the Jewish Rehabilitation Hospital (n=4) and the *Institut de Réadaptation de Montréal* (n=1). They were recruited between April 1st and December 31st, 2004. Informed consent was obtained from all patients or from their legal guardians. The MISA was administered twice for each patient – at time 1, when they were on a prescribed diet of purees and at time 2, when their treating therapist had determined that they were ready to progress to a minced diet. The evaluations at time 1 and time 2 were administered by two different therapists, neither of whom were the treating therapists. This ensured that both therapists were blind to the results of the other evaluation.

2.5 Pilot Study Results

Please refer to section 2.3 and Appendix A, for details on the MISA.

MISA scale scores and Total scores were recorded for each of the five patients, at their first evaluation (time 1), when they were on a pureed diet, and at their consecutive dysphagia evaluation (time 2) when they were determined to have improved ingestive skills. Individual patient scores at time 1 and time 2 were compared.

Out of the 5 MISA scales (Positioning, Self-feeding, Solid-ingestion, Liquid ingestion and Texture management), the Solid ingestion scale showed the most significant within-patient differences between time 1 and time 2. An overall improvement in 3 out of 5 individuals was noted, as well as maintenance of the maximum score in one individual on the solid-ingestion scale. Please see figures 2.5.1-2.5.5 for illustration of pilot-study results.

With respect to the liquid-ingestion scale, results indicated considerable variation in scores. One reason for this was that the individuals were not prescribed the same viscosity of liquids. All participants improved from evaluation 1 to evaluation 2. Even individuals on the same viscosity obtained different scores on the liquid ingestion scale. This means that the scale appropriately evaluated the patient's ingestive skills as opposed to just assigning a score based on what liquid viscosity they could tolerate. This supports the use of this scale for discriminative purposes between individuals on different liquid viscosities.

On the texture management scale considerable differences were noted between and within individuals, which are self-evident. Individuals who were on higher textured diets (i.e., minced diets) scored higher on this scale by default (because scoring for this scale corresponds to solid

textures and liquid viscosities tolerated). Hence information obtained from this scale score was limited.

One of the major weaknesses identified in the design of this pilot study was that all individuals were assessed on their prescribed diet only. Hence, the score for solid texture management is in essence predetermined by the diet. The marked difference that we saw in the scores was largely due to the differences in liquid viscosity.

The positioning scale showed that the majority of individuals scored at the upper end of the scale and this was maintained from time 1 (when they were on purees) to time 2 (when they were progressed to a minced diet). In this scale we may have seen a 'ceiling effect'. In future studies, a larger sample would be required to determine if the positioning scale has an adequate range of values. This may be more likely if we have patients with greater difficulties with postural control. On the self-feeding scale, 4 out of 5 individuals showed an improvement of 1 to 3 points and 1 individual maintained the maximum score (21pts) between time 1 and time 2. This improvement/maintenance of the second score is consistent with our expectation that there will be functional recovery, since the individuals are in rehabilitation.

In summary, the scores on the Solid-ingestion, Liquid-ingestion and Texture management scales contributed most to the results. The positioning and self-feeding scales did not add much more information.

Figure 2.5.1. Positioning scale score distribution for n=5

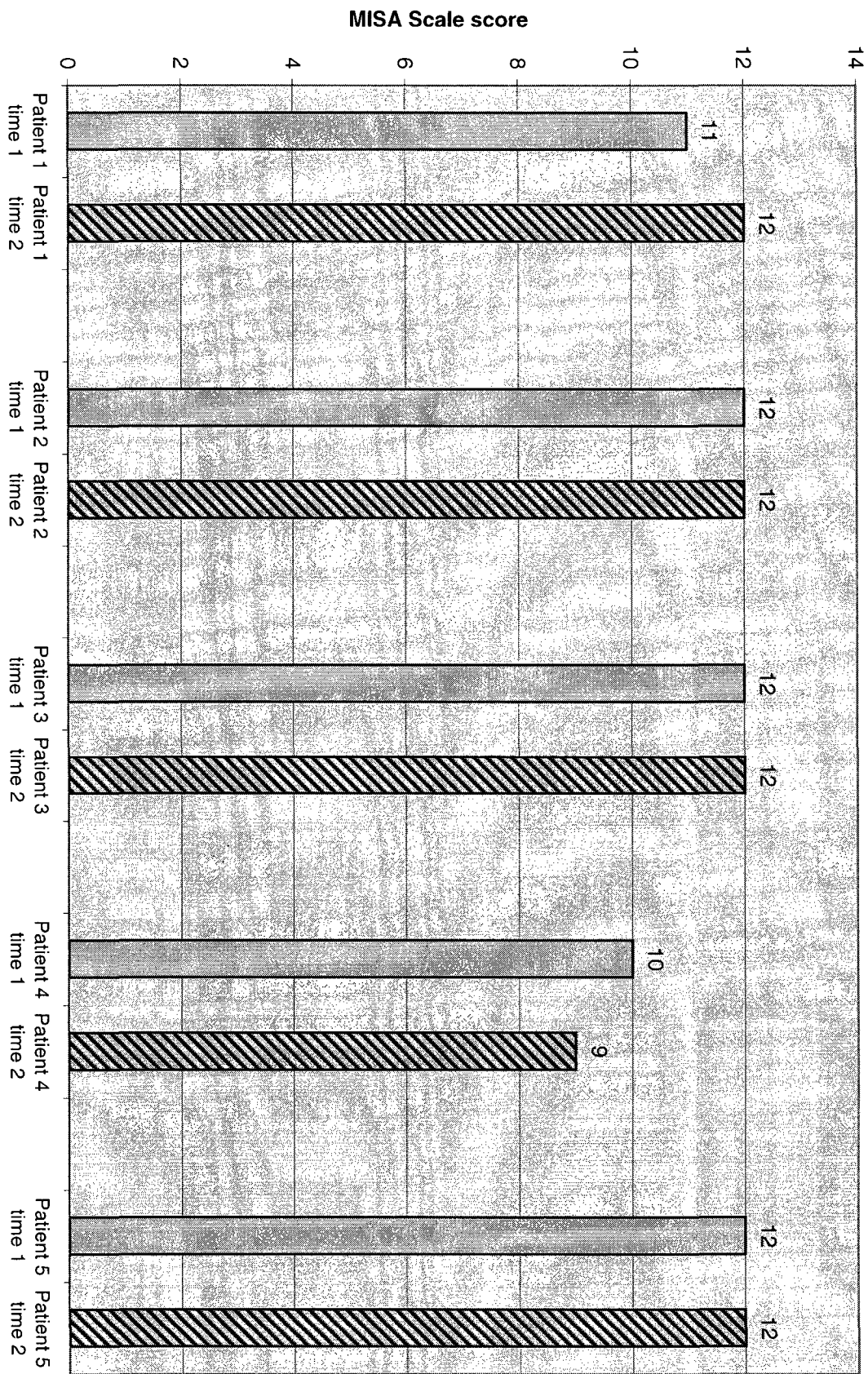
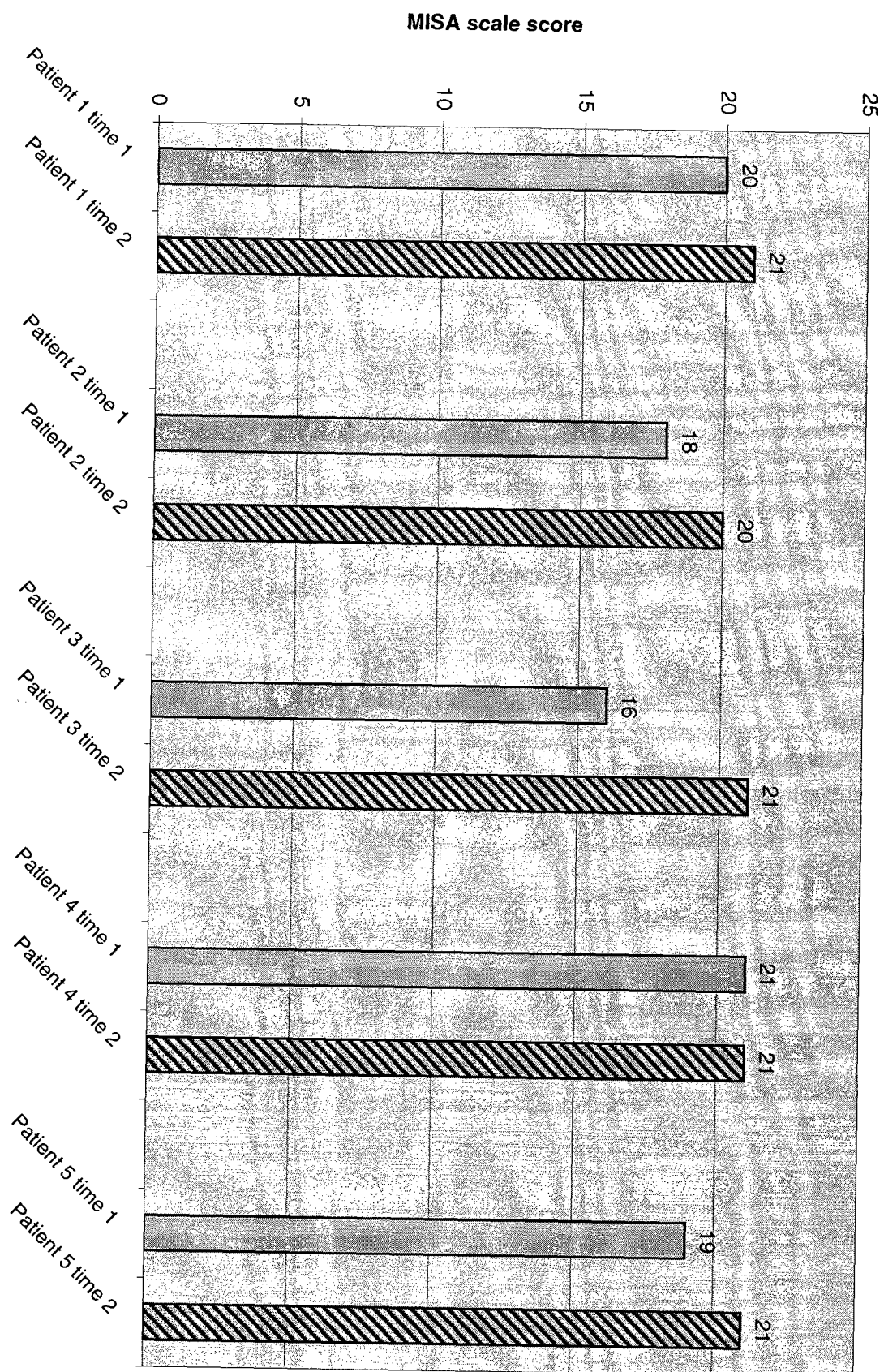


