

The Effect of Mobility Device Use on Strength, Fatigue and Quality of Life  
in Persons with Multiple Sclerosis

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**ABSTRACT:** The variability of symptoms in persons with multiple sclerosis (MS) leads to dilemmas in clinical decision-making related to mobility device prescription. When is a good time to consider a switch to wheeled mobility? What is the best type of wheeled mobility? What are the changes one can expect as they transition? Three studies addressed these questions. First, we investigated the characteristics of individuals with MS who are about to transition to wheeled mobility. Seven ambulatory individuals with MS performed the timed 25-foot walk test (T25FW), and completed questionnaires measuring quality of life (QoL), self-reported fatigue, and participation. These individuals were not able to ambulate at functional speeds and had “sedentary” activity levels. They also had QoL below that of the general population. Next, we investigated changes that accompany a transition in primary means of mobility. Eleven individuals with MS or other chronic conditions leading to a decline in mobility function participated. We collected strength, fatigue, participation and QoL data at baseline, and after mobility intervention. Substantive results revealed that individuals may not experience the expected declines in strength and endurance as they transition. Furthermore, they experienced improvements in QoL concomitant with amount of daily device use. Methodological results revealed difficulties in conducting longitudinal mobility studies, and addressed research design barriers. Finally, we investigated whether a difference exists in the type of wheeled mobility issued to veterans with MS when compared to veterans with a spinal cord injury (SCI). Using

the National Prosthetic Patient Database, we isolated all veterans with MS or an SCI who received a wheelchair or scooter in 2000 and 2001. We found that the quality of wheeled mobility devices issued to individuals with MS was inferior to those issued to individuals with SCI.

These studies provide preliminary evidence that individuals with MS may be waiting too long to transition to the use of wheeled mobility. When they do receive a wheelchair, veterans with MS tend to receive a lower quality of wheelchair. Finally, we made suggestions for conducting longitudinal mobility research in this population, and emphasized the need for future studies.

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## **PREFACE**

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## **1. INTRODUCTION**

MS affects approximately 2.5 million people worldwide. MS is an autoimmune disorder of the central nervous system (CNS). Lesions affect regions of the brain and/or spinal cord. These lesions cause inflammation, demyelination, axonal transection of the region they affect, resulting in a wide range of symptoms and physical limitations that vary greatly from one person to the next. In addition, the progression of the disease varies from one person to the next. This great variability leads to dilemmas in clinical decision making related to mobility. Is there a difference in the type of wheeled mobility issued to individuals with MS, when compared to others, such as individuals with an SCI, who have a clearer clinical course? When is the correct time to tell a patient to consider a wheelchair or scooter? Will the decision to switch to a mobility device cause a decline in strength? These questions do not have clear answers. What is clear is that more information would help both the patient and the clinician.

### **1.1. Quality of Life in Multiple Sclerosis**

*“If we intend to measure the effect of treatments on what patients consider important, then we would seem to have little choice but to measure health-related quality of life.”*(Rothwell PM, 1998)

There is a large body of literature that focuses specifically on various aspects of quality of life in people with multiple sclerosis. Quality of life has been defined as the extent to which hopes and ambitions are matched by one's experience (Calman, 1984). One study by Nortvedt and colleagues demonstrated that people with MS had markedly lower scores on all quality of life dimensions when compared to the general population (Nortvedt et al, 1999). Moreso, Lankhorst et al (1996) revealed a substantial deterioration of quality of life measures in individuals with MS when compared to other patients with chronic illnesses. Correlates for a decreased quality of life in this population exists in the areas of fatigue, physical disability, neurological impairment, depression, and anxiety, to name a few (Merkelbach et al, 2002; Janardhan, & Bakshi 2000; Fruehwald et al 2001).

One correlation of particular interest has been seen between quality of life and mobility (Aronson, 1997; Evers and Karnilowski, 1996). It has been reported that 85% of the patients with MS reported gait and motor disturbances as their chief complaint (Baum & Rothschild, 1983). In fact, studies have shown that this population is particularly predisposed to balance deficits and consequent increased risk of falls (Frzovic et al 2000). Interestingly, motor problems and pain were among the primary behaviors causing stress to caregivers of individuals with MS (Knight et al, 1997). Regardless, it is not uncommon for individuals with MS to insist on walking despite decreased safety (DeLisa et al, 1985).

Despite compelling studies illustrating an evident need for improved assistive device prescription in people with MS, there have been a surprisingly limited number of studies focusing specifically on quantitative measures for mobility in MS. This may help explain the statistic encountered by

Perks et al (1997), describing that 59% of individuals in Scotland with MS state their current wheelchair does not meet their mobility needs (Perks et al, 1997). Several factors may contribute to this disturbing statistic. First, Rothwell and colleagues investigated the correlation between patients with MS perceptions and assessment of disability with that of their doctors (Rothwell et al, 1997). In this study, investigators found that doctors are not good at estimating quality of life in their patients with MS. While doctors emphasized the physical manifestations of the disease, their patients were, instead, much more concerned with the less tangible aspects of quality of life, including mental health and vitality. According to Phillips and Zhao (1993), a lack of consideration of the consumer's opinion when selecting an assistive technology is a major factor related to technology abandonment. If the rehabilitation professional is not considering the user's personal need, inappropriate devices may be issued. In light of this, it is not surprising that a study published by Wheeler and colleagues found that, when compared to other wheelchair users, individuals with MS are particularly skeptical, critical, and questioning about explanations given by health care providers regarding mobility selection (Wheeler et al, 1996).

All of the above studies indicate that there exists a great need to explore the types of wheeled mobility commonly issued to individuals with MS as well as specific correlations between quality of life and assistive technology selection. It is well known that having an appropriate mobility device will significantly influence how a person with a disability perceives his or her life, and that, in general, they prefer using mobility equipment to human assistance (Buning et al, 2000). For individuals with MS, however, it has been shown that one out of two cases will require the assistance of another person for everyday mobility (Baum & Rothschild, 1983). It is

likely that individuals with MS are not receiving mobility devices that allow them to function effectively in their environment.

Definitions of disability have increasingly been measured based on the functional limitations resulting from the disease, rather than the disease symptoms themselves (Iezzoni, 2000). Therefore, emphasis on intervention should be placed on optimizing the ability a person has to perform desired tasks, and on overall outcome. Ironically, however, secondary providers continue to predominantly base reimbursement guidelines on quantifiable aspects of disability. This poses a serious issue, since, for individuals with MS, alternative mobility devices are often necessary to compensate for symptoms that are difficult to assess and quantify, such as fatigue. Sadly enough, fatigue is often perceived as not being a legitimate symptom, and many times is even dismissed as neurosis (Rolak, 1993; Burnfield & Burnfield, 1978). Therefore, it is not surprising that, though not formally published, it has been the experience of many clinicians that assistive technologies in this population are obtained via non-optimal means, such as through a friend or family member. Given the great importance of proper fitting and positioning in wheelchair selection (Boninger et al, 2000), the potential for decreased satisfaction with the assistive technology and a significantly decreased functional mobility is great.

## **1.2. Biomechanics of Mobility in Multiple Sclerosis**

### ***1.2.1. Wheelchair propulsion in MS:***

The Human Engineering Research Laboratory, a VA Center of Excellence, has been dedicated to advancing the quality of life in individuals with disabilities through assistive technologies. Recently, significant efforts have been made to characterize manual wheelchair propulsion in

individuals with MS and to investigate factors contributing to a decreased satisfaction with wheelchair function in this population. Studies like these are especially important since it has been recommended that in the later stages of MS, intervention should be focused on the impairment level of MS, and should emphasize functional activities and ameliorating environmental access (Freeman et al, 2002).

Investigators at University of Pittsburgh were among the first to take a close look at the biomechanics of wheelchair propulsion in people with MS (Fay et al, 2004). In this study, the biomechanics of wheelchair propulsion in people with MS was compared to other expert wheelchair users. Their study showed that individuals with MS propel their wheelchair significantly slower than control counterparts, and are actually unable to attain a target speed of 1.2 m/sec, considered a standard for functional mobility (Lerner-Frankiel et al, 1986). Further, kinematic analysis showed that these individuals propel their wheelchair in the least efficient propulsion style, expending more energy than control counterparts (Fay et al, 2004). Boninger et al (2002) has shown that there are four different patterns for propelling a manual wheelchair. These four patterns include 1) semicircular pattern (SC), 2) single looping over propulsion (SLOP), 3) double looping over propulsion (DLOP), and 4) the ARC pattern. Of these four styles, the SC pattern was shown to be the most efficient and the least likely to contribute to upper extremity injury. On the other hand, the ARC pattern was shown to be the most energy consuming, and the least efficient. Fay et al (2004) showed that individuals with MS were much more likely to use the ARC pattern for manual wheelchair propulsion when compared to other manual wheelchair users. These results are particularly significant in this population where energy conservation is so essential. Further analysis revealed that people with MS actually



generated a “braking moment” with each stroke of the wheelchair (Fay et al, 2004). Using bilateral Smart<sup>WHEELS</sup> (Cooper et al, 1997), capable of measuring three-dimensional forces and moments, it was shown that with each wheel contact and release, these individuals produced a moment opposite to the direction of forward propulsion (Fay et al, 2004). Considering these significant findings, we decided to investigate further the ability of current clinical measures to predict the ability to functionally propel a manual wheelchair in this population. The clinical measures tested, including manual muscle testing, sensory testing, and spasticity rating were not sensitive enough to predict this functional limitation. Therefore, it may be difficult for clinicians to recognize the need for mobility device intervention at an early enough stage of disease progression, before participation in daily activities and quality of life are affected.

### ***1.2.2. Strength testing and MS:***

In a study comparing 15 individuals with MS to 15 control subjects, Lambert et al (2001) found that individuals with MS had peak torque production 25.7% and 20.8% lower than controls for dominant flexors and for non-dominant flexors of the lower extremity, respectively. While the mechanism for muscle weakness in MS is still unclear, some findings have provided important information in this area. First, Kent-Braun and colleagues found a 26% reduced muscle fiber cross-sectional area relative to controls, a comparable percentage to the torque production findings of Lambert and colleagues (Kent-Braun et al, 1997). Even so, Lambert et al (2001) demonstrate that fat free mass differences did not account for the differences in strength between individuals with MS and control subjects. In their study, there was no significant difference in force production. Instead, they concluded that strength differences were attributed to a decreased muscle quality. Along these lines, Rice et al (1992) conducted a study looking at the motor

neuron firing rates during an isometric exercise protocol and found rates to be significantly lower than seen in control subjects. This indicates a decreased ability for muscle activation in this group of individuals. Haan and colleagues (2000) had similar findings when they investigated the contractile and fatigue properties of the quadriceps muscle in 17 people with MS. They found that individuals with MS were only able to generate about  $\frac{3}{4}$  of the maximal force-generating capacity of their muscles. The force and speed characteristics, however, were not significantly different from control subjects, again supporting the idea that strength changes are not a result of an impaired contractile mechanism. Finally, studies by Kent-Braun et al have demonstrated a higher prevalence of fast-twitch muscle fibers in the group with MS when compared to control counterparts (Kent-Braun et al, 1996). Fast-twitch muscle fibers have a greater reliance on anaerobic energy supply and demonstrate a reduced muscle oxidative capacity. Therefore, an increased percentage of this muscle fiber type would contribute to a decreased endurance and an increased fatigability.

Fay et al (2001) highlighted the need for more sensitive clinical measures of strength in individuals with MS. Their study compared the isokinetic strength of individuals with MS as determined with the use of a BioDex System 3 (Biodex Medical, Shirley, NY) against a manual muscle test grade (American Spinal Injury Association and International Medical Society of Paraplegia, 1996) as determined by a physical or occupational therapist. They found that the MMT results were not correlated with isokinetic measures of strength, indicating that the MMT may not be the most appropriate test for quantifying strength in populations with MS. Additional research, therefore, is needed for the development of new, more effective clinical examination that more accurately describes the strength of individuals in this population (Fay et al, 2001).

### ***1.2.3. Fatigue testing and MS:***

Murray et al (1985) found that up to 40% of individuals with MS claim that fatigue is the most serious symptom they experience. With this in mind, several studies have concentrated efforts on investigating the mechanism of fatigue in MS. Certain aspects of fatigue have been well established in this population. First, it is generally accepted to be strongly temperature dependent (Krupp et al, 1988). Also, people with MS commonly describe their fatigue as a general lack of physical energy rather than a weakness of a specific muscle group (Krupp et al, 1988). This often leads to a cycle of *fatigue*→ *decreased activity*→ *increased fatigue*. One study by Sheean et al (1997) took an electrophysiological (EMG) look at the mechanism of fatigue in MS. All subjects performed a fatiguing protocol while EMG data were collected. Results revealed evidence of an exercise-induced reduction in force generation. Interestingly, this reduction in strength was only evident with sustained contraction. This is supported by findings from Schwid et al (1999) that demonstrated that static fatigue was not associated with strength of the same muscle. Therefore, it may be difficult, clinically, to detect fatigue in this population, since most standardized clinical evaluation tools do not incorporate prolonged measures of strength and ability. Sheean et al (1997) also found no correlation between the amount of inducible fatigue and the amount of self-reported fatigue experienced in everyday life, contributing further to the mystery of fatigue in this population. This is further supported by findings of Sharma and colleagues (1995), where they reported that muscular fatigue did correlated with clinical evidence of upper motor neuron dysfunction, and with metabolic changes during exercise, but not with perceived fatigue ratings.

Controversy has traditionally existed regarding how much physical exercise is necessary and beneficial versus how much will actually contribute to an increased exacerbation rate. Commonly individuals with MS experience a decline in strength and an increased fatigue concurrent with an increased core body temperature (Poinchtera-Mulcare, 1993). None-the less, it has become more and more widely accepted that people with MS should be encouraged to participate in regular physical activity for improved cardiovascular conditioning as well as for the psychosocial benefits that often accompany physical activity (Petajan et al, 1996) and that individuals with MS can, in fact, exercise with no detrimental effects (Poinchtera-Mulcare, 1993). Even so, care must be taken to control external variables such as the level of exertion, environmental temperature, etc. This is important to keep in mind when considering delaying mobility device prescription for the sake of increasing physical activity. If this were the case, an especially hot day, or a day of increased fatigue symptoms would inevitably lead to a decreased ability to perform everyday tasks, the very definition of disability.

#### ***1.2.4. Gait in MS:***

The plaque-like lesions that characterize MS may affect one or many control centers of the CNS, including the vestibular, visual, and/or somatosensory centers. This being the case, balance, and consequent falls may be a serious problem. In a study by Cattaneo et al (2002), 50 patients with MS were recruited to quantify the risk of falls and to report on specific variables associated with falls in this population. Through outcome questionnaires as well as objective measures of strength, spasticity, and transfer skills, a regression analysis was performed. Subjects were divided into a faller group or a non-faller group, based on the total number of falls in the two months prior to data collection. Of all the subjects collected, 32% reported 2 or more

falls in the two months prior to the study, and 59% reported at least one fall two months before. For people who were classified as fallers, performance on balance testing was significantly worse when compared to non-fallers. Other characteristics of the faller group included the inability to run, walk, walk on an uneven surface, or pick up an item off the floor.

### **1.3.Purpose**

The significant limitations often experienced by individuals with MS in the areas of ambulation and manual wheelchair propulsion have been highlighted above. The lack of research in this area as it relates to assistive technology intervention is evident, leading to what we believe to be a high incidence of improper assistive technology prescription. All of this will have a profound effect on overall quality of life in this population. Despite this, it is undeniable that the transition to alternative forms of mobility is often perceived as an indicator of decline in overall function and of increasing disability. People perceive an increased reliance on assistive technology as a hindrance to maintaining strength and conditioning. However, this must be taken very carefully in this population, considering fatigue is what frequently emerges as the one symptom that most commonly interferes with physical functioning (Krupp et al, 1988). Energy conservation strategies are commonly recommended for the management of fatigue. In this, the patient is advised to preserve their energy as much as possible for necessary and desired tasks. Undoubtedly, therefore, a tremendous discrepancy often exists between what the individual, the health care practitioner, and/or the secondary providers believe is optimal intervention, versus what will actually lead to a maximized everyday functioning and, ultimately, quality of life.

The purpose of this project was three-fold: 1. to examine signs that a switch to wheeled mobility might be indicated for individuals with MS and to characterize individuals with MS who are

about to switch to wheeled mobility, 2. to investigate physiological and quality of life changes accompanying a change in primary means of mobility in persons with MS and 3. to determine whether there is a difference in the type of wheeled mobility issued to veterans with MS when compared to veterans with an SCI. These aims were addressed in a series of three studies. The first study investigates the characteristics of individuals with MS who are about to transition to wheeled mobility, as well as the usability of functional ambulation and self-reported fatigue as a surrogate measure of declines in physical activity and participation. The second study investigates the physiological and quality of life changes that accompany a change in primary means of mobility, and gives methodological considerations for conducting longitudinal mobility research in individuals with MS. Finally, the third study investigates whether a difference exists in the type of wheeled mobility issued to veterans with MS when compared to veterans with a spinal cord injury (SCI). Through these studies, we hope to provide individuals with MS and their clinicians with the information necessary to make more informed decisions regarding mobility device selection, ultimately leading to and increased quality of life.

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## **2. CORRELATES OF AMBULATORY ABILITY IN PERSONS WITH MULTIPLE SCLEROSIS WHO ARE ABOUT TO TRANSITION TO A NEW PRIMARY MEANS OF MOBILITY: A PILOT STUDY**

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## 2.1.ABSTRACT

Background: The purpose of this study was to characterize individuals with MS who are about to transition in their primary means of mobility. Additionally, we investigated the correlation between functional ambulation measures and subjective fatigue with physical activity, quality of life and participation. Methods: Seven individuals with clinically definite MS who had a prescription for a new wheeled mobility device participated in this study. All subjects completed the Timed 25 Foot Walk Test (T25FW), and completed three questionnaires: the Modified Fatigue Impact Scale (MFIS), the Short Form-36 (SF-36), and the Craig Handicap Assessment Reporting Technique (CHART). Study participants also monitored their daily activity using a pedometer for one week. A Spearman's correlation coefficient was used to relate the T25FW and physical activity, as well as with variables of the SF-36 and the CHART. In addition, a Spearman's correlation was used to measure the relationship between MFIS and variables of the SF-35 and the CHART. Results: The T25FW was significantly correlated with average daily steps ( $p=0.023$ ), and the MFIS was significantly correlated with both the mobility and occupational scores of the CHART ( $p= 0.012$  and  $0.05$ , respectively). Discussion: The T25FW and the MFIS may be good indicators of daily physical activity and participation in daily activities, respectively. Future investigations should seek to define scores for both of these measures that clinicians could use to determine when is the most appropriate time to transition to wheeled mobility for people with MS.

Key Words (7-10): Multiple Sclerosis, Walking, Gait, ambulation, Fatigue, T25FW, physical activity, mobility, pedometer

## 2.2. INTRODUCTION

Multiple sclerosis (MS) is a demyelinating disease of the central nervous system, affecting approximately 2.5 million people worldwide, and 400,000 people in the United States ([www.nmss.org](http://www.nmss.org)). Primary symptoms reported in individuals with MS include muscle weakness, spasticity, and fatigue, among others. These symptoms can affect how effectively individuals are able to participate in activities of daily living. Muscle weakness and fatigue can lead to decreased physical activity levels, deconditioning, increased risk for falls, impaired mobility, and ultimately, decreased quality of life. This can become a vicious cycle leading to increased disability and dependence. Baum and Rothschild reported that over 50% of individuals with MS require assistance for daily mobility (1983).