Figure 2.5.2 Self-feeding scale score distribution for n=5



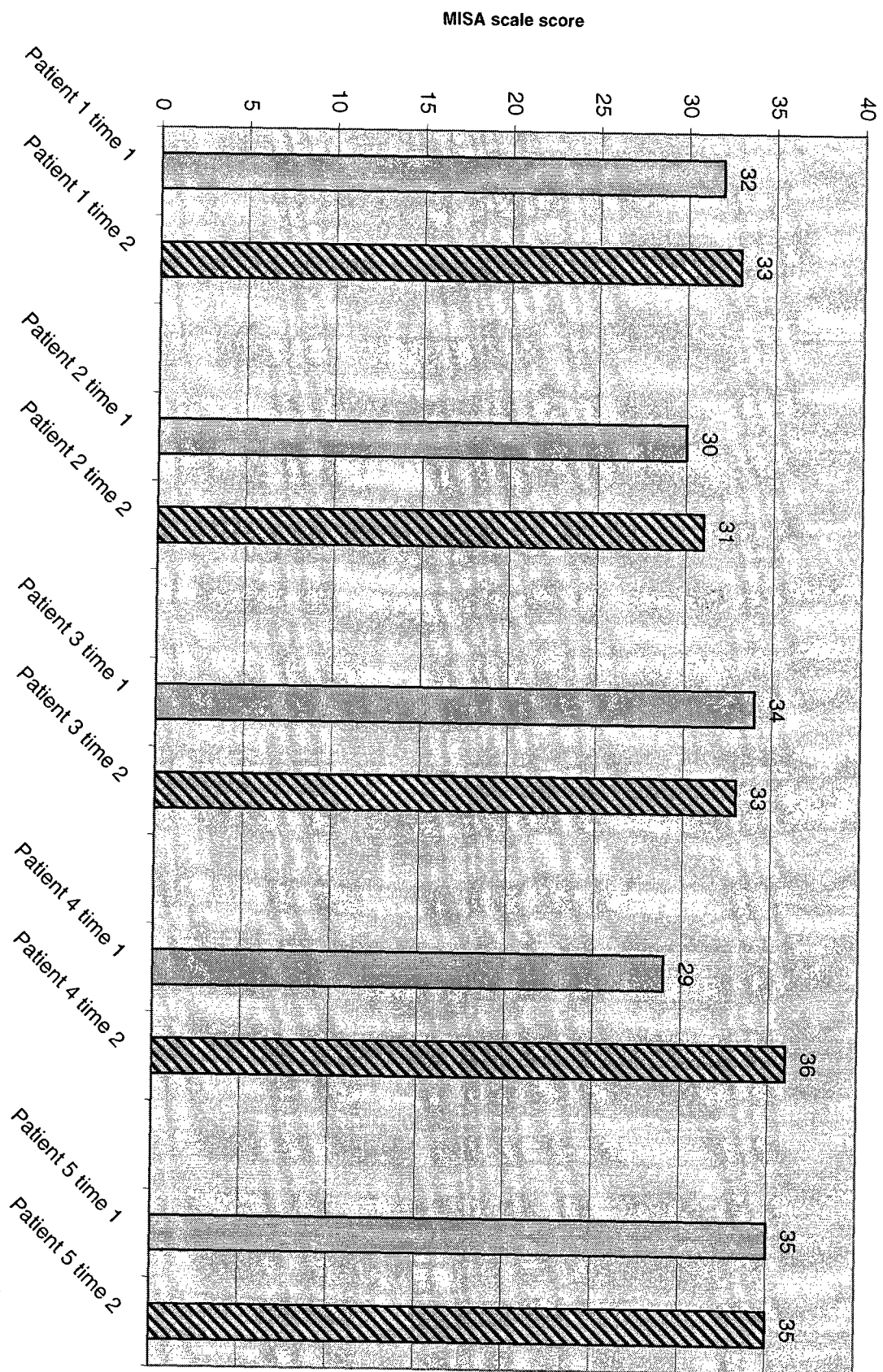


Figure 2.5.3 Solid-ingestion scale score distribution for n=5

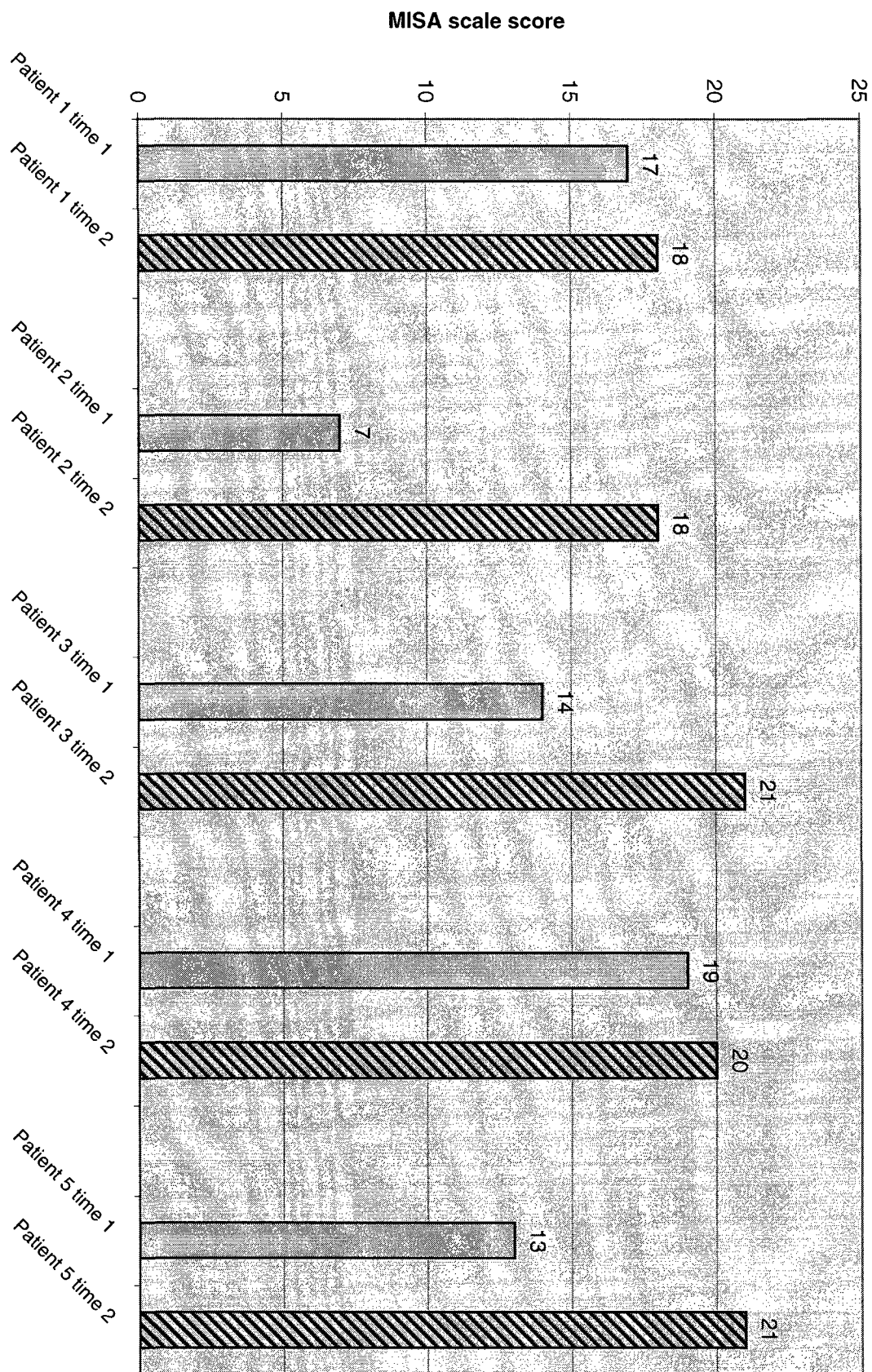
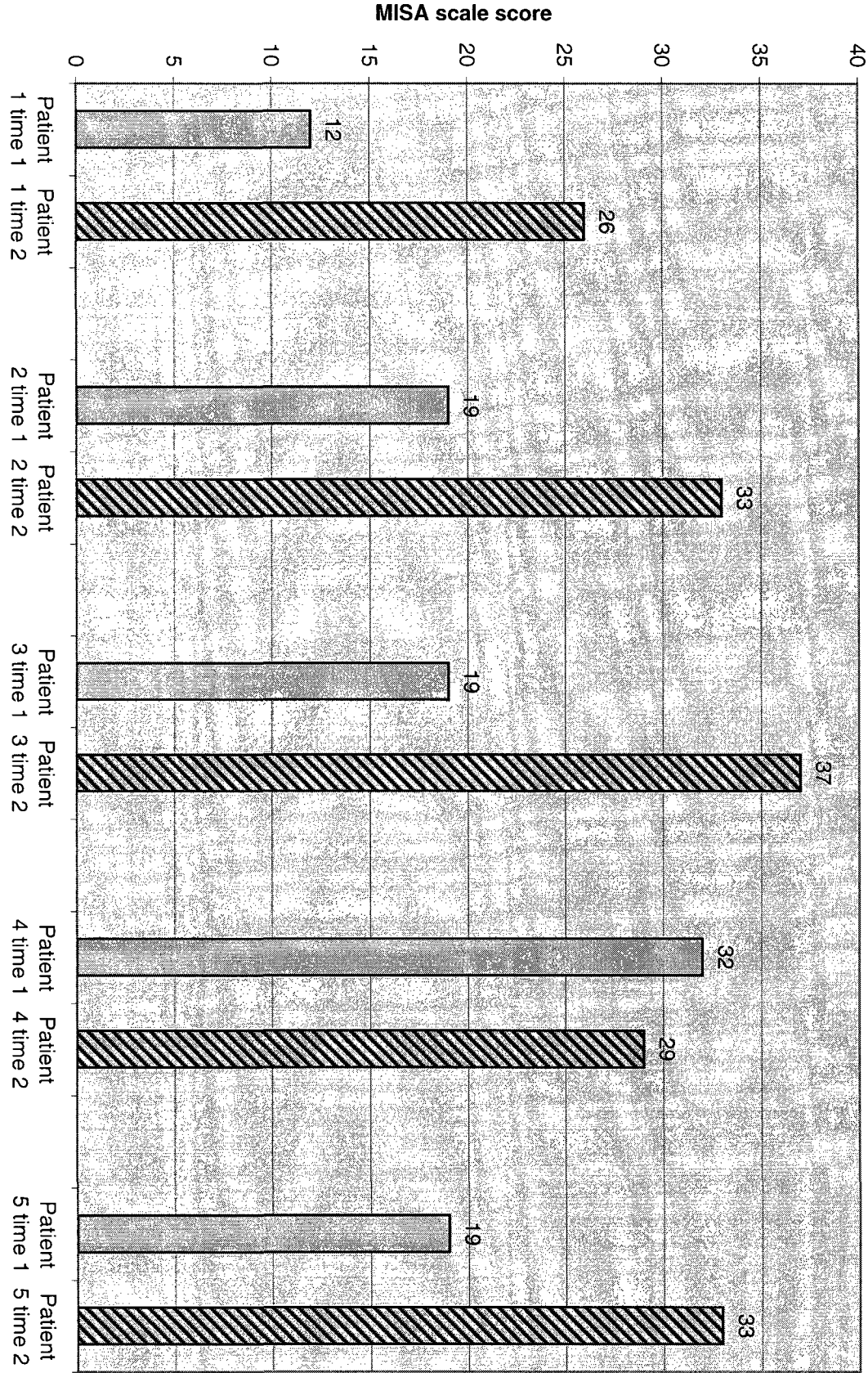


Figure 2.5.4 Liquid-ingestion scale score distribution for n=5

Figure 2.5.5 Texture management scale score distribution for n=5



2.6 Weaknesses identified from the pilot study:

1. The minimum score for solid texture management is, in essence, predetermined by the diet.
2. It was not possible to differentiate between different functional feeding levels of individuals on purees.
3. There was a lot of variation with respect to liquid-ingestion because individuals were not prescribed the same liquid viscosity, in contrast to the same prescribed solid texture.
4. It was reported during feedback sessions that there may be an inconsistency in systematically offering all patients the cup and straw. It was noted that due to increased viscosity, some patients may or may not try to drink the liquid with a cup or from a straw but use a spoon instead, and this would automatically give them a lower score.