It is very difficult to know if and when to transition from ambulation to wheeled mobility as a primary means of mobility. Many individuals believe transitioning to a wheelchair too soon will lead to increased deconditioning and subsequent increased disability (Iazonni et al, 2003). They believe prolonging ambulation as long as possible will allow them to maintain their lower extremity strength. On the other hand, it is possible that the increased effort associated with delaying the transition to a wheelchair as a primary means of mobility may lead to increased subjective feelings of weariness, weakness, and/or lack of energy (Merkelback et al, 2002). Fatigue has been reported to be the number one symptom in persons with MS affecting daily activity (Krupp et al, 1988). Increased subjective fatigue will ultimately lead to a decreased ability to participate in activities of daily living. It may be for this reason that individuals with MS have lower self-perceived quality of life scores when compared to individuals with other chronic disorders (Lankhorst et al, 1996). This is significant since quality of life has been



defined as the extent to which hopes and ambitions are matched by one's experience (Calman, 1984). It is important that clinicians have quick and effective tools for measuring how active individuals with MS are in their daily lives, and how much fatigue is interfering with their ability to participate in activities of daily living. Decreased physical activity and participation may be an indication that a mobility device intervention is needed.

The primary objectives of this paper are to 1. describe individuals with MS who are about to transition in their primary means of mobility, 2. determine how well the Timed 25 Foot Walk test (T25FW) estimates the average number of daily steps in ambulatory persons with MS who are planning to transition in their primary means of mobility, and 3. determine how self-reported fatigue correlates with both quality of life and participation in activities of daily living in this population.

## **2.3.METHODS**

### ***2.3.1. Participants***

This study included ambulatory individuals who had clinically definite MS as determined using the McDonald criteria (McDonald et al, 2001), and who were referred to an assistive technology clinic for a new wheelchair (manual wheelchair, power wheelchair, or scooter). At the time of enrollment, subjects who were currently ambulating as their primary means of mobility (Expanded Disability Status Scale score of  $\leq 7.0$ ) had a prescription for a new wheelchair or scooter, but had not yet received their new mobility device. All individuals were between the

ages of 18 and 65 years, had no significant cognitive impairment (Mini Mental Scale Exam score of > 26 (Folstein et al, 1975)), and were not clinically depressed (CES-D score of <22 (Radloff, 1977)). Any subject who had an MS exacerbation within 3 months of recruitment was excluded from the study. Subjects were recruited through the Center for Assistive Technology at the University of Pittsburgh. The Highland Drive Veterans Administration Investigational Review Board approved the study, and all study participants provided informed consent prior to testing.

### ***2.3.2. Procedures***

#### **2.3.2.1. Questionnaires:**

Quality of life was measured using the SF-36 Health Survey (Freeman et al, 2000), widely acknowledged as the “Gold Standard” for generic measures of health status. The internal consistency, reliability, and validity of this survey as a measure of health-related quality of life in multiple sclerosis have been confirmed (Freeman et al, 2000; Ware et al, 1993). There are ten outcome variables from the SF-36 including: 1. physical functioning (PF) 2. social functioning (SF), 3. role limitations physical (RP), 4. bodily pain (BP), 5. general medical health (GH), 6. mental health (MH), 7. role limitations emotional (RE), 8. vitality (VT), 9. composite physical health status (PCS) and 10. composite mental health scores. Limitations, such as marked floor and ceiling effects, as well as poor responsiveness for change have been demonstrated in individuals with MS (Freeman et al, 2000). Therefore, it has been recommended that this tool be used in conjunction with other measures.

All subjects also completed the Craig Handicap Assessment and Reporting Technique (CHART), a 27-question outcome tool used for measuring quality of life in terms of participation in

everyday activities as well as in social activities (Whiteneck et al, 1992). Three outcome variables of the CHART were considered: the physical independence score, the mobility score and the occupation score. Two additional questions, not included in the calculations for scoring CHART domains were added which asked the subjects whether or not they had fallen in the last month, and if so, how many times.

Self reported fatigue over the four weeks prior to the test visit was assessed using the Modified Fatigue Impact Scale (MFIS)(Fisk 1994a, Fisk 1994b). The MFIS is a shortened version of the 40-item Fatigue Impact Scale (FIS) questionnaire designed to assess the problems in patients' quality of life that they attribute to their symptoms of fatigue. In the initial validation studies, FIS subscales had good internal consistency (Fisk et al, 1994b). The fatigue guidelines development panel of the MS Council for Clinical Practice Guidelines (1998) has recommended the MFIS as the main outcome measure for assessing MS-related fatigue.

#### **2.3.2.2. Objective Measures:**

All participants underwent neurological testing to obtain an Expanded Disability Status Scale (EDSS) score (Kurtzke, 1983). Ambulatory function was assessed using the timed 25-foot walk test (T25FW) where subjects were instructed to walk 25 feet as fast as they were safely able, using whatever type of walking aid they felt was necessary. In order to maintain consistency between subjects, instructions for completing the T25FW were scripted, and all testing took place on the same 25-foot tiled surface.

At the end of laboratory testing, subjects were given a pedometer, and instructed to wear the pedometer from the time they woke up to the time they went to bed for 7 days. Each night before going to bed, subjects were asked to record the pedometer reading on a form provided by our laboratory. Subjects were called periodically throughout the 7 days to ensure that they were wearing the pedometer and recording the readings. If the subject forgot to wear the pedometer one day, they were asked to continue wearing the pedometer for an extra day in order to make sure that every subject had 7 full days of recorded pedometer readings. Subjects wore a Yamax Digi-Walker™ pedometer at their hip, attached with a clip to the waistband of their pants. The Digi-Walker was chosen because it has been shown to be among the most accurate for counting steps (Schneider et al, 2004)

### *2.3.3. Statistical Analysis*

Subject characteristics, including age and time since diagnosis, as the MFIS, SF-36 domain scores, the CHART outcome variables, and T25FW scores are reported as means plus or minus standard deviations. EDSS scores are reported as frequency counts.

For the week-long ambulation monitoring, average daily recorded steps are presented as well as the total steps recorded over the course of one week

Because the sample size was small, nonparametric statistics were completed to calculate correlations. A Spearman's two-tailed correlation was to determine the relationship between:

- T25FW and average daily steps ambulated
- the ten individual measures from the SF-36 and the T25FW
- three outcome variables of the CHART and the T25FW

- MFIS score with the ten individual measures from the SF-36
- MFIS score with the 3 outcome variables of the CHART
- MFIS score with T25FW

Data were considered statistically correlated at  $p \leq 0.05$ . This cut-off point was chosen since our sample size was small, and since this was a pilot study to identify whether the T25FW and the MFIS could be used as surrogate tools for estimating quality of life and daily participation. Therefore, if our preliminary findings reveal a correlation between variables, this will indicate a need for further investigation.

## **2.4.RESULTS**

### ***2.4.1. Participants***

Seven females with MS participated in this study. The average age of the participants was 51.2 +/- 6.8 years (range of 48.0 to 63.4) and the average time since diagnosis with MS was 10.4 +/- 6.8 years (range: one year to 19 years). Five of the subjects had fallen at least once in the last month.

## 2.4.2. Procedures

### 2.4.2.1. Questionnaires:

The MFIS is a 5-item questionnaire and possible scores range from 0 to 20, with '20' being the maximal effect of fatigue on ability to perform everyday activities. Participants in this study had an average score on the MFIS of 14+/-3 (range of 9 to 19).

A comparison between SF-36 domains in the US general population versus subjects with MS is shown in Table 1. In our study, individuals with MS scored considerably lower on all domains of the SF-36, with the exception of RE and MH, where they scored higher than published norms.

**Table 1** SF-36 average domain scores (Physical Functioning (PF), Role Physical (RP), Bodily

<b>Population</b>	<b>PF</b>	<b>RP</b>	<b>BP</b>	<b>GH</b>	<b>VT</b>	<b>SF</b>	<b>RE</b>	<b>MH</b>	<b>PCS</b>	<b>MCS</b>
General US	84	81	75	72	61	83	81	75	50	50
MS	35	25	52.3	48.4	20	53.6	85.7	85.7	26.8	53.5

Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Emotional (RE), Mental Health (MH), Physical Composite Score (PCS), and Mental Composite Score (MCS)) in the general US population vs. subjects with MS

\*General US population scores taken from <http://www.pdsa.org/conference2004/265.8>,

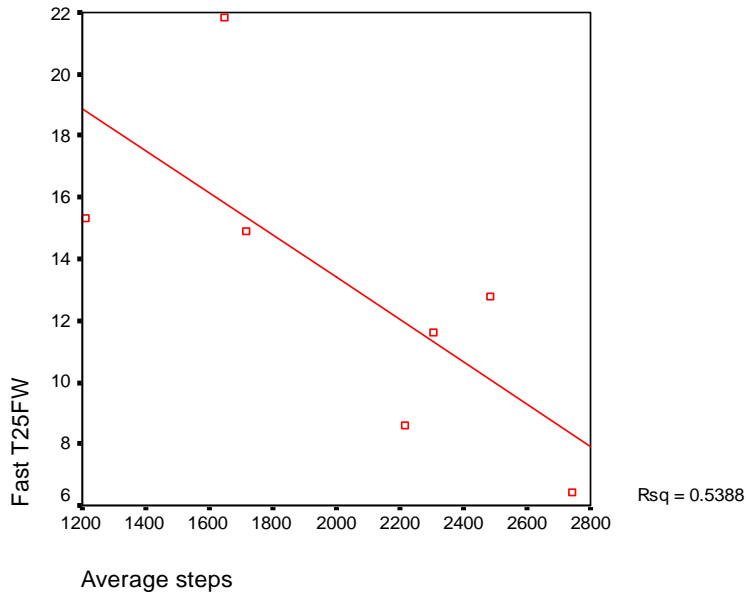
The maximum score for each domain of the CHART is 100, considered to be the level of performance of a typical, non-disabled individual. In this study, individuals with MS had an average physical independence score very close to non-disabled individuals (97.5), however, scored approximately 25% lower than non-disabled individuals in the mobility score and the occupation score (75.6 and 75.7, respectively).

#### **2.4.2.2. Objective Measures:**

When considering functional mobility, our sample group was homogenous, according to the EDSS. Five of the subjects in this study had an EDSS score of 6.0 and used a single point cane for ambulation. The remaining two subjects had an EDSS score of 6.5 and used a wheeled walker for ambulation (subjects # 3 and #6). The EDSS ranges from 0 to 10, with 0 being no impairment, and 10 being death as a result of MS (Kurtzke, 1983). An EDSS score of 6.0 is given when the individual requires intermittent or constant unilateral assistance (cane, crutch or brace) to walk 100 meters with or without resting. An EDSS score of 6.5 is given when the individual requires constant bilateral support (cane, crutch or braces) to walk 20 meters without resting.

The average time to complete the T25FW was 13.1 +/- 5.0 seconds (0.61 m/sec), with a range of 6.4 to 21.8 seconds. The average daily number of steps was 2,047 +/- 538.1 (Table 2). The T25FW and the average number of steps ambulated per day was significantly correlated at  $p=0.023$  ( $r^2 = 0.5388$ )(Figure 1).

**Figure 1** Spearman’s correlation between T25FW and average daily number of steps



The T25FW was not significantly correlated to any of the outcome variables of the SF-36, the CHART, or with the MFIS.

**Table 2** Pedometer readings for all subjects

<b>Subject #</b>	<b>Average daily number of steps</b>	<b>Total number steps over 7 days</b>	<b>Number of times fallen in last month</b>
<b>1</b>	1,718	12,025	10
<b>2</b>	2,744	19,211	0
<b>3</b>	2,217	15,519	>20
<b>4</b>	1,646	11,524	1
<b>5</b>	2,306	16,142	1
<b>6</b>	2,484	17,387	0
<b>7</b>	1,213	7,958	2
<b>Average of Allsubjects</b>	2,047	14,249	



While the MFIS score did not correlate with any of the SF-36 outcome variables, it significantly negatively correlated with the CHART mobility score ( $p=0.012$ ), and the CHART occupation score ( $p= 0.05$ ). Therefore, as subjects reported increased self-reported fatigue, they demonstrated a decreased mobility and occupation scores of the CHART.

## **2.5.DISCUSSION**

It is undeniable that the transition to alternative forms of mobility is often perceived as an indicator of decline in overall function and of increasing disability. People perceive an increased reliance on assistive technology as a hindrance to maintaining strength and conditioning. However, for the MS population, fatigue frequently emerges as the one symptom that most commonly interferes with physical functioning (Krupp et al, 1988). Therefore, energy conservation strategies are commonly recommended for the management of fatigue. The patient is advised to preserve their energy as much as possible for necessary and desired tasks. Undoubtedly, a discrepancy often exists between what the individual, the health care practitioner, and/or the secondary providers believe is optimal intervention, versus what will actually lead to a maximized everyday functioning and, ultimately, quality of life. We conducted this study in order to describe a population of individuals with MS who are about to transition to a new means of primary mobility and to correlate clinical tests of gait speed and subjective fatigue with measures of quality of life and daily participation.

### ***2.5.1. Participants***

All the subjects who participated in our study were female. While MS does primarily affect females, 38 percent of individuals with MS are males ([http://health.yahoo.com/health/ceters/women/\\_19238199.html](http://health.yahoo.com/health/ceters/women/_19238199.html)). The average age of individuals who are transitioning to the use of a wheeled mobility device in our study was 51.2 +/- 6.8. This is in line with a study published by Baum and Rothschild (1983) which showed that the average age of individuals with MS needing mobility assistance both indoors and outdoors is 52 years. However, in this same study, the average duration of disease of those individuals needing mobility assistance both indoors and outdoors was 28.9 years, whereas it was only 10.4 +/- 6.8 in our sample population.

### ***2.5.2. Procedures***

#### **2.5.2.1. Questionnaires:**

When comparing SF-36 domain scores to the general population, individuals with MS from this study scored lower on all domains measuring the effect of physical functioning on quality of life. For the two domains quantifying mental and emotional health (RE and MH), individuals with MS scored higher than the average given for the general US population. This result indicates that the decreased quality of life seen in individuals with MS who are transitioning in their primary means of mobility is primarily due to physical, and not emotional or cognitive, impairments. This is not surprising since only individuals without significant depression and no cognitive impairments were included in this study.

Individuals with MS scored an average of 97.5% out of a possible 100% on the physical independence domain of the CHART. This domain incorporates the ability of the individual to maintain an independent existence (<http://www.craighospital.org/Research/Disability/CHART%20Manual.pdf>). This is consistent with results found from the SF-36, since the physical independence domain of the CHART included the ability of the individual to instruct and direct others who are assisting them. Therefore, this measure is not purely a function of physical ability, as the name might suggest, but includes cognitive abilities. On the other hand, individuals with MS scored lower than non-disabled individuals for both the mobility and occupation scores of the CHART, which are both primarily measures of physical ability. According to the Craig Hospital guide for using the CHART (<http://www.craighospital.org/Research/Disability/CHART%20Manual.pdf>), the occupation score measures the individual's "ability to occupy time in the manner customary to that person's sex, age, and culture." This score is calculated by asking the subject to report the time spent in various activities, while weighting the relative value society places on different activities. For example, priority is given to employment, schooling and active homemaking and maintenance. According to the same reference, the mobility score measures the ability of the individual to get around in their environment. This is estimated by asking the subject to report the hours per day out of bed, days per week out of the house, nights per year spent away from home, accessibility of the home, and transportation utilization.

The MFIS was significantly correlated to the mobility score and the occupation score of the CHART. Therefore, variables of the CHART primarily measuring functional ability are related to the individual's self-reported fatigue, whereas the same is not true when considering the

relationship between self-reported fatigue and cognitive functioning, as measured by the physical independence score of the CHART. From these results, we believe that the 5-item MFIS may be a quick and effective clinical tool surrogate for estimating the amount of time spent in important daily activities, and how effectively the individual moves about in their own surroundings.

#### **2.5.2.2. Objective Measures:**

The average number of steps taken/day for all our subjects was 2,047. This is much lower than the average number of steps taken in unimpaired individuals, which different research studies have described to be between 7,000 and 13,000 (Miller and Brown, 2004, Schneider et al, 2004, Tudor-Locke et al, 2004, Tudor-Locke et al, 2001). Even when excluding volitional physical activity such as participation in sport or exercise, evidence supports that 6,000-7,000 steps/ day is representative of normal daily activity (Tudor-Locke et al, 2002). It is now widely accepted that 10,000 steps/day be considered a level of physical activity found in “healthy adults”, and there is growing evidence that this level of physical activity is associated with indicators of good health such as decreased body fat and lower blood pressure (Tudor-Locke et al, 2001). Individuals with an average of less than 5,000 steps/day have been shown to be more likely to be classified as obese, and may be considered a satisfactory index for a sedentary lifestyle (Tudor-Locke et al, 2004).

It has been shown that pedometers underestimate walking distance in individuals with slower gait (Melanson et al, 2004), as is the case for the individuals included in this study. However, because our subjects ambulated fewer than half of the number of daily steps than what is considered sedentary, we expect that, even accounting for the fact that the pedometer

underestimates steps in individuals with a slower gait velocity, these individuals are not maintaining a healthy level of physical activity. These results have shown that individuals with MS are considered to be sedentary at the time when the decision is made to transition to a wheelchair, and that these individuals are not engaging in a sufficient amount of physical activity to be considered “healthy”. Therefore, since these individuals are already sedentary, it might be late for a transition. It is possible that they should transition sooner, before their decreased ability to ambulate begins to affect their activity level. Furthermore, by relying on ambulation for regular mobility, they are likely to have increased energy expenditure, ultimately increasing their subjective fatigue. An increased subjective fatigue will undoubtedly decrease their ability to participate in important daily activities, as we have seen when correlating fatigue with the CHART mobility and occupation scores.

When considering the T25FW, individuals with MS ambulated at 0.63m/sec. This is much slower than previously reported functional walking speed of 1.2m/sec, the speed required to safely cross a street within the time allowed by a traffic signal (Lerner-Frankiel et al, 1986). We also found the T25FW, an easy to administer tool that may have good potential at estimating the amount of daily physical activity in persons with MS. Ideally, clinicians would use this tool to be aware of physical activity in persons with MS. When the individual is not participating in a sufficient amount of physical activity to maintain a healthy lifestyle, and yet is spending a significant amount of energy ambulating as evidenced by increased fatigue, the clinician may recommend that the individual transition to a new form of primary mobility. It is our belief that implementing this type of system will lead to an earlier transition to a wheeled mobility, which would result in a decreased subjective fatigue, and ultimate increased quality of life.