2.7 Modifications implemented in the main study:

Two known extreme groups of patients with stroke are compared, with respect to solid textures. One of the earlier concerns regarding the ethics and safety of testing patients on less viscous liquids than prescribed was resolved by continuing to assess patients only with the prescribed liquid viscosity in Group 1 and 2. The variation in scores is expected to be reflective of the different viscosities. Inconsistency in test administration was reduced by systematically offering all patients a cup and straw for nectar viscosity and regular liquids.

2.8 Summary

Chapter 2 outlined the rationale for the study. It also provided an overview of the methodology of the pilot study, including details of the study design. Pilot study results and inferences are also presented in this chapter, which provided the basis for the larger study.

Chapter 3: METHODS

3.1 Chapter overview

This chapter provides details of the objectives of the study and the methodology employed. It also offers a brief description of the institutions in which the research was conducted, as well as details on the inclusion criteria and grouping of patients. The Analysis section of this chapter outlines the data analyses that were undertaken with the goals of describing the sample, verifying the similarity between patients with dysphagia and those without, and finally, determining the discriminative ability and the internal consistency of the MISA in individuals presenting with stroke.

3.2 Objectives

The main objective of this study was to determine the discriminative validity of the McGill Ingestive Skills Assessment (MISA) in elderly individuals presenting with stroke. To do so, various clinical/functional outcomes and patient characteristics were studied to identify suitable known groups and their correlations were explored and analyzed. The secondary objective was to reevaluate the internal consistency of the MISA when used with an elderly population with stroke.

3.3 Study design

An observational study was conducted to determine the extent to which the MISA can discriminate between ‘known/extreme’ groups of individuals with stroke, who had been admitted to an acute-care-hospital or a rehabilitation center. Forty-one patients were sampled from stroke units in acute-care hospitals and rehabilitation centers in the Montreal and Laval regions. Patients were recruited by sequential sampling and allocated to one of two groups (according to their ingestive performance at the time of accrual):

Group 1: individuals with stroke and without dysphagia, who were on a regular diet and

Group 2: those with stroke and dysphagia, who were on a pureed diet (irrespective of liquid intake)

Data from these forty one patients were used to re-establish the internal consistency of the MISA.

3.4 Locations of the study

The study was conducted at 3 institutions: The Montreal Neurological Institute (MNI), the *Institut de Réadaptation de Montréal (IRM)* and the Jewish Rehabilitation Hospital (JRH; Laval).

The MNI is an acute care hospital center and is one of three stroke-program sites in the McGill University Health Centre (MUHC). It is a specialized 135-bed facility with 10 day-clinics. Clinical departments in the MNI include neurology, neurochemistry, electroencephalography, neuropathology, neurophysiology, neuroradiology, neurosurgery, nuclear medicine, and neuroanaesthesia. Patients presenting with stroke are most often admitted through the Emergency department. A neurological examination is conducted following admission and a CT and/or MRI scan may be requested. The average duration of hospital stay is 1-2 weeks, during which the main goals are stabilization of the patient's medical condition, inpatient rehabilitation and discharge planning.

The *IRM* is a 104-bed hospital affiliated with the University of Montreal, specializing in the functional rehabilitation of patients with brain injuries, amputations and strokes. Patients with stroke, who are admitted to the *IRM* are typically younger (mean age range of 40-50 years) than the average geriatric population and have an approximate length of stay of 4-6 weeks. The rehabilitation program at the *IRM* is intensive and aimed at facilitating community reintegration. Patients may also continue to receive outpatient rehabilitation for a few weeks following discharge.

The JRH is a 120-bed rehabilitation institution, situated in Laval, Quebec. Patients may be admitted to the JRH from acute and sub-acute care hospitals in the Montreal and Laval regions. The Neurology program is one of many programs offered at the JRH. It provides services to an adult clientele requiring intensive inpatient rehabilitation following a stroke, or other neurological disorders such as Multiple Sclerosis, Parkinson's disease, or Guillain-Barré syndrome. Clinical services in the neurology program are offered by a multidisciplinary team, working to maximize the individual's level of autonomy through physical rehabilitation and social and professional reintegration. Patients are admitted to the Neurology program only if they meet the following eligibility criteria: 1) being medically stable, 2) having the potential to follow a rehabilitation program, 3) being capable of participating in 2 or more therapy sessions per day, for a minimum 30 minutes in each session, 4) having demonstrated some functional improvement since the onset of the condition, and 5) having demonstrated that they are able to participate in an intensive rehabilitation program (i.e. able to follow simple instructions, absence of significant cognitive deficits).

3.5 Inclusion Criteria

Individuals who were admitted to the participating acute-care hospital or rehabilitation centers and were less than 6 weeks post-stroke (either first stroke or repeated stroke) were selected for the study. Diagnosis of stroke was the key inclusion criterion for the purpose of this study and was established by a neurologist following a neurological examination and/or a Computed Tomography (CT) scan.

All patients recruited for the study were screened for dysphagia (using a bedside swallowing assessment) by a clinician on the stroke team who was not involved in the study and was blind to the nature and purpose of the study. Those who did not present with dysphagia and who were on a regular diet were recruited into Group 1 (the non-dysphagia group). Patients with strokes, suspected of having dysphagia, were evaluated by the dysphagia clinician (occupational therapist or speech language pathologist) to establish a diagnosis of dysphagia. This is the usual approach in the clinical environment, since it is only the rare elderly patient with stroke who is referred for a videofluoroscopy. Patients with a confirmed diagnosis of dysphagia were then recruited into Group 2 (dysphagia group). A positive diagnosis of dysphagia was made if patients presented with four or more signs and symptoms from the following list: ‘difficulty’ swallowing, coughing, wet/‘gurgly’ voice quality during or after the ingestion of food or liquid, choking associated with eating, sensation of food sticking in the throat (globus), drooling, regurgitation of food, change in respiration pattern after swallowing, atypical chest pain during or after meal times, prolonged meal times (longer than 30 minutes) and avoidance of food (following the stroke – primarily due to fear of choking).

3.6 Exclusion Criteria

Individuals with a comorbid diagnosis of Parkinson’s disease who had a known history of dysphagia were excluded due to the associated motor problems that may contribute to dysphagia. As well, individuals presenting with dysphagia not due to the stroke were excluded. Individuals with a history of unresolved dysphagia prior to their recent stroke were also excluded.

Individuals with a diagnosis of dementia were not excluded, since a large percentage of the elderly population have some degree of dementia and this would have restricted the sample size considerably.

3.7 Sample Recruitment

Patients meeting the inclusion criteria were identified and approached by a clinician on the stroke team, who introduced them to the nature and purpose of the study. If the patient expressed an interest in participating, informed consent was obtained from the patient or from their legal representative by the clinician on the stroke team. Once informed consent was obtained at the respective centers, the research assistant was contacted by the stroke team clinician.

3.8 Sample

Patients who met the inclusion criteria were recruited sequentially from the designated institutions (see above) from September 2005 to August 2008. Dysphagia evaluations using the MISA were conducted on all participants by trained research assistants.

3.9 Procedures

Following contact by the stroke team clinician, the research assistant set up an appointment with the patient for a mealtime observation and conducted a chart review. Demographic and clinical information were collected from the chart: patient's age, sex, past medical history and comorbid conditions.

3.10 McGill Ingestive Skills Assessment (MISA)

The MISA is a recently developed reliable, clinical observational tool for assessing elderly individuals with feeding difficulties. It is comprised of 43 items grouped into 5 scales, with a maximum total score of 129. A higher score is indicative of less ingestive difficulties. The minimum possible score for an item is one point. Therefore the minimum scale score corresponds to the number of items in the scale.

Patients on a prescribed diet of purees automatically score 6 points lower on the texture management scale for solids for two main reasons. First, it is because a low score for purees is a characteristic of the scale and second, because it would be unethical to offer these patients higher food textures that have previously been deemed unsafe. The texture management scale score (for solids) ranges from 8 to 24. The solid ingestion scale score ranges between 12 and 36 points and is not dependent on the food texture tolerated. This latter feature makes it possible to explore within group differences despite limitations in the texture management scale. Please refer to chapter 2 and Appendix A for a detailed description of the tool.

The MISA was administered by the designated research assistant at the center, no later than one week following receipt of informed consent. Patients were observed during their regular mealtimes at either lunch or dinner, in their usual environment (in their hospital room/public dining area or dysphagia room). The research assistant conducting the assessment was present for the duration of the meal for observation and scoring of the MISA. Patients were allowed to obtain assistance during the meal from nursing aides, or family members, but not from the research assistant, if such was the 'usual' practice.

3.11 Research Assistants

At the commencement of the study two research assistants were recruited from the participating institutions. Although it was originally intended that the research assistants would be blind to the hypothesis of the study, due to slow recruitment and limited funds, the principal investigator was also required to evaluate patients and hence blinding was not maintained for all. As well, given that all research assistants were clinicians, the food textures being served would be cue the assistant to the abilities of the subject being evaluated. Hence, even under the best of circumstances, blinding is practically impossible.

Training of the research assistants was provided by the test-developer (H. Lambert, Ph.D.). Training consisted of a seminar provided on the use of the MISA. Following the seminar, research assistants scored 5 video-taped meal-time recordings. Any discrepancies in scoring were discussed until a reliability of 0.9 was achieved.

3.12 Ethical considerations

This study was approved by the Research Ethics Board of McGill University (REB), for the McGill University Health Center acute-care hospital and by the *Centre de Recherche Interdisciplinaire en Réadaptation du Montréal (CRIR)*. Please see Appendices B through M. Ethical approval was also obtained from the Jewish Rehabilitation Hospital (JRH) and the *Institut de Réadaptation de Montréal (IRM)*. Consent forms were provided either in English or French as per the language preference of the patient. If patients were unable to give consent independently, consent was obtained from their legal guardian. Consent forms were made available in regular and large print as required. A similar procedure was followed for the pilot study with respect to ethical review and receipt of consent, and was deemed to be suitable.

Considering that the administration of the MISA involved ‘observation’ of the mealtime, there was no direct patient contact between patient and research assistant. As well, there was no foreseeable risk to the patient, for participating in the study, other than the risks of regular mealtimes. Prior to commencement of the study, it was established that if a patient choked or aspirated during the meal, all necessary hospital procedures would be employed. Patients were informed that they were free to withdraw from the study at any time, and would continue to receive care as ‘usual’. The research assistants were also strictly advised to discontinue the assessment if it was determined that the patient’s safety was jeopardized. The assessment was to be terminated with no repercussions to the patient and appropriate safety measures, such as notifying the nurse in charge, were taken.

3.13 Sample Size

The two groups, Group 1 (no dysphagia, regular diet) and Group 2 (dysphagia, pureed diet) are statistically independent. All significance levels were Bonferroni-adjusted (Bonferroni, 1935). The level of significance (α) was established *a priori* at 0.01 and the power of the test at 0.90. Sample size calculations reflect comparisons between Groups 1 and 2.

3.13.1 Sample size calculation

The minimum important difference (MID) is often used to compare observed between-group differences and to determine the necessary sample size for a study. The MID has not yet been determined for individuals using the MISA. The most common approach for establishing the MID is the anchor-based method, requiring a longitudinal study that has yet to be conducted with this instrument. Therefore, sample size calculations for our study were based on pilot study results and assumed that the actual mean difference between the Solid Ingestion scale-scores in the two populations is equal or higher than 4 points, and that pooled within-group SD will not exceed 3.5 points. Then, under the conservative assumptions of a mean difference of 4 points and a SD of 3.5 points, the number of patients required to ensure high (80% or 90%) statistical power of a 2-tailed independent-groups t-test at a 0.01 significance level were calculated. As in earlier sample size calculations, we assumed that (because of easier recruitment of "controls", i.e., patients without dysphagia), the size of the control group will be 50% higher than that of the group of patients with dysphagia. Based on these assumptions, we found that a total of 28 patients (17 controls + 11 with dysphagia) would be necessary to ensure an adequate power of 80%, while 35 patients (21 controls

+ 14 with dysphagia) would offer excellent power (90%). Since a power of 0.90 or higher was desired, 41 patients were recruited.

3.14 Analysis

Although the MISA is a rank ordered scale, the use of parametric techniques with ordinal scales has been supported in the literature (Gaito, 1980). Hence, study groups were compared on relevant socio-demographic and clinical characteristics, including age, gender, dysphagia status, type of stroke, location of lesion, stroke severity and liquid ingestion, using descriptive statistics such as: means and standard deviations or proportions for categorized variables. Preliminary data inspection indicated a non-normal sample distribution for all variables, except age. This is consistent with earlier studies acknowledging the non-Gaussian population distribution (Lambert et al., 2006). For quantitative variables, normality of distributions was assessed using the Kolmogorov-Smirnov test at a significance level of 0.05. Since the null hypothesis of normality was rejected, the between-group differences were tested using either a 2-tailed non-parametric Mann-Whitney U- test for two group comparisons, or a Kruskal-Wallis test for >2 group comparisons. Since multiple statistical tests were being performed, the Bonferroni correction was used to lower the alpha value, in order to avoid false positive results.

To further explore the characteristics and associations of patients with and without dysphagia, the magnitude and direction of variability was examined using Spearman's rho. All correlations <0.4 were considered to be low, and those >0.7 were considered high. Correlations in between 0.4 and 0.7 were deemed to be moderate. Lastly, Cronbach's alpha, which is a reliability index used to estimate the internal consistency of multi-item assessments, was calculated to reflect the homogeneity of the MISA (Cronbach, Glesser, Nanda and Rajaratnam, 1972). The value of Cronbach's alpha is dependent on the average inter-item correlation and the number of items in a scale. Alpha values should generally range between 0.70 and 0.95 (Nunnally, 1978; Scientific Advisory Committee of the Medical Outcomes Trust, 2002) to be deemed satisfactory.

To facilitate understanding, a 'measurement paradigm' was used. This refers to the construct, the instrument and the scales. In this study, the construct of interest was 'ingestive skills' and it was measured using the MISA. The convergent and divergent construct validity of the MISA

has previously been studied. What remains to be determined is validity of the MISA using known groups.

Chi-square tests were used to test the differences in dysphagia status between groups separated on important factors (defined below):

Dysphagia status: no dysphagia vs. dysphagia, which was defined as follows

Based on clinical findings, patients in the 'No dysphagia' group tolerated regular solids and those in the 'Dysphagia' group were able to tolerate purees only (irrespective of liquid intake).

Liquid ingestion: regular liquids vs. modified liquids, was defined as follows:

Despite not having dysphagia with respect to solids, some individuals in the 'No dysphagia' group were only able to tolerate modified liquids.

Factors affecting ingestion

1. First stroke vs. repeated strokes

Based on the literature (Samsa et al., 1999, Jorgensen et al., 1995), it is anticipated that individuals with subsequent strokes have poorer outcomes than those with first strokes. And since dysphagia is closely related to stroke recovery, our hypothesis is that individuals with repeated strokes have a higher potential for dysphagia.

2. Stroke severity

Discharge destination has previously been used as a proxy for stroke severity. Discharge destination was grouped as follows: home, rehabilitation and assisted living. The choice of this variable as a proxy has been validated by Brown et al., (1999). In retrospect, it would have been ideal to use a standard stroke scale such as the Canadian Neurological Scale (Coté, Hachinski, Shurvell, Norris, & Wolfson, 1986), however this was not done. We hypothesize that patients with more severe strokes (i.e., those discharged to assisted living) have a poorer functional outcome than those with milder strokes, who were discharged home or to rehabilitation.

3. Lesion location: brainstem strokes vs. sub-cortical strokes

Stroke location was divided into four groups (brainstem, cerebellar, subcortical and cortical) based on CT scan information and neurological reports found in the chart. Due to inadequacy of the data available on the location of lesion, they were defined as follows: Left and right middle cerebral artery infarcts were identified as cortical strokes. All subcortical strokes were further defined and included thalamic, subcortical and lacunar strokes. Brainstem strokes included brainstem and posterior artery infarcts. The most significant differences were expected between brainstem strokes and sub-cortical strokes. According to the literature, brainstem strokes are associated with more severe ingestive difficulties than sub-cortical strokes and hence we hypothesize poorer MISA scores for patients with brainstem strokes than those with sub-cortical strokes.

4. Stroke type: hemorrhagic strokes vs. ischemic strokes

The two main types of strokes in the sample were hemorrhagic and ischemic. Ischemic strokes are expected to be different from hemorrhagic strokes with respect to prevalence and stroke recovery, which leads to potential differences in difficulties with ingestion. Our hypothesis is that individuals with hemorrhagic strokes have poorer ingestive skills (indicated by lower MISA scores) than those with ischemic strokes.

3.14.1 Exploration of patient characteristics and associations

One of the main factors of analysis was dysphagia status. Patients were allocated to either the 'Dysphagia' group or the 'No dysphagia' group as defined above. Although liquid ingestion was not a major focus in our study, between-group comparisons were conducted to study the differences between patients who were able to tolerate regular liquids and those who were only able to tolerate modified liquids.

The following characteristics were studied based on dysphagia status: age, gender, stroke severity (home vs. rehab vs. assisted living), location of lesion (brainstem vs. sub-cortical) and type of stroke (ischemic vs. hemorrhagic). Based on previous validity studies using the MISA, (Lambert, 2003, 2005, 2006) we hypothesized that there would be a significant difference between the two groups based on the above characteristics. We expected that MISA scores for participants with dysphagia would differ from those without by at least 4 points ($\pm$ S.D:3.5points).

For the analysis, patients were categorized into two sub-groups (≤ 80 years and > 80 years) according to the age distribution, but irrespective of their ingestive status. Patients in the younger sub-group were expected to have a higher ingestive performance than their older counterparts. Since both variables (Total MISA score and age group: ≤ 80 years and > 80 years) are categorical, a chi-square test was used.

Gender was also expected to be a variable of import. Since stroke recovery is known to be different for males and females (Wyller, 1999), this implies that ingestive skills may also be different based on gender. We hypothesized that males with dysphagia will score higher than their female counterparts. We also hypothesized that participants without dysphagia will not differ based on gender.

3.14.2 Internal consistency of the MISA

As a psychometric study, one of the aims of this study was to establish that the measurement tool (i.e., the MISA) is reliable, when used in the elderly, post-stroke population. To this end, Cronbach's Alpha Coefficients were calculated to determine the internal consistency of the items within the corresponding sub-scale, and of the sub-scales to the Total MISA score. It was hypothesized that the results would be similar to previous results obtained during test development (Lambert, 2002).

3.14.3 Validity of the MISA

Only discriminative validity was examined. This was done through known groups and correlational analyses, using a Bonferroni correction because of the multiple comparisons. The known groups were stroke severity, type of stroke and location of lesion as defined earlier in the chapter.

3.15 Summary

This chapter described the methods and procedures that were used to determine the discriminative validity of the MISA. It included details on the loci of the study, sample recruitment, and statistical analyses that were conducted.

Chapter 4: RESULTS

4.1 Chapter overview

In this chapter the main results of the study are presented. Included is information on existing relationships between patient characteristics and selected clinical and functional outcomes.

4.2 Description of the Study Sample

Table 4.2.1 displays the socio-demographic and clinical characteristics of all participants included in the study. Forty one patients with stroke aged 47 to 94 years, who were less than six weeks post-stroke, were recruited. Participants were on average 74.4 years old (S.D.:11.5 years). Thirty three percent of the participants were above 80 years of age and 46% were male.

Patients were grouped primarily according to their solid intake. Twenty four patients (59%) had no dysphagia and were on a regular, solid diet, compared to 17 (41%) on a pureed diet. It was noted that 3 of the 24 (12.5%) individuals with no dysphagia, with respect to solids did have ingestive difficulties with regular liquids. The average Total MISA score for individuals able to tolerate regular solids and regular liquids was 125.2 (S.D.:3.6) out of a possible score of 129. However, for the 3 individuals able to tolerate regular solids, but who required modified liquids, the average Total MISA score was significantly lower ($p<0.01$), with a mean of 116.3 (SD -4.0). For the patients with dysphagia and problems with solids, only two of the 17 were able to tolerate regular liquids. These patients had an average Total MISA score of 108 (S.D.: 2.8). The majority of individuals ($n=15$; 88.2%) in the dysphagia group displayed ingestive problems with liquid intake and were able to tolerate modified liquids only. Their average Total MISA score was 88.7 (S.D.: 7.3).

The majority (48.8%) of patients in the sample were discharged to rehabilitation centers. Sixty-one percent had a cortical stroke and for 66% it was a first stroke. Approximately 32% went home following hospitalization and a few ($n=7$) were discharged to assisted living. Twenty-nine patients were recruited from the MNI, one from the *IRM* and 11 were from the JRH. There were no refusals or withdrawals. One patient recruited at the MNI died while in hospital.

Table 4.2.1 Socio-demographic and Clinical Characteristics of the Sample

Characteristic	Number (%)	Characteristic	Number (%)
Age		Ingestive difficulties	
≤80 years	28 (67.0)	Dysphagic (puree diet)	17 (41.0)
>80years	13 (33.0)	Non-dysphagic (regular diet)	24 (59.0)
Gender		Regular liquids (irrespective of solid intake)	23 (56.0)
Male	19 (46.3)	Modified liquids (irrespective of solid intake)	18 (44.0)
Female	22 (53.7)		
Number of strokes		Comorbid conditions	
First stroke	27 (65.9)	Hypertension	20 (22.2)
Repeated stroke	14 (34.1)	Any neurological condition	16 (17.8)
Type of stroke		Any cardiovascular condition	18 (20.0)
Ischemic	33 (80.5)	Diabetes Type 2	10 (11.1)
Hemorrhagic	8 (19.5)	Any pulmonary condition	5 (5.6)
Stroke location		Other	21 (23.3)
Brainstem	1 (2.4)		
Cerebellar	4 (9.8)		
Cortical	25 (61.0)		
Subcortical	11 (26.8)		

*Patients in the sample may have had more than one co-morbid condition.