### ***2.5.3. Limitations***

As previously mentioned, a limitation of this study is the small sample size. Future studies should include more individuals with MS, both male and female, who are transitioning in their primary means of mobility. In addition, with a larger sample size, it would be beneficial to investigate the relationship between outcome variables in individuals with a wider range of ambulatory ability. For example, is the T25FW more effective at predicting physical activity in persons with no ambulatory restrictions when compared to individuals who require the use of a walking aid? This is likely to be the case, since it has been suggested that pedometers may underestimate walking activity in individuals who ambulate at slower speeds (Melanson et al, 2004). The average daily steps of the individuals in our sample ranged from 1,283 to 2,744. While it is likely that the pedometer is underestimating the actual number of steps taken, we believe it is unlikely that it is underestimating activity to the extent that they would not longer be considered sedentary. Future studies should also investigate the reliability of pedometers in individuals with altered gait patterns, as is commonly seen in persons with MS. One study investigated the ability of pedometers to estimate physical activity in individuals with hemiparetic stroke (Macko et al, 2002). This study found that the conventional pedometer does not accurately measure number of steps and cadence in this population. However, because the gait impairment in this population is unilateral, these findings are not necessarily true to individuals with MS, who collectively demonstrate a wide variety of gait patterns.

We were able to find a correlation between the MFIS and participation in daily activities, as well as a correlation between the T25FW and average daily physical activity; however, we did not establish definitive clinical indicators of the need for mobility device intervention. Ideally,

clinicians would have ranges of time to ambulate 25 feet or of self-reported fatigue that would alert them that a transition to wheeled mobility might be indicated. Future studies should seek to determine specific scores at which clinicians should begin to consider mobility device intervention.

## **2.6.CONCLUSION**

Individuals from our study who were about to transition in their primary means of mobility did not ambulate at a functional speed, even when asked to ambulate as fast as they were able for the T25FW. They were also found to be sedentary, with lower physical measures of quality of life when compared to the general population.

The T25FW was found to correlate significantly with the average daily number of steps in this population. Similarly, the MFIS correlated significantly with physical functioning aspects of the CHART. Taken together, the T25FW and the MFIS may be quick and easy-to-administer tools for estimating physical activity and participation in daily activities. This information could be useful to clinicians about when to consider wheeled mobility intervention.

## **2.7.ACKNOWLEDGEMENTS**

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### **3. PRELIMINARY EVIDENCE OF A NEED FOR AN EARLIER TRANSITION IN AMBULATORY INDIVIDUALS WITH MULTIPLE SCLEROSIS: A METHODOLOGICAL REPORT**

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### 3.1. ABSTRACT

**Background:** To date, no empirical evidence exists that investigates what physical and quality of life changes individuals can expect as they transition in primary means of mobility. The purpose of this project was to examine changes in quality of life measures, muscle strength and muscle fatigue that parallel changes in functional mobility. **Methods:** Individuals with chronic conditions who had a prescription for a new type of wheeled mobility participated in this study. Testing took place over three visits: upon wheeled mobility prescription (V1), upon wheeled mobility receipt (V2), and after using the wheeled mobility for a time equivalent to the time between V1 and V2 (V3). Functional mobility was assessed using the Timed 8-meter Walk test (T8) and a timed 8-meter wheelchair propulsion trial. Isometric muscle strength and fatigue was tested using the Biodex 3. Quality of life, participation in daily activities, and self-reported fatigue was assessed using the Short Form-36 (SF-36), the Craig Handicap Assessment Reporting Technique, and the Modified Fatigue Impact Scale, respectively. **Results:** Eleven, six and 3 individuals completed V1, V2, and V3 testing, respectively. At V1 testing, the average speed to complete the T8 was 0.63m/sec. This was the same average speed for the manual wheelchair propulsion trial at V1. All individuals who completed the T8 over the three trials had less than 20% change between visits. Only 6 subjects could complete Biodex testing at V1 secondary to not meeting testing criteria, and only 1 subject completed testing over all three visits. For this individual, muscle strength of the lower extremity muscles tested actually increased after wheeled mobility intervention. Increases in SF-36 scores seemed to be related to amount of wheeled mobility use over time. **Discussion:** A transition to the use of wheeled mobility may not lead to the expected decrease in muscle strength and ambulatory ability. Furthermore, the benefit of mobility device use on quality of life measures seems to parallel

amount of device use. Future studies should further investigate the benefits to be gained from a transition to a wheeled mobility for people with chronic conditions.

### **3.2.INTRODUCTION**

Multiple sclerosis (MS) presents with an unpredictable pattern of symptoms. This means that individuals with MS have limited knowledge about their personal prognosis. This may lead to a state of uncertainty, and has the potential to make decisions regarding treatment options difficult. One such decision often includes when and how to transition to an increased reliance on wheeled mobility.

There have been several articles published which recognize mobility impairment as a major functional limitation for individuals with MS (Baum and Rothschild, 1983; Perks et al, 1997; Finlayson et al, 2003; Fay et al, 2004). Yet, despite the prevalence of mobility impairment in individuals with MS, and its use as a measurement of disease progression, most research studies considering mobility status use functional mobility as an outcome measure for treatment interventions such as exercise programs or pharmacologic treatments (Dario et al, 2001; Wiles et al, 2001; Wiles et al, 2003; DeBolt and McCubbin, 2004; Ozgocmen et al, 2005). Few studies focus on improving the efficacy of mobility device prescription in this population.

The lack of research considering the appropriate time to transition to an alternative form of primary mobility is likely to lead to suboptimal daily functioning in persons with MS. It has been reported that 85% of the patients with MS reported gait and motor disturbances as their chief complaint (Baum & Rothschild, 1983), and studies have shown that individuals with MS are particularly predisposed to balance deficits and consequent increased risk of falls (Frzovic et al 2000). In a study investigating the prevalence of falls in individuals with MS, of all the



subjects collected, 32% reported 2 or more falls in the two months prior to the study, and 59% reported at least one fall during this same time (Cattaneo et al, 2002).

Often, patients are prescribed manual wheelchairs for mobility assistance in order to improve mobility while decreasing fatigue and the risk of falls. It has been reported that, among those individuals with MS who use a manual wheelchair, a majority state that their wheelchair does not meet their mobility needs (Perks et al, 1993). Recent research indicates that people with MS are ineffective at propelling a manual wheelchair, and are unable to do so in a manner that is consistent with the demands of everyday tasks (Fay et al, 2004). The next logical step, therefore, would be a progression to a powered means of mobility. Yet, to the patient and to the secondary payers, this may seem like a drastic overall change. A power wheelchair has traditionally been a symbol of increased disability and dependence, and resistance to such a modification is often great. Among practitioners, it is also commonly believed that a transition to manual and motorized wheelchairs will accelerate declines in strength and functional abilities through disuse. As a result, a dichotomy exists between what might be most empowering for the individual, versus the acceptance of the assistive technology by patients and prescribers.

In a study by Boeije and Janssens (2004), individuals with MS were surveyed about their perceived seriousness of wheelchair usage. From the responses, subjects were divided into three groups. The largest group was characterized by individuals for whom the loss of mobility represented “loss of independence, a shrinking social world, adaptations to the house or even having to move, and the need for help.” Ultimately, however, these individuals felt they would get used to using a wheelchair. The second group said that usage of a wheelchair for mobility

would be the worst thing to happen to them. These individuals feared losing all their independence and being treated differently by others. The smallest of the three groups were those individuals who saw the use of a wheelchair as a minor inconvenience. Along these lines, another study by Janssens et al (2003) showed that differing levels in disease impairment alter the individual's perception of using a wheelchair. That is, in individuals with MS, those with greater functional disability view the use of a wheelchair as "less serious" when compared to those individuals who are less functionally affected. It can be argued, that as one's mobility becomes more limited, they increasingly view a wheelchair as an enabler, rather than a symbol of disability. These studies reveal that many individuals with MS possess misconceptions about the impact of transitioning to a wheelchair as their primary means of mobility. For this reason, these individuals may feel the need to delay a transition as long as possible.

The significant limitations often experienced by individuals with MS in the areas of ambulation and manual wheelchair propulsion are undeniable, and the lack of research in this area as it relates to assistive technology intervention is evident. With this in mind, the purposes of this study were both substantive and methodological. They were: 1. to examine changes in quality of life measures that parallel changes in functional mobility, 2. to investigate changes in strength and fatigue accompanying a change in primary means of mobility in persons with MS, and 3. to develop hypotheses for more definitive and refined research design and methods. Through this study, we hope to provide individuals with MS and their clinicians with information that can prove to be helpful in making a more informed decision regarding mobility device selection, ultimately leading to an increased quality of life. Quality of life has been defined many different ways, and yet, most definitions incorporate the match between one's life experiences and their

life expectations. For an individual with mobility impairments, an appropriate wheeled mobility device, that allows them to perform and participate in the activities important to them, has the potential to close the gap between what a person experiences and what they expect out of life. We hypothesize that a transition to wheeled mobility will lead to a small to negligible rate of decline in ambulatory ability and muscle strength. However, the decrease in subjective fatigue and the increased ability to participate in everyday activities allowed through the used of a wheelchair or scooter will result in an overall increased quality of life.

### **3.3.METHODS**

#### ***3.3.1. Participants***

We aimed to recruit a total of 20 people from assistive technology clinics throughout the Pittsburgh region. Subjects were included in this study if they:

- Had MS as diagnosed by the McDonald criteria (McDonald et al, 2001)
- Were able to ambulate as their primary means of mobility (EDSS  $\leq$  7.0 (able to ambulate at least 5m with bilateral assistance),
- Did not already own a wheelchair or scooter.
- Had been referred for a wheelchair (power or manual) or scooter and
- Were between the ages of 18 and 65 years

Subjects were excluded from this study if they:

- Had any other diagnosis besides MS causing a decline in mobility status

- Had significant depressive symptoms (CESD>13 (Radloff, 1977) or cognitive impairment (MMSE<26) (Folstein et al, 1975)
- Had experienced a MS exacerbation within 3 months prior to inclusion
- Had a history of a hernia in the last 2 months
- Were hospitalized or had a surgery within the last two months
- Were pregnant

The study was approved by the Veterans Administration Pittsburgh Healthcare System (VAPHS) Investigational Review Board (IRB), and all participants provided written informed consent prior to inclusion in the study.