4.3 Internal consistency of the MISA

As expected, all of the subscale scales correlated with the MISA Total score with the correlations varying between 0.75 and 0.92 and an overall Cronbach's alpha of 0.85. The items in the Positioning scale correlated with each other and with the Total MISA scale score. All item-scale correlations were between 0.86 and 0.93 and the overall standardized alpha for the subscale was 0.86. Most of the items of the Self-feeding scale correlated well (0.67-0.83) with the subscale scale and the Total MISA score, except the two items addressing demonstration of good judgment by the patient and ability to tolerate the effort associated with the feeding activity. These showed a much lower correlation (0.21-0.28). The standardized alpha for the Self-feeding subscale was 0.89. In the Solid ingestion subscale, only the items addressing respiration and clearance of airway after eating solids demonstrated low correlations (0.05 and 0.27 respectively). All items in the Liquid ingestion scale and Texture management scale correlated with their respective subscales with the correlations ranging from 0.85 -0.93 and the overall alpha of 0.89 and 0.85 respectively.

4.4 Discriminative validity of the MISA and correlational analyses

The results of the analyses exploring the differences between patients with and without dysphagia are presented in Table 4.4.1. Spearman's correlations were done to explore the relationships between variables. To examine the discriminative validity of the MISA, the following hypotheses, (based on clinical experience, anatomy and research literature) were tested:

- Individuals with stroke, who were older than 80 years, would demonstrate poorer ingestive skills as evaluated by the MISA than those who were younger (80 years or less).
- Men would score higher (on the MISA) than women in the 'dysphagia' group. However no gender differences were expected in the 'No dysphagia' group.
- Patients who were discharged home (i.e., those who had milder strokes) would have better functional outcomes (including ingestive performance), compared to those who were discharged to rehabilitation or assisted living.
- Patients with brain stem strokes would have the poorest ingestive skill performance compared to those with lesions in other locations (cerebellar, cortical or subcortical).
- Individuals with two or more strokes would fare more poorly than those with a first stroke.

- Individuals with ischemic strokes would not have significantly different scores from those with hemorrhagic strokes.

Results were deemed to be statistically significant at $p < 0.01$ (with the Bonferroni correction). Between-group differences addressing dysphagia status and Total MISA score, and based on age and gender were analyzed using the Mann-Whitney U test. Results were significant for both analyses, indicating that patients in the younger cohort scored significantly higher ($p < 0.005$) than those in the older group. The mean Total MISA for younger patients (with or without dysphagia) was 116.4 (out of a maximum of 129), with a standard deviation of 15.3 points and for older patients (with or without dysphagia) was 97.5 (S.D. = 16.9). Men scored significantly higher ($p < 0.01$) on the Total MISA score than women, with a mean difference on the Total MISA score of 14.2 points. As a group, the men had a higher proportion of individuals without dysphagia (79%) than women (41%). The Total MISA score correlated moderately with age but was low with gender. Both were negative and significant ($r = -0.58$; $p < 0.001$ and $r = -0.34$; $p < 0.02$ respectively).

Statistical analyses (Kruskal Wallis/Fisher's Exact test) addressing the relationship between Total MISA score and stroke characteristics were significant for stroke severity (discharge destination; $p < 0.005$) and location of lesion ($p < 0.01$), despite the unequal distribution of patients in each of the subgroups. Patients who were discharged home had the highest end-range of MISA scores (126.1) and those who were discharged to assisted living had the lowest range of Total MISA scores (95% CI: 77.1 to 102.7). These results support our hypotheses that the MISA can discriminate between known groups of patients based on stroke severity and location of lesion. Patients who were in the group discharged to rehabilitation (95% CI: 104.9 to 121.1) showed some end-range overlap of Total MISA scores with those who were discharged to home. However, the range for those discharged to assisted living was distinct, with no overlap.

A Fisher's Exact test was done for location of lesion and dysphagia status. Significant results were obtained, $p < 0.001$. Comparison between the groups based on Total MISA score and lesion location also produced significant results ($H = 9.65$, 3df, $p < 0.01$). Hence, the MISA was able to distinguish between the various lesion locations (brainstem, cerebellar, cortical and subcortical). This finding is in agreement with our hypothesized outcome.

The results for the analyses of groups based on first or repeated stroke and type of stroke were found to be non-significant. Research literature reports that approximately 30% of all strokes are recurrent strokes. In our sample, there were almost twice as many individuals with first stroke

(n=27) when compared to those with repeated stroke (n=14), which is not representative of the population distribution. The average Total MISA score for patients with a repeated stroke was lower (109.4, S.D. =19.2) than those with a first stroke (112.0, S.D. =17.7). There was considerable overlap of the 95% confidence interval for the two groups (please see table below). The average Total MISA score was lower for the group of individuals with ischemic strokes (109.5, S.D. =18.9) when compared to the group with hemorrhagic strokes (114.3, S.D. =13.6).

Correlations between the Total MISA score and first or repeated stroke, and between Total MISA score and location of lesion were low, negative and insignificant ($r = -0.07$, $p < 0.67$ and $r = -0.14$, $p < 0.35$ respectively). Similarly, low and insignificant correlations were obtained between the Total MISA score and type of stroke. In this case, the correlation was positive ($r = 0.06$, $p < 0.7$).

Statistical analyses (Mann-Whitney U test) addressing the relationship between Total MISA score and dysphagia status (presence or absence of dysphagia) and type of stroke were not significant, which is in agreement with our hypothesis. There was a highly, significant difference ($p < .0001$) between the Total MISA score and dysphagia status (based on solid ingestion) and between the Total MISA score and liquid intake, which implies that individuals with no dysphagia (with respect to solid and/or liquid intake) scored higher than those with dysphagia. This is expected and in agreement with the hypothesis established *a priori*. Since multiple between-group tests were done, a Bonferonni's correction was used to reduce the Type I error (Dunn, 1955).

Table 4.4.1 Differences between Patients with Stroke with Dysphagia and those without (n=41)

		n	Mean (S.D.)	95% CI	Mann-Whitney's U statistic/ Kruskal- Wallis' statistic
Age	≤80 years	28	116.4(15.3)	110.5 to 122.4	79.00**
	>80 years	13	97.5 (16.9)	87.3 to 107.7	
Gender	Male	19	118.1(12.8)	111.9 to 124.3	124.50*
	Female	22	103.8(19.4)	95.2 to 112.4	
First vs. Subsequent stroke	First stroke	27	112.0(17.7)	105.0 to 119.0	164.00
	Second stroke	14	109.4(19.2)	98.3 to 120.5	
	Brainstem	1	129.0	129.0	
Location of lesion	Cerebellar	4	127.0(3.4)	121.6 to 132.4	9.65*
	Cortical	25	105.3(17.8)	97.9 to 112.6	
	Sub-cortical	11	116.2(13.5)	107.1 to 125.2	
Type of stroke	Ischemic	33	109.5(18.9)	102.8 to 116.2	143.50
	Hemorrhagic	8	114.3(13.6)	102.9 to 125.6	
	Home	13	119.2(11.4)	112.3 to 126.1	
Discharge destination	Rehabilitation	20	113.0(17.2)	104.9 to 121.1	12.69**
	Assisted Living	7	89.9(13.8)	77.1 to 102.7	
	Deceased	1	89.0	89.0	
Dysphagia status	No dysphagia (regular solids)	24	124.2(4.7)	122.2 to 126.2	0.00***
	Dysphagia (purees only)	17	91.0(9.4)	86.2 to 95.8	
Liquid intake	Regular liquids	23	123.7(6.1)	121.1 to 126.4	8.00***
	Modified liquids	18	93.3(12.6)	87.1 to 99.6	

Results are statistically significant at the Bonferroni adjusted p-level of *p<0.01, **p<0.005, ***p<0.0001

Table 4.4.2 Characteristics of the Ingestive Skills of Patients with Stroke, with and without Dysphagia (n=41)

MISA scale	Patients with Stroke without Dysphagia, n=24	Patients with Stroke and Dysphagia, n=17
	Mean (S.D.)	Mean (S.D.)
Positioning	11.1 (1.3)	9.6 (2.4)
Self-feeding	20.3 (1.2)	16.9 (3.8)
Solid ingestion	35 (1.3)	28.6 (4.2)
Liquid ingestion	19.8 (1.7)	14 (2.8)
Texture management	37.9 (3.2)	21.8 (3.2)
Total	124.3 (4.8)	91 (9.4)

4.5 Summary

In summary, three of our six hypotheses have been supported by statistically significant between-group differences. The first of these hypotheses stated that individuals with stroke, who were older than 80 years, would demonstrate poorer ingestive skills as evaluated by the MISA than those who were 80 years or less. The second hypothesis pertained to gender differences, and stated that men would score higher (on the MISA) than women in the 'dysphagia' group. The final supported hypothesis affirmed that individuals who were discharged home had milder strokes and higher ingestive skills than those discharged to rehabilitation or assisted living.

Due to the fact that the only patient recruited into the category for brainstem stroke, did not present with dysphagia, no significant differences were found between individuals with brainstem stroke and those with subcortical stroke. Hence our hypothesis, based on this premise was not supported. The other two hypotheses that were not supported proposed significant differences between individuals with first strokes and those with recurrent stroke, as well as between individuals with ischemic strokes and those with hemorrhagic strokes. As mentioned earlier, this could be because our criteria excluded individuals with unresolved dysphagia due to previous strokes, and individuals who were exclusively on tube feeding. If these individuals had been included, they would have contributed to the heterogeneity of the sample and would have probably also contributed to a decreased average Total MISA score, which may have produced statistically significant between-group differences.

Chapter 5: DISCUSSION

5.1 Chapter overview

For this thesis, we studied the performance of a relatively new tool, the MISA, which was developed and initially validated by Lambert (2002) in a long-term care setting. Dr Lambert studied the intra-rater and inter-rater reliability, as well as the score stability of the MISA. Reliability estimates for the MISA were higher than 0.80 for most of the subscales. With respect to validity, preliminary psychometric testing of the MISA (Lambert, 2002) addressed convergent validity, by comparing patients' MISA scores to functional outcome measures and cognitive assessments, namely the Functional Independence Measure (FIM) and the Mini-Mental State Evaluation (MMSE). From the results of this study, it was concluded that the MISA was appropriate for making valid inferences in an adult population (in long-term care) with neurogenic, ingestive difficulties. While earlier validation studies were comprehensive and enlightening, a new measurement tool should always be tested by another researcher in a different setting, with a new sample to confirm its psychometric properties. This has now been established for the MISA for two of its psychometric properties, internal consistency and discriminative validity. Chapter 5, includes a discussion of the results of the study, with respect to the sample and the measurement tool, the MISA. It also provides an overview of the inferences drawn from the study. The new sample enabled the study of the ingestive performance of elderly individuals in the acute post-stroke phase in the hospital and rehabilitation setting.

5.2 The Sample

5.2.1 Age and Gender

The prevalence of stroke is known to be higher among the elderly (individuals aged 65 years and older; Canadian Stroke Network, 2008), than the general population. However, since the average life span of individuals in Canada is 80 years, there are fewer individuals aged 80 years and over (Statistics Canada, 2008). This was reflected in our sample distribution, with the majority (70%) of patients in the younger group (≤ 80 years) and only 30% in the older cohort. As noted in the results, the Total MISA score not only correlated moderately and negatively with age, but patients in the younger sub-group demonstrated significantly better ingestive performance, as measured by the MISA, than individuals in the older cohort. This is in agreement with earlier

studies, such as the Copenhagen Stroke Study (Nakayama et al., 1994) and more recent studies by Kugler et al. (2003) and Rosen et al. (2005), which reported inversely proportional stroke outcomes with age. This is a fairly obvious relationship, considering that advanced age is often associated with a number of comorbidities and a decrease in functional capacities, which would, in turn, negatively influence ingestive skill performance. It explains why older individuals present with poorer ingestive skills, although ingestive skills do not diminish due to advanced age alone (Fucile, Wright, Chan, Yee, Langlais, & Giselle, 1998)

The negative correlation of the Total MISA score to gender is also an expected outcome, since gender differences in stroke outcomes have been shown to be statistically significant ($p < 0.05$), with men performing better than women (Gargano & Reeves, 2007). This is substantiated by the fact that stroke recovery is different for males and females (Glader et al., 2003; Holroyd-Leduc et al., 2000; Kapral et al., 2005; Di Carlo et al., 2003; Gargano & Reeves, 2007; Wyller, 1999). Despite the number of studies addressing gender differences and stroke recovery, the specific cause of these differences remains uncertain. One reason, proposed by various researchers (Gargano & Reeves, 2007; Glader et al., 2003) for these gender differences, is the poorer psychological status (more depression) in women. This may negatively affect their functional recovery, including ingestive performance, post-stroke, which is one aspect of stroke recovery.

5.2.2 Stroke characteristics

Contrary to our hypothesis, there was no significant difference between patients with a first stroke and those with subsequent strokes. This could be due to the fact that research aimed at studying the differences between first and recurrent strokes often addresses long-term outcomes, in the order of years, compared to weeks, and is usually based on historical data collection. In our study, patients were evaluated within 6-8 weeks post-stroke. Although no statistically significant difference (between individuals with first stroke and those with repeated strokes) was found, the average Total MISA score for individuals with recurrent strokes was lower (109.4, S.D.=19.2) than for individuals with first stroke (112.0; S.D.=17.7). Another important reason for the lack of a significant difference between these two groups, with first and recurrent strokes, is the criterion of our study which excluded individuals with unresolved dysphagia. Hence, the individuals in the

group with recurrent strokes in our sample were clinically similar to the individuals in the group with first strokes, with respect to dysphagia status.

Discharge destination was used as a proxy for stroke severity in this study. However, it is important to remember that discharge destination is often influenced by various factors, such as, the availability of a viable support system for patients who are to be discharged home, hospital discharge policies regarding length of stay, as well as the patient's age and comorbid conditions. As anticipated, the Total MISA score correlated moderately with discharge destination. Stroke severity as measured by discharge destination: home/rehabilitation/assisted living significantly differentiated between the known groups of individuals and is based on a well-established premise that stroke severity is inversely proportional to functional outcomes (Stern et al., 1971; Feigensen et al., 1977 and Jiminez & Morgan, 1979). Hence, from the data, we can infer that patients who have had milder strokes and were discharged home were at a higher functional level than those who were discharged to rehabilitation or to assisted living.

Location of lesion was categorized into four groups (brainstem, cerebellar, subcortical and cortical). Based on the literature (Logemann, 1983, 1989, Ritky, Rajeshwari & Oscar, 1996), we hypothesized that there would be significant differences in ingestive skills related to the location of the lesion. Dysphagia status, in terms of the presence or absence of dysphagia (based on clinical presentation), and the Total MISA score did indeed show significant differences across lesion locations. However, we expected patients with brainstem strokes to fare more poorly than those with sub-cortical strokes, with respect to ingestive skill performance. Anatomically, swallowing is initiated by activation of the cortical motor strip or stimulation of the motor cortex. The reflexive portion of the swallow is controlled by the swallowing center in the brainstem (Doty, 1968; Alberts & Homer, 1995). Strokes affecting the brainstem are typically responsible for the most severe cases of dysphagia, due to the fact that the nuclei of the cranial nerves involved in swallowing are located in the brainstem. This was not evident in our sample and is most probably due to the extremely small sample size ($n=1$) for the group with brainstem stroke and also to the fact that the single patient with brainstem stroke was from the 'No-dysphagia' group and had attained the maximum score of 129 on the MISA. Subcortical strokes are less devastating in their outcomes with respect to ingestive skills because the sensory and motor pathways are affected (Logemann, 1989).

A significant difference was obtained between patients with cerebellar strokes and those with cortical strokes, with patients with cortical strokes faring more poorly than those with cerebellar

strokes. One plausible explanation for this difference could be that most of the individuals with dysphagia (15 out of 17) had cortical strokes. All individuals who presented with cerebellar strokes belonged to the group without dysphagia. Another reason for differences between the two groups may be based on the physiology of functional recovery post stroke. The main clinical features of cerebellar stroke include impaired coordination and imbalance, whereas cortical strokes affect motor performance. Therefore, the primary area of ingestive performance where the effects of a cerebellar stroke would be most noted is self-feeding. However, patients often compensate for impaired coordination during self-feeding by using the non-affected hand more. This is less of an issue if it is the non-dominant side that has been affected. In our sample, all patients with cerebellar strokes scored the maximum of 21 points on the self-feeding scale demonstrating their ability to fully compensate for any deficit. In the case of patients with cortical strokes however, functional recovery occurs by reorganization of the motor cortex, which may take 3-6 months post-stroke (Hamdy et al., 1998), allowing more time for any deficits to become noticeable. Future studies aimed at addressing the impact of location of lesion on dysphagia status, would need to ensure a more balanced sample of different locations.

Patients with ischemic strokes and those with hemorrhagic strokes were expected to differ on frequency and dysphagia status. Ischemic strokes make up 80-85% of all strokes, while hemorrhagic strokes are responsible for 15-20%. A similar distribution was seen in our sample with 33 out of the 41 patients in the sample presenting with ischemic strokes. The Total MISA score differed by a mean of 4.8 points between the patients with ischemic stroke and those with hemorrhagic stroke. These results were non-significant for type of stroke and dysphagia status. These results could have been obtained because, although hemorrhagic strokes potentially cause more severe damage than ischemic strokes, the main differences in outcome are primarily in the immediate post-stroke phase. Since patients in our study were evaluated up to 8 weeks post-stroke, patients with the hemorrhagic strokes may have recovered some of their functions by the time they were evaluated for this study. Given the current health care system, it may be possible to evaluate patients within a week post-stroke to further clarify between group differences. Another possible reason for the non-significant results is that although we anticipated patients with hemorrhagic strokes to do worse, we excluded patients who were exclusively tube fed. It would have been unethical to evaluate them solely for research purposes, once their NPO (nothing by mouth) status

had already been established. These individuals could possibly have belonged to the group with hemorrhagic strokes.

5.2.3 Dysphagia status: solid and liquid ingestion

As expected, the clearest group distinction was between individuals with and without dysphagia. Dysphagia status was based on the patient's ability to tolerate food and drink. Modification of food textures and thickening of fluids are a compensatory technique for the therapeutic management of dysphagia (Martin, 1991; Pardoe, 1993; Curran & Groher, 1990; Langmore 1993). A number of studies have been conducted by dieticians and dysphagia clinicians, addressing the characteristics of food and drink in relation to a patient's dysphagia status (Strowd et al., 2008; Felt et al., 1990; Womak & Pope, 1992; Li et al., 1992).

There was a highly significant, negative correlation, between the Total MISA score and dysphagia status, implying that individuals without dysphagia scored higher than those with dysphagia with respect to solid ingestion. Similar results were obtained by a comparison of means between the Total MISA score and liquid intake, indicating that patients requiring modified liquids had a poorer ingestive skill status when compared to those able to tolerate regular liquids. This was an expected and intuitive result, in agreement with the hypothesis established *a priori*.

Ingestive skills were measured on each of the 5 scales of the MISA, patient positioning, self-feeding skills, solid and liquid ingestion and texture management. It is well worth noting that there was good distribution of scale and Total MISA scores, i.e., no floor and ceiling effects for the groups with and without dysphagia respectively. Our hypothesis for dysphagia status (solid and liquid ingestion) was based on the fact that there is a range of 'Normal' and 'Impaired' ingestive skills due to the variability of patient characteristics. Patients in the dysphagia group scored between 86 and 96 for the Total MISA score, whereas patients without dysphagia scored between 122 and 126. The lack of overlap between the two group scores further supports the discriminative ability of the MISA. It can also be hypothesized that individuals on minced and soft textures may be expected to score between 97 and 121. This would be advantageous for determining cut off scores for standardization of diet modification.

Similarly, significant findings were obtained with respect to liquid ingestion. However, the range of Total MISA scores for individuals with regular liquids (121 to 126) was much narrower than those who were able to only tolerate modified liquids (87 to 100). This may be explained by

the fact that the group with modified liquids included individuals receiving three different liquid viscosities: nectar, honey and pudding. The grouping for liquid ingestion was done in this manner because two of the three centers only offered honey viscosity and regular liquids.

5.3 Internal consistency of the MISA

Cronbach's alpha measures the extent to which the items in a tool, such as the MISA, correlate highly with each other and with the total score of the subscale or scale. In our study, Cronbach's alpha was calculated to evaluate item to subscale correlations and subscale to total MISA correlations. As noted by Streiner and Norman, (2003), in general, the value of Cronbach's alpha should lie between 0.7 and 0.9, for a scale to demonstrate 'good' internal consistency/reliability. However, for use in clinical practice, when decisions are made for individuals on a case-by-case basis, an alpha value of 0.85-0.95 is necessary to decrease the standard error of measurement (Nunnally, 1978).

When the items of a particular subscale are poorly correlated, Cronbach's alpha is usually low (<0.7) and vice versa. If the average inter-item correlation is low, alpha will be low and vice versa. However, alpha values >0.9 , indicate item redundancy. A high number of items in a scale also contributes to an inflated alpha value and may cause a scale to 'look' more homogeneous than it actually is (Cortina, 1993).

The results showed that the 5 subscales (Positioning, Self-feeding, Solid-ingestion, Liquid-ingestion and Texture management) correlated well with the Total MISA score, with correlations ranging between 0.75 and 0.92 and an overall Cronbach's alpha of 0.85. The standardized alpha values for all subscales were good (ranging from 0.84 to 0.89). All except a few item-scale correlations (identified below) were high (between 0.86 and 0.93). This is consistent with earlier reliability studies done by Lambert (2002) during development and preliminary psychometric testing of the MISA. Two items on the self-feeding subscale, addressing the patient's focus at meal-time and physical effort, showed lower correlations (0.21-0.28). Low correlations were also obtained in the solid-ingestion sub-scale, evaluating respiration and ability to clear airway after eating solids (0.05 and 0.27 respectively). These findings could be due to the fact that although these items evaluate ingestive skill, they may not specifically address the domains of self-feeding and solid ingestion. All items in the Liquid ingestion scale and Texture management scale correlated well with their respective subscales.