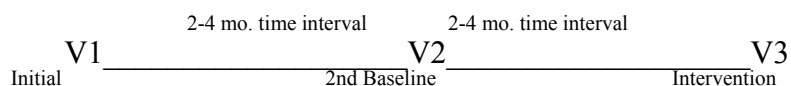
In addition, an investigator at the Denver, CO Veterans Health Administration (VHA) wheelchair clinic was trained to collect study data. The protocol conducted in Denver mimicked exactly the protocol performed at the Pittsburgh, with exception of wheelchair mobility monitoring using the datalogger (described below). All testing took place at either the Pittsburgh Highland Drive Veterans Health Administration Medical Center (VAMC), or the Denver VAMC. Subjects were offered transportation to the testing site, since it has been shown that transportation may be the factor of greatest importance in improving participation (Schwartz and Fox, 1995).

### ***3.3.2. Study design***

A quasi-experimental, longitudinal design was used, and all subjects served as their own controls (Figure 2). The first visit, V1, occurred at or near the time in which the subject was prescribed a power wheelchair or scooter. The second visit, V2, was at the time of assistive technology

delivery, which typically occurs an average of two to four months after the initial testing phase. Changes occurring during the interval between V1 and V2 served as a control for those that occurred after the transition to the alternative mobility device. Subjects were asked to come in for the third visit, V3, at a time equivalent to the time between V1 and V2, +/- 4 weeks (Figure 2). All data collection was the same over the three visits, unless precluded by exclusion criteria.

**Figure 2** Testing longitudinal design



We attempted to recruit a total of 20 subjects with MS from both the Center for Assistive Technology in Pittsburgh, PA, as well as the Denver VAMC wheelchair clinic. Based on means and standard deviations of the SF-36 (Trefler et al, 2004), and non-published research completed at our laboratory on changes in social participation as measured by the CHART, we expected to have 80% power to detect significant differences in quality of life and participation at an alpha of 0.05. We expected to see large increases (change in score by 15 points) in the SF-36 over time, and we expected to see decreases of 6-10% in muscle strength over time after the intervention based on the work of Kent-Braun and Bloomfield (Kent-Braun et al, 1997; Bloomfield, 1997).

### **3.3.3. Protocol**

In order to control for external variability that may have contributed to measurement error, the room temperature for testing was maintained at 70°F +/- 3°, and all testing began between 9:30 am and 11am. First visit testing took approximately 4 hours, and subsequent visits took between 2.5-3.5 hours.

#### **3.3.3.1. Functional Testing**

Each subject performed the timed 8 meter walk test (T8). For this test, subjects were asked to ambulate 8 meters on a tiled surface as fast as they were able, using whatever type of ambulation aid they felt was necessary. Subjects were encouraged to walk with the least amount of assistance possible. They were then asked to repeat this ambulation trial, this time walking the 8 meters at their own normal walking speed (NWS-T8). Again, they used whatever type of ambulation aid necessary.

Subjects were also asked to propel an ultralight wheelchair the same 8 meter distance, and the time in which they completed this task was recorded. The ultralight wheelchair was provided by the laboratory, and was adjusted so that each individual had approximately one inch between each side of their hips and the wheelchair when sitting.

#### **3.3.3.2. Maximal Voluntary Contraction**

Prior to strength testing, subjects' blood pressure was recorded. Any individual with a systolic blood pressure  $> 160$ , diastolic blood pressure  $> 90$  or heart rate  $< 50$  or  $> 100$ , was excluded from strength testing. Strength testing was performed using the Biodex 3 (Biodex Medical, Shirley, NY). Subjects were positioned in the Biodex such that the joint under consideration was aligned with the center of rotation of the system. For each joint tested, subjects were asked to perform up to 10 sub-maximal repetitions of the test in order to become familiar with the procedure. After 3 minutes of seated rest, subjects were asked to perform two five-second maximal isometric repetitions, with a five-second rest in between each repetition in order to obtain a maximal voluntary contraction (MVC). Subjects were asked to watch the computer screen

during testing for visual feedback, and verbal feedback was scripted. MVC testing was performed in the following order:

- Knee extension at 90°- subject in sitting, 90° hip flexion
- Knee flexion at 90°- subject in sitting, 90° hip flexion
- Ankle dorsiflexion (DF) in neutral dorsiflexion/ plantarflexion- subject in sitting, hip in 95° hip flexion, 15° knee flexion with thigh supported
- Hip flexion at 90°- subject in sitting
- Elbow flexion at 90°- upper extremity in approximately 45° scaption
- Elbow extension at 90°- upper extremity in approximately 45° scaption

Between each muscle testing, subjects were given 2-3 minutes of rest. The peak torque (PT) was calculated for each of the six muscles tested as the mean peak torque production over two repetitions. The total PT ( $PT_{total}$ ) was used in the analysis, and was calculated as the summed total PT of each of the muscles tested.

### **3.3.3.3. Questionnaires**

After completing MVC testing, subjects were asked to complete a series of four forms in Microsoft Access format. These forms included an intake form, which asked information regarding the subject's date of diagnosis, primary means of mobility, ability to ambulate, and number of falls in the last month, the Short Form-36 (SF-36) Health-related quality of life questionnaire (Ware et al, 1993), the Craig Handicap Assessment Reporting Technique (CHART) (Whiteneck et al, 1992) which measures participation in daily activities, and the Modified Fatigue Impact Scale (MFIS) (Fisk, 1994a; Fisk, 1994b), which measures how fatigue has affected the individual's ability to perform daily activities over the past week. There are ten

outcome variables from the SF-36 including: 1. physical functioning (PF) 2. social functioning (SF), 3. role limitations physical (RP), 4. bodily pain (BP), 5. general medical health (GH), 6. mental health (MH), 7. role limitations emotional (RE), 8. vitality (VT), 9. composite physical health status (PCS) and 10. composite mental health scores. In a previously described study, we have shown that, when compared to published norms, individuals with MS who are about to transition in their primary means of mobility have markedly decreased quality of life scores in the domains of the SF-36 that measure physical, and not mental functioning (Ambrosio et al, in review). Therefore, for this study, we considered only the PF, SF, RP, BP, GH, and PCS. The three outcome variables considered in the CHART were the physical independence score, the mobility score and the occupation score. Subjects who were familiar using computers completed the forms independently, with an investigator observing the procedure. Otherwise, the investigator asked the subject the questions and filled out the forms on the computer. Completing all questionnaires took between 45minutes to 1 hour.

#### **3.3.3.4. Static Fatigue Testing**

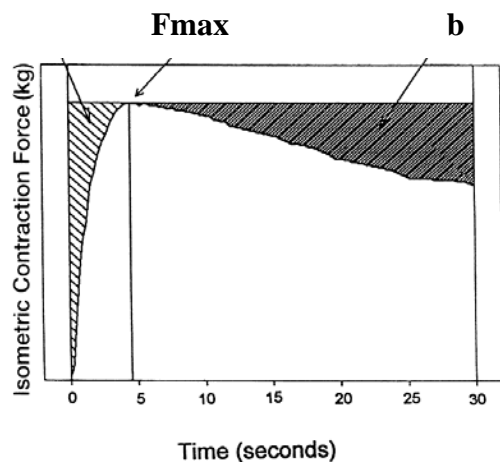
After completing the questionnaires, the subjects were asked to return to the Biodex and perform a 30-second sustained maximal isometric contraction of the same muscles as tested in the MVC trials, and in the same order. Joint positions in which the subjects were tested during the MVC trials were recorded so that the same positions were used for the static fatigue testing trial. Again, subjects were given 2-3 minutes of rest in between each muscle testing. The static fatigue index (SFI) for each muscle was calculated based on a model proposed by Schwid, et al (1999) (Figure 3). In this model, the time to generate a maximal contraction is removed from the equation ( $T_{max}$ ), and from the remaining time, the ratio of the area under the force versus time



curve (AUC) over the theoretical area if the individual were able to maintain a maximal contraction ( $F_{max}$ ) for the remainder of the 30-second trial. The SFI is then representative of the area between these two curves, area 'b' in Figure 3, given as a percentage. The equation for SFI is given as:

$$\text{Equation 1: } \text{SFI} = 100\% \times [1 - (\text{AUC} / [F_{max} * (30 - T_{max})])]$$

**Figure 3** Force vs. Time Curve (Adapted from Schwid et al, 1999)



### 3.3.3.5. Electromyography

During strength and static fatigue testing, the Noraxon MyoSystem 1200 EMG system (Noraxon; Scottsdale, AZ) was synchronized with Biodex measurements to concurrently collect surface EMG data. Bipolar disc-shaped surface electrodes were placed over the dominant side quadriceps, tibialis anterior, biceps and triceps as described by Basmajian (Basmajian, 1980). Alcohol was used to cleanse the skin prior to adhering the electrode, and the inter-electrode distance was approximately 1 cm. The EMG signal was sampled at a rate of 1000 Hz. During the static fatigue trial, a power density spectrum was obtained by a Fast Fourier Transformation using a 2-second data window. We then took an average of the power spectral slope across all four muscle groups tested ( $PS_{tot.}$ ) in order to quantify muscle fatigue.

#### **3.3.3.6. Mobility Monitoring**

After completing V1 testing, each subject was given a pedometer, and they were asked to record the pedometer reading each night. Subjects who completed visits V2 and V3 were once again provided with a pedometer. In addition, we mounted our data logger on their wheelchair or scooter. The data logger provides total distance traveled in the wheelchair and the speed at which they are traveling (Spaeth et al, 2000). Subjects were instructed to disregard the pedometer and the datalogger, and continue with their daily activities as normal. Together with the pedometer data, we could get an idea of how active the subject is while walking and using their wheelchair. We were also able to record how much the individual is actually using their new wheelchair. At the end of one week, investigators visited the subject's home to retrieve the data logger and the pedometer.