These outcomes confirm the internal consistency of the MISA and support its use in a geriatric population with stroke. Future studies could employ factor analysis to further investigate the item to scale fit.

5.4 Summary

In summary, the sample characteristics were found to be fairly representative of the elderly, post-stroke population. The MISA demonstrates adequate discriminative ability with a number of 'known' groups, such as age, gender, severity of stroke and location of lesion. The lack of group differences for first versus repeated stroke and type of stroke may be explained by our exclusion criteria. Hence, the results of the study, on the whole are significant, and therefore, provide more evidence that scores from the MISA may be used to make interpretations about the performance of individuals assessed on this questionnaire.

Chapter 6: STUDY LIMITATIONS, SIGNIFICANCE AND CONCLUSION

6.1 Chapter overview

Although considerable efforts were made to optimize the study and its design, the current study has a few limitations that will be discussed in this chapter. These limitations were primarily due to issues of practicality and time constraints. This chapter also presents the important clinical and research contributions of the study, and further discusses the ethical considerations that were taken into account.

6.2 Study limitations

The MISA discriminates between the ‘known/extreme’ groups. Since we used ‘extreme’ groups, this is only a first distinction. The next step should assess the ability of the MISA to discriminate between groups for which the expected differences will be smaller, for example between individuals on pureed and minced solid textures or between individuals on honey and nectar - viscosity liquids.

Furthermore, the present study employed a cross-sectional design in which subjects’ MISA scores are compared at a single point in time. This design makes it difficult to assess the temporal aspects of the association between subjects’ status and MISA scores and increases the risk of confounding by the differences in unmeasured patient characteristics. Indeed, even if we attempted to control for patients’ age and stroke severity, patients with dysphagia and those without may differ on ‘type’ of stroke, functional status, or pre-morbid condition, and such differences may affect the results of our comparisons. To reduce the risk of such confounding by potential between-patient differences, unaccounted for in the analysis, future research should rely on a longitudinal design with repeated measures of the MISA at two (or more) time points. This will allow the analysis to focus on within-subject changes over time on the MISA scores. One advantage will be that between-subject differences of potential confounders will affect both earlier and later scores, so that the difference itself will not be confounded. Another important advantage of the longitudinal design will be that it will directly assess the responsiveness to change of the MISA score. This is an essential psychometric property of the scale that may be considered as an outcome measure for future clinical trials or prognostic studies (Fortin, et al., 2000). However, to assess responsiveness to change, it would be necessary to refine the procedures for both, the selection and

evaluation of the study subjects. One approach to assess responsiveness to change is to select two groups such that subjects in one group are a priori known to improve compared to subjects in the second (Streiner & Norman, 1995). A classical approach is to rely on the data from a randomized clinical trial in order to compare subjects treated with an intervention of established effectiveness with those in the placebo or control group (Fortin et al., 2000; Katz, Larson, Phillips, Fossel, & Liang, 1992). An alternative is to assess all study participants with an external criterion for a clinically meaningful change, considered as a 'gold standard'. Patients who improved according to the 'gold standard', are compared to those who did not change (Fortin et al., 2000).

As noted in the methods section, blinding of the evaluators administering the MISA was not feasible and may have contributed to biased results. In an attempt to reduce this bias, chart reviews were conducted only after the administration of the MISA, and where possible, by a research assistant who had not evaluated the patient.

This study is limited in scope because patients were recruited from acute-care hospitals and rehabilitation centers only and showed some areas in which they were not truly representative of the population, such as non-significant differences based on type of stroke or on first versus recurrent stroke. Long-term care centers were not included in our study population. Geographic location bias is reduced since we recruited patients from across Montreal and Laval regions and similar, previous studies done in these regions have reported no bias (Lambert et al., 2003; Lambert, Gisel, Groher, Abrahamowicz, & Wood-Dauphinee, 2004; Lambert et al., 2005).

6.3 Significance of the study and Conclusions

Current clinical guidelines in North America for stroke intervention provide a general outline for therapists regarding which assessments or interventions may be useful in the management of dysphagia. Presently however, most references to diet modification are limited to mentioning that this may be an appropriate intervention. The most detail provided for diet modification is the use of the Dysphagia Diet Classification (McCullough, Pelletier, & Stelle, 2003) to allow for some standardization. However, the timing of progression of patients to a higher-textured diet is determined by the therapist and based on clinical judgment, professional experience and expertise.

Confirmation of the internal consistency of the MISA contributes to its psychometric strength for use in dysphagia evaluation and management. Establishment of the discriminative

validity of the MISA facilitates further studies using MISA scores to distinguish ‘less-extreme’ groups of individuals as well as studies addressing the responsiveness of the MISA. These results can then be used to direct clinical intervention with respect to diet modification. Statistical analyses such as Receiver Operating Characteristics (ROCs) may be used in the future to determine the range or specific cut-off, which will contribute to more objective clinical interpretation of the MISA scores.

6.4 Summary

The results of this study confirm the discriminative validity of the MISA using known groups, and reconfirm the internal consistency of the instrument. This chapter also addressed the significant contributions of the study and its limitations. Based on the results of this study, as well as previous research, the MISA holds considerable promise not only as a bedside evaluation tool of ingestive skills, but also for its possibility to facilitate the standardization of clinical evaluation and management of dysphagia.

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APPENDICES

Appendix A: The McGill Ingestive Skills Assessment (MISA)

McGill Ingestive Skills Assessment

Patient name : _____

Room number : _____ File # : _____ Date : _____

Scale	# Items	Patient score	Maximum	% score
				(Patient score -# Items) X 100 (maximum-# items)
Positioning	4		12	
Self-Feeding Skills	7		21	
Liquid Ingestion	7		21	
Solid Ingestion	12		36	
Texture Management: solids	5		15	
Texture Management: liquids	8		24	
TOTAL	43		129	



Positioning

1 point

2 point

3 point

Maintains symmetry of posture

never or rarely

sometimes

always or almost always

Maintains adequate head position for feeding

never or rarely

sometimes

always or almost always

Maintains 90 degree hip angle

never or rarely

sometimes

always or almost always

Able to sit upright without leaning on arm

requires constant support of arm

requires occasional support

does not need support of arms to maintain position

**Self-Feeding Skills****1 point****2 point****3 point**

Able to grasp utensil functionally and bring it to the mouth

never or rarely or does not self-feed

sometimes

always or almost always

Able to grasp cup/glass functionally and bring it to the mouth

never or rarely or does not self-feed

sometimes

always or almost always

Selects appropriate utensil for food item

never or rarely or does not self-feed

sometimes

always or almost always

Takes appropriately-sized mouthfuls

never or rarely or does not self feed

sometimes

always or almost always

Demonstrates good judgment

never or rarely

sometimes

always or almost always

Able to focus on meal

unable to focus

occasionally distracted

able to remain focused

Tolerates physical effort of meal

fatigued throughout the meal

becomes fatigued part-way through the meal

no fatigue noted

**Liquid Ingestion****1 point****2 point****3 point**

Seals lips on cup

never or rarely

sometimes

always or almost always

Able to use a regular straw

does not suck or does not suck hard enough

drinks with difficulty

drinks without difficulty

Prevents leakage of liquid from cup while drinking

significant loss

light to moderate amounts

no leakage

Prevents leakage of liquid from mouth before swallow

significant loss

light to moderate amounts

no leakage

Able to take a sequence of sips

never or rarely

sometimes

always or almost always

Demonstrates same voice quality after drinking

total loss of voice or voice becomes wet, hoarse or gurgly after drinking a small quantity of liquid or does not vocalize despite stimulation

voice becomes wet, hoarse or gurgly after drinking a large quantity of liquid

no change in voice with drinking

Demonstrates clear airway after liquids

does not clear throat when needed or ineffective clearing

clears throat effectively

does not need to clear throat during meal

**Solid Ingestion****1 point****2 point****3 point**

Closes upper lip on utensil	never or rarely	sometimes	always or almost always
Prevents the loss of food from the mouth before swallowing	constant loss or loses large amounts occasionally	loss of small amounts	no loss
Uses functional chewing pattern	no chewing effort or suckling only	vertical movements, 'munching'	normal rotary chewing pattern
Chewing appropriate to food item	never or rarely	sometimes	always or almost always
Positions bolus when chewing	on the hard palate or does not form a cohesive bolus or does not chew	on the incisors or on the molars from time to time	always on the molars
Quantity of food remaining in mouth after swallow	more than half of bolus	less than half of bolus	no residue
Location of food remaining in mouth after swallow	on the hard palate or in the cheeks	around the tongue or on the teeth	no residue
Swallows without extra effort	never or rarely	sometimes, or only for certain types of solids	always or almost always
Swallows only once or twice per mouthful	never or rarely	sometimes, or only for certain types of solids	always or almost always
Respiration during the meal	occasional severe difficulty or minor difficulty throughout meal	occasional minor difficulty	no difficulty
Demonstrates same voice quality after eating	total loss of voice or voice becomes wet, hoarse or gurgly after eating a small quantity of solid or does not verbalize despite stimulation	voice becomes wet, hoarse or gurgly after eating a lot of solid	no change in voice
Demonstrates clear airway after solids	does not clear throat when needed or ineffective clearing	effective clearing	does not need to clear throat



Texture Management – solids

1 point

2 point

3 point

Capable of eating heterogeneous textures	never or rarely	sometimes	always or almost always
Capable of eating fibrous solids	never or rarely	sometimes	always or almost always
Capable of eating hard solids	never or rarely	sometimes	always or almost always
Capable of eating minced/ granular solids	never or rarely	sometimes	always or almost always
Capable of eating sticky solids	never or rarely	sometimes	always or almost always
Capable of eating soft solids	never or rarely	sometimes	always or almost always
Capable of eating puree	never or rarely	sometimes	always or almost always
Capable of eating pudding	never or rarely	sometimes	always or almost always



Texture Management - liquids

1 point

2 point

3 point

Capable of drinking water	never or rarely	sometimes	always or almost always
Capable of drinking thin juices	never or rarely	sometimes	always or almost always
Capable of drinking nectar consistency liquids	never or rarely	sometimes	always or almost always
Capable of drinking honey consistency liquids	never or rarely	sometimes	always or almost always
Capable of drinking pudding consistency liquids	never or rarely	sometimes	always or almost always

Appendix B: Certification of Ethical Acceptability for Research Involving Human Subjects

Appendix C: Ethics Approval - McGill Institutional Review Board – 2006-2007

Appendix D: Ethics Approval - McGill Institutional Review Board – 2007-2008

Appendix E: Ethics Approval - McGill Institutional Review Board – 2008-2009

Appendix F: Ethics Approval - CRIR – 2004-2005

Appendix G: Ethics Approval - CRIR – 2005-2006

Appendix H: Ethics Approval - CRIR – 2006-2007

Appendix I: Ethics Approval - CRIR – 2007-2008

Appendix J: Consent form – English

15 DEC. 2005

REC
28 NOV. 2005
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Consent Form

The Discriminative Validity of the McGill Ingestive Skills Assessment

Erika G. Gisel, Ph.D., OTR, erg.