#### **3.3.4. Statistical Analysis**

Gender was described using frequency counts. Means +/- standard deviations were calculated for continuous data including age, and years since diagnosis. Given the difficulties we encountered with subject recruitment, only descriptive statistics for testing variables are presented.

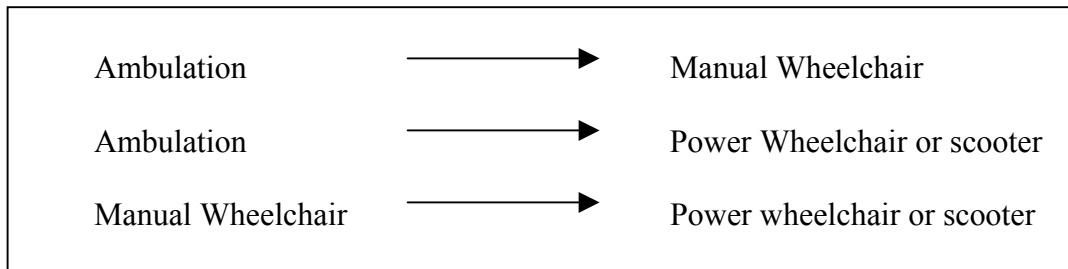
### **3.4.RESULTS**

#### **3.4.1. Participants**

Initial Pittsburgh VA IRB approval for recruiting subjects was obtained in July, 2003. Recruitment was solicited via fliers, pamphlets, and by contacting local rehabilitation clinics and MS support societies. From July to September, we were unable to recruit any ambulatory

subjects with MS. Therefore, in September 2003, we submitted an IRB modification in which we intended to recruit not only ambulatory subjects with MS who were transitioning to the use of a wheeled mobility, but also individuals with MS who were transitioning from a manual wheelchair to the use of a power wheelchair or scooter (Figure 4).

**Figure 4** Patterns of mobility transition considered

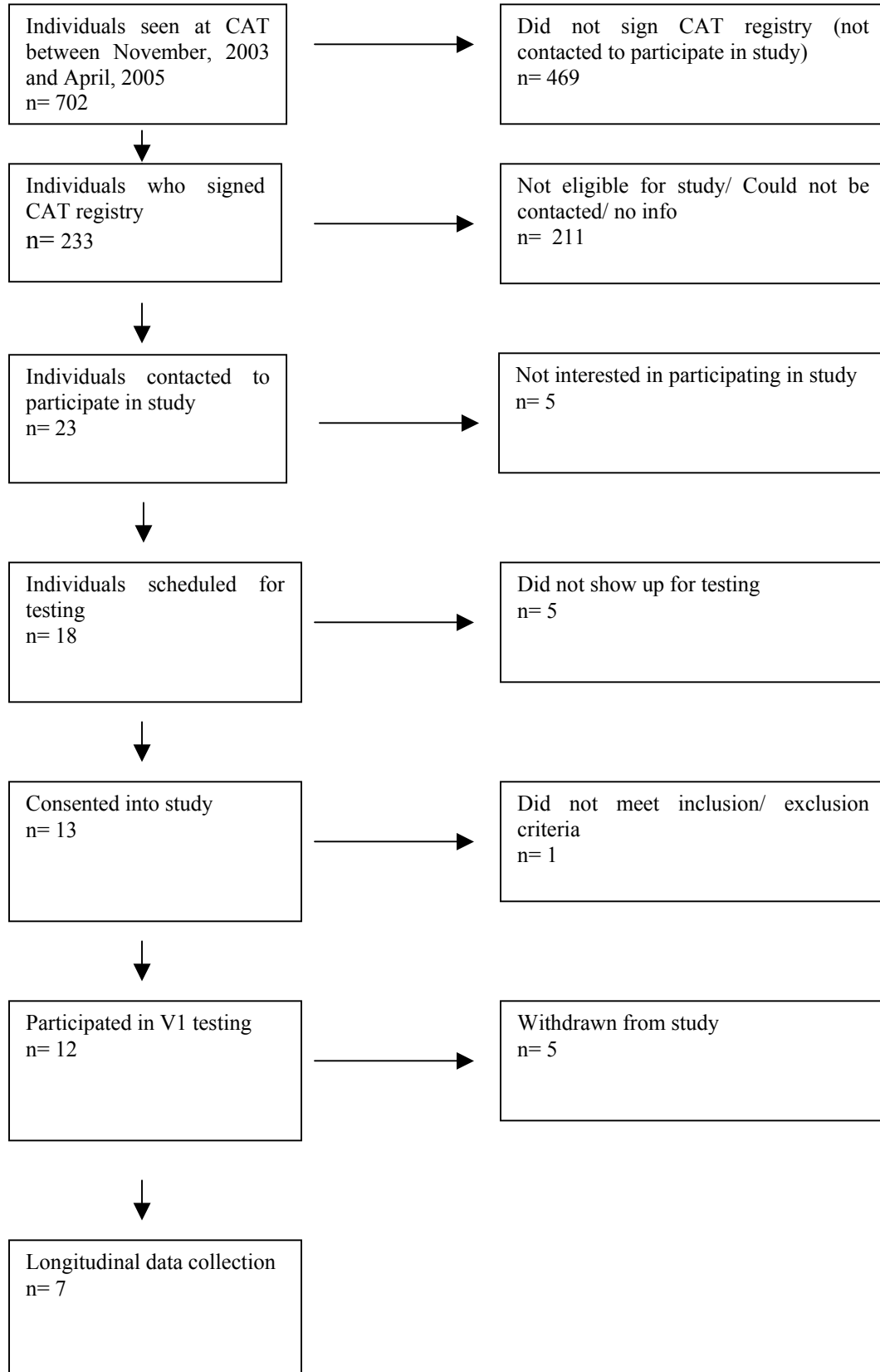


The first subject was consented and tested in October, 2003. At the time of the yearly review in March, 2004, only three subjects with MS who were transitioning in their primary means of mobility had been recruited. Therefore, in the yearly review, we submitted a modification to include all individuals with chronic disorders who were transitioning in their primary means of mobility, either from ambulation to the use of any type of wheeled mobility, or from the use of a manual wheelchair to the use of powered mobility. Chronic disorders considered included all those diagnoses leading to a decline in mobility status, not including those resulting from cardiac conditions, orthopedic, or other conditions that would preclude strength testing. All individuals needed to have a prescription for their first powered mobility. In total, between July 2003 and April 2005, 13 subjects were recruited.

Of all subjects recruited, six of the subjects were excluded or withdrawn from the study. The first individual was withdrawn after her first visit because she was denied the new wheelchair that was prescribed, and she decided she no longer needed to transition in her primary means of

mobility. The second individual, who was transitioning from the use of a manual wheelchair to the use of a powered wheelchair, was excluded because she later told us that she had a scooter that she had been using quite regularly, since before the time of her 1<sup>st</sup> visit. Because she did not meet the inclusion criteria, neither her V1 nor V2 data were included in the analysis. The third individual was excluded from the study because, after the first visit, the subject used the reimbursement for participating in the study to fix an old scooter he had. Within two weeks of completing his first visit, he was using the scooter as his primary means of mobility outside of the home. The fourth individual scored 22 on the MMSE, and, therefore, did not meet inclusion criteria. Finally, the fifth individual was withdrawn from the study because she never returned our follow-up calls. Therefore, in total, 13 individuals completed the informed consent for participation in the study, 11 individuals' data were considered for V1, 6 for V2, and 3 for V3 (Figure 5).

**Figure 5** Flow chart of participation



The study protocol was submitted to the Denver IRB was accepted in January, 2004. From this date to April of 2005, 5 subjects were consented to the study. However, only one was included. This subject completed both V1 and V2 testing. Of the other four that were consented, two of the subjects had high blood pressure prior to beginning testing, and did not continue further, and the other two subjects did not meet the MMSE criteria, and were excluded from the study. Denver data is not included in the analysis.

#### **3.4.1.1. Subject Demographics**

Nine females and two males participated in this study. The average age of the participants was 49.9 +/- 7.1 years (range: 37.5-63.3 years). Nine of the 11 subjects had MS as diagnosed by a neurologist, one had osteoarthritis, and one had degenerative disk disorder as their major diagnosis resulting in mobility impairment. The average time since diagnosis was 12.8 +/- 7.2 years (range: 7 months to 20 years). Three of the individuals, two of which were non-ambulatory, reported having a manual wheelchair at the time of inclusion in the study. One individual had an EDSS score of 5.0 (Ambulatory without aid for about 200 meters. Disability impairs full daily activities), 7 individuals had an EDSS score of 6.0 (Intermittent or unilateral constant assistance (cane, crutch or brace) required to walk 100 meters with or without resting), one had a score of 6.5 (Constant bilateral support (cane, crutch or braces) required to walk 20 meters without resting), and the remaining 2 had an EDSS score of 8.0 (Essentially restricted to bed, chair, or wheelchair, but may be out of bed much of day; retains self care functions, generally effective use of arms). Eight of the 11 subjects who participated in this study had fallen at least once in the last month (range: 1 to ">20").

After completing V1, regular phone calls were made to subjects in order to have an idea of when they were scheduled to receive their new mobility device. The second visit was then scheduled at or near the time of mobility device delivery. For the five subjects who completed second visit testing, the average time in between V1 and V2 was 15.3 weeks +/- 4.1 (range: 11 weeks to 20 weeks). Four of the 5 subjects had MS.