Introduction

Following a stroke many people have difficulties with feeding and swallowing. Persons with feeding difficulties are at greater risk for having poor nutrition, becoming dehydrated and having other medical problems such as infections of the lungs, and in older persons, pressure sores. We have recently developed a new test, called the *McGill Ingestive Skills Assessment (MISA)* that allows us to examine feeding skills in the person's regular mealtime environment. The MISA identifies the person's ability to eat a regular table diet and to drink liquids. At this stage we do not know yet whether the MISA can also measure the progress in eating and drinking, as a person recovers from a stroke.

Therefore, Dr. Gisel from McGill University and her collaborators, Dr. Sharon Wood-Dauphinee, Dr. Celine Lamarre and Ms Franceen Kaizer, are conducting a study to determine how well the MISA can distinguish between groups of individuals with stroke with and without feeding problems.

Goals of the Study

The present study is necessary to establish how well the MISA can distinguish between groups of individuals with stroke, with and without feeding problems. If this can be established, it will greatly enhance the MISA's usefulness to determine when a person is ready for the change from a pureed diet to a more solid diet.

Nature of my Participation

This study consists of one mealtime evaluation where you will be observed taking your meal independently or with the accustomed helper in the usual environment. The examiner does not interact with you or your helper but observes your feeding ability during the meal and scores the MISA. You will be seated with the hips flexed and feet well supported. The evaluation takes no longer than the duration of the meal, which is usually less than 30 minutes.

Evaluation The mealtime evaluation will take place within the first week of your admission to rehabilitation at the Montreal Rehabilitation Institute (MRI) or at the Jewish Rehabilitation Hospital (JRH). Participants may be on a pureed diet (dysphagia diet I) or a regular diet and may require thickened liquids, and must be within 4 weeks of the stroke.

Examiners An occupational therapist will administer the evaluation.

Benefits

There will be no immediate benefits to you, the participant. However, we hope that the MISA will be able to measure the differences we are anticipating. If so, the MISA will be used in rehabilitation facilities to document changes over time and in response to treatment. This will mean major progress in this area of rehabilitation, because the effectiveness of treatments can be measured with greater confidence.

Risks

This study does not pose any direct risks to you. However, you may feel inconvenienced because the examiner will observe you while you are eating. Should you experience difficulties eating or drinking during the time of the evaluation, you will receive all procedures that are necessary by the hospital staff.

Confidentiality

All information collected will be kept strictly confidential. The information we collect in this study will be grouped together for analysis. No publication or presentation about this study will reveal any information that could be used to identify you. All information will be kept in a locked filing cabinet in Dr. Gisel's office at McGill University for 5 years after the termination of this study.

Voluntary Participation and Withdrawal

Your participation in this study is voluntary and you may withdraw from the study at any time. If you withdraw, you will continue to receive the same care at the JRH or the MRI as if you had not been enrolled in this study.

Additional Information

If you would like additional information or have any questions or concerns regarding this study, please contact Dr. Erika Gisel at: School of Physical & Occupational Therapy, McGill University, 3630 Promenade Sir-William-Osler, Montreal, Quebec H3G 1Y5; telephone (514) 398-4510, fax (514) 398-8193. If you wish to speak to someone who is outside the research project at the JRH regarding your rights as a research subject, please contact the hospital representative, Mrs. Michelle Nadon at (450) 688-9550 ext. 4417 or at the MRI, Mrs Ginette Desjardins at (514) 340-2085 ext. 2175. You may also speak to the research coordinator of the Centre de Recherche Interdisciplinaire en Réadaptation du Montréal métropolitain (CRIR), Mrs. Anik Nolet at (514)527-4527, ext. 2643.

Discriminative Validity of the McGill Ingestive Skills Assessment

Consent to Participate

I, the undersigned, have read and understand the nature and extent of my participation and the risks that I may be exposed to, as presented to me in this consent form. All questions I had concerning the different aspects of this study have been answered to my satisfaction.

I agree voluntarily to participate in this study and I know that I may withdraw from this study at any time without risk to the care that I will receive. I was allowed sufficient time to make this decision, and I understand that a copy of this consent form will be kept in my medical record. A signed copy of this consent form must be given to me.

Signature

Date

Assent of the Participant
(Able to understand the nature of the study)

Date

Legal Representative

Date

Witness

Date

Responsibility of the investigator or his/her representative

The research project and its procedures have been described to the participant and/or his representative. A member of the research team (researcher or occupational therapist) has answered all their questions and explained that participation is voluntary. The research team commits itself to adhere to the procedures of the research that have been described in this consent form.

Signature of the researcher or
representative who obtained consent

Date

Signature of the researcher or representative
and position (block letters)

Date

11-23-05

Appendix K: Consent form – French

Formulaire de consentement**La validité discriminatoire de « L'Évaluation des Capacités d'Ingestion
'McGill' »**

Erika G. Gisel Ph.D., OTR, erg.

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APPROUVÉ***Introduction***

À la suite d'un accident vasculaire cérébral (AVC) plusieurs personnes ont des difficultés de déglutition. Ces personnes sont à risque élevé d'un déficit nutritionnel et de déshydratation rendant ces personnes susceptibles de complications médicales telles les infections et les plaies de pression, sans oublier les pneumonies d'aspiration. Nous avons récemment développé un nouveau test, appelé l'Évaluation des Capacités d'Ingestion 'McGill' (ECIM) qui nous permet d'évaluer les habiletés de la personne à se nourrir dans son environnement habituel. Actuellement, L'ECIM peut confirmer la capacité d'une personne à s'alimenter avec des textures solides et liquides régulières. Présentement, nous ne savons pas encore si l'ECIM peut également mesurer le progrès accompli à manger et boire, au fur et à mesure qu'une personne récupère d'un accident vasculaire cérébral.

L'étude, menée par le D^r Erika Gisel de l'Université McGill et ses collaboratrices, D^r Sharon Wood-Dauphinee, D^r Céline Lamarre et Mme Franceen Kaizer, concerne la clientèle AVC ayant des problèmes de dysphagie et nous permettra de déterminer jusqu'à quel point l'ECIM peut distinguer entre des groupes de personnes ayant été victimes d'un accident vasculaire cérébral avec ou sans problèmes pour manger.

Objectifs de l'étude

La présente recherche est nécessaire afin de déterminer jusqu'à quel point l'ECIM peut distinguer entre des groupes de personnes ayant été victimes d'un accident vasculaire cérébral avec ou sans problèmes pour manger. Si cette distinction peut être établie, cela augmentera énormément l'utilité d'ECIM pour déterminer quand une personne est prête à passer d'une diète en purée à une diète en texture plus solide.

Nature de ma participation

Pour cette étude, il y aura une évaluation qui sera faite lors de la prise de repas; vous serez observé alors que vous prenez votre repas seul ou avec l'aide habituel dans votre environnement habituel. Il n'y aura pas d'interaction entre l'examineur et vous ou votre aide, mais l'examineur observera votre habileté de vous nourrir durant votre repas et cotera l'ECIM. Vous serez assis normalement avec les hanches fléchies et les pieds appuyés. L'évaluation ne prendra pas plus de temps que le repas, qui est habituellement moins de 30 minutes.

Évaluation L'évaluation sur l'heure du repas se tiendra dans la première semaine suivant votre admission pour la réadaptation à l'Institut de Réadaptation de Montréal (IRM) ou à l'Hôpital juif de réadaptation (HJR). Les participants peuvent être sur une diète de purée (la diète de dysphagie I) ou une diète régulière, et pourraient avoir besoin des liquides épaissies et devriez être dans les 4 semaines suivant l'AVC.

Examineurs Un ergothérapeute fera l'évaluation.

Avantages

Vous ne retirerez aucun avantage à participer à cette étude. Néanmoins, nous espérons que l' ECIM sera capable de mesurer les différences que nous prévoyons. Si tel est le cas, l' ECIM sera utilisé pour nous documenter sur des changements au cours du temps et sur des changements en réponse au traitement, ce qui signifiera des progrès importants dans ce domaine de la réadaptation, à cause du fait que l'efficacité des traitements pourront être mesurés avec plus de certitude.

Risques

Cette étude ne vous expose à aucun risque. Toutefois, vous pourriez ressentir un certain inconfort à être observé lorsque vous mangez. Si, au cours de l'évaluation, vous ressentez des difficultés en mangeant ou en buvant, vous recevrez du personnel de l'hôpital toutes les procédures nécessaires.

Confidentialité

Toute l'information recueillie sera gardée strictement confidentielle. L'information que nous recueillerons pour cette étude sera regroupée pour analyse. Aucune publication ou présentation sur cette étude ne révélera de l'information qui pourrait servir à vous identifier. Toute l'information sera gardée dans un classeur barré dans le bureau du D^r Gisel à l'Université McGill pour une durée de 5 ans suivant la fin de l'étude.

Participation volontaire et retrait

Ma participation au projet de recherche décrit ci-dessus est tout à fait libre et volontaire. Il est entendu que je pourrai, à tout moment, mettre un terme à ma participation sans que cela n'affecte les soins et les services de santé que je reçois ou recevrai de l'Hôpital juif de réadaptation et de l'Institut de réadaptation de Montréal.

Information supplémentaire

Si vous désirez de l'information supplémentaire ou si vous avez des questions ou des inquiétudes concernant cette étude, veuillez contacter D^r Erika Gisel: École d'ergothérapie et physiothérapie, Université McGill, 3630 Promenade Sir-William-Osler, Montréal, Québec, H3G 1Y5; téléphone: (514) 398-4510, télécopie: (514) 398-8193. Si vous désirez parler à une personne qui n'est pas impliquée dans le projet concernant vos droits en tant que participant à la recherche vous pouvez vous adresser à Mme Michelle Nadon au (450) 688-9550 poste 4417 à l'HJR ou Mme Ginette Desjardins au (514) 340-2085 poste 2175 à l'IRM. Vous pouvez également parler à la coordonnatrice du comité d'éthique du Centre de Recherche Interdisciplinaire en Réadaptation du Montréal métropolitain (CRIR), Mme Anik Nolet au (514) 527-4527, poste 2643.

Consentement à la participation

Je déclare avoir lu et compris le présent projet, la nature et l'ampleur de ma participation, ainsi que les risques auxquels je m'expose tels que présentés dans le présent formulaire. J'ai eu l'occasion de poser toutes les questions concernant les différents aspects de l'étude et de recevoir des réponses à ma satisfaction.

Je, soussigné(e), accepte volontairement de participer à cette étude. Je peux me retirer en tout temps sans préjudice d'aucune sorte. Je certifie qu'on m'a laissé le temps voulu pour prendre ma décision et je sais qu'une copie de ce formulaire figurera dans mon dossier médical. Une copie signée de ce formulaire d'information et de consentement doit m'être remise.

Signature

Date

Assentiment du Participant
(capable de comprendre la nature de ce projet)

Date

Représentant légal

Date

Témoin

Date

Responsabilité du chercheur et son représentant légal

Le projet de recherche et ses procédures ont été décrit au participant et/ou son représentant. Un membre de l'équipe de recherche (chercheur ou ergothérapeute) a répondu à toutes leurs questions et ont expliqué que la participation est volontaire. L'équipe de recherche s'engage à adhérer aux procédures de la recherche telles qu'elles ont été décrites dans ce formulaire de consentement.

Signature du chercheur ou représentant qui a
Obtenu le consentement

Date

Signature du chercheur ou représentant et poste
(lettres moulées)

Date