**Table 3** Description of subject participation and withdrawal

<b>Subject # (transition)</b>	<b>Diagnosis</b>	<b>Visit 1</b>	<b>Visit 2</b>	<b>Visit 3</b>	<b>Comments</b>
<b>1 Amb- PWC</b>	MS	10/13/2003	03/03/2004 (20 weeks)	09/07/2004	
<b>2 Amb- scooter</b>	MS	11/06/2003	01/28/2004 (12 weeks)	04/29/2004	Ambulation to scooter
<b>3 Amb-PWC</b>	MS	12/22/2003			Power wheelchair denied
<b>4 MWC- PWC</b>	MS	05/13/2004	11/18/2004 (27 weeks)		At second visit, informed us that she used both a manual wheelchair and a scooter before having a prescription for a power wheelchair.
<b>5 Amb- PWC</b>	MS	05/19/2004			Decided not to get the power wheelchair.
<b>6 MWC- PWC</b>	MS	05/20/2004	09/13/2004 (20 weeks)		Manual wheelchair to power wheelchair. Power wheelchair was broken for 1 month in between V1 and V2
<b>7 MWC- PWC</b>	MS	06/02/2004			Used reimbursement money from V1 to fix an old scooter
<b>8 MWC- PWC</b>	Post-polio	06/08/2004			Did not meet MMSE criteria.
<b>9 Amb- PWC</b>	Osteoarthritis	08/18/2004			Has not returned phone calls
<b>10 Amb- scooter</b>	Degenerative Disk Disorder	09/22/2004	12/08/2004 (11 weeks)	02/24/2004	
<b>11 Amb- PWC</b>	MS	09/23/2004			Has not yet received wheelchair.
<b>12 Amb- PWC</b>	MS	11/17/2004	03/29/2005 (18 weeks)		
<b>13 Amb- PWC</b>	MS	01/27/2005			

*Note: Yellow highlighting indicates that the subject was withdrawn from the study.*



### 3.4.2. Protocol

#### 3.4.2.1. Functional Testing

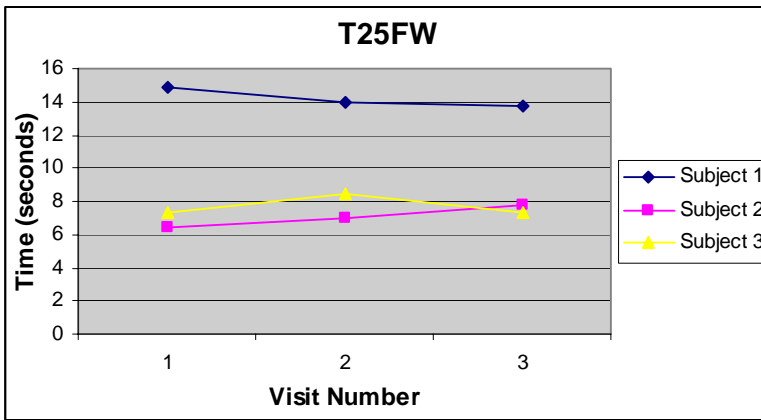
Two individuals who participated in this study were non-ambulatory. Therefore, at V1, nine individuals, seven with MS, completed the T8 with an average time of 12.6 +/- 4.8 seconds (0.63m/s). The normal walking speed trial, (NWS-T8) average time to complete the T8 was 14.1 +/- 3.7seconds (0.57m/s).

The average time to complete the 8 meter wheelchair propulsion trial was 12.7 +/- 4.8 seconds (0.63m/s). One of the 12 individuals did not complete the wheelchair propulsion trial because the laboratory did not have an appropriately fitting ultralight wheelchair. All three individuals who completed V1, V2 and V3 completed the ambulation trials each time. Results are shown in Table 4 and Figure 6.

**Table 4** Time to complete T8 (seconds) over V1, V2, and V3

<b>Subject #</b>	<b>V1 (sec)</b>	<b>V2 (sec)</b>	<b>V3 (sec)</b>	<b>% Change V1-V2</b>	<b>% Change V2-V3</b>
<b>1</b>	14.9	14.0	13.75	-6	-2
<b>2</b>	6.41	7.03	7.72	+13	+9
<b>3</b>	7.31	8.4	7.34	+13	-13

Figure 6 Timed 25 Foot Walk test over three visits, n = 3



Note: The average # of weeks between V1 and V2 = 14.3; average # of weeks between V2 and V3 = 17.0

Since one of the individuals who returned for V2 was non-ambulatory, 4 individuals completed the T8 during their second visit. The average time to complete the T8 was 10.9 +/- 3.7 seconds (0.73m/s). The average time to complete the NWS-T8 was 12.8 +/- 3.1 (0.63m/s). For the wheelchair propulsion trial, one individual requested not to perform the trial because she felt unsafe using the ultralight wheelchair secondary to decreased trunk stability. Another subject did not complete the trial because the laboratory did not have a large enough ultralight wheelchair. Finally, another subject did not complete the trial because of a protocol error. Therefore, two individuals completed the wheelchair propulsion trial during V2. For these individuals, the average time to propel the wheelchair 8 meters was 11.41 +/- 3.01 seconds (0.70 m/s)

### 3.4.2.2. Maximal Voluntary Contraction

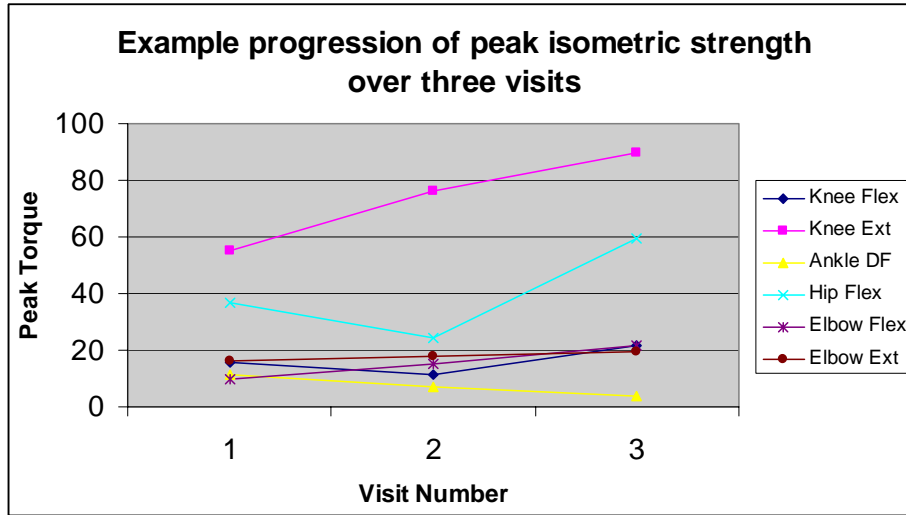
Initial strength measurements were completed for 6 subjects who completed the first visit testing. All 6 of these subjects had MS (see Table 5 for a summary of peak torques). Four of the subjects had blood pressures in excess of the acceptable level, and, therefore, did not complete testing. One subject did not complete strength testing secondary to reported low back pain as a result of osteoporosis. The average  $PT_{total}$  for the subjects tested was 184.7 +/- 54.2.

**Table 5.V1** average peak torques in newtons (N) (n=6)

<b>Knee Flexion (N)</b>	<b>Knee Extension (N)</b>	<b>Ankle Dorsiflexion (N)</b>	<b>Hip Flexion (N)</b>	<b>Elbow Flexion (N)</b>	<b>Elbow Extension (N)</b>
20.8 +/- 6.0	66.1 +/- 32.0	12.2 +/- 4.9	42.7 +/- 16.9	22.6 +/- 8.2	20.4 +/- 3.8

Subjects who did not complete strength testing during V1 did not complete strength testing during V2. This was the case for 2 of the 5 subjects who returned to complete V2. In addition, one subject, who was able to complete strength testing during V1, had blood pressure measurements outside the acceptable range during V2, and therefore could not complete this portion of the testing. Therefore, V2 strength testing was completed in 2 subjects. For these 2 subjects, the average was  $PT_{total}$  124.5 +/- 38.9.

Figure 7. Peak Isometric Strength



Note: The # of weeks between V1 and V2= 12; the # of weeks between V2 and V3=13 Example progression of peak isometric strength over three visits for knee flexion (Knee Flex), knee extension (Knee Ext), ankle dorsiflexion (Ankle DF), hip flexion (Hip Flex), elbow flexion (Elbow Flex), and elbow extension (Elbow Ext), n=1

### 3.4.2.3. Questionnaires

Tables 6 and 7 display a summary of SF-36 and the CHART scores, respectively, for the V1 subject testing scores. A domain score of 100 is considered to be the level of performance of a typical, non-disabled individual.

**Table 6** Visit 1: SF-36 summary scores for 10 domains: physical functioning (PF), social functioning (SF), role physical (RP), bodily pain (BP), general health (GH), and physical composite score (PCS), subjects n=11

Variable	PF	SF	RP	BP	GH	PCS
Subjects	25.9	51.1	22.7	46.5	39.0	24.3
Mean +/-	+/-	+/-	+/-	+/-	+/-	+/-
SD	27.5	28.2	36.1	29.2	30.4	10.7
General US population	84	83	81	75	72	50

**Table 7** Visit 1: CHART summary scores for 3 domains: physical independence, mobility, and occupation scores, n=11.

<b>Variable</b>	<b>Physical Independence</b>	<b>Mobility</b>	<b>Occupation</b>
Mean +/-	83.6 +/- 28.9	81.7 +/-	64.7 +/-
SD		24.6	39.2

The average MFIS score for the V1 subjects was 13.3 +/- 3.0 (n=11)

Tables 8 and 9 display a summary of SF-36 and the CHART scores for the V2 subjects.

**Table 8** Visit 2: SF-36 summary scores for 10 domains: physical functioning (PF), social functioning (SF), role physical (RP), bodily pain (BP), general health (GH), and physical composite score (PCS), n=5

<b>Variable</b>	<b>PF</b>	<b>SF</b>	<b>RP</b>	<b>BP</b>	<b>GH</b>	<b>PCS</b>
Mean +/-	17.0+/-	67.5+/-	10.0+/-	44.6+/-	38.4+/-	23.0+/-
SD	22.0	34.9	13.7	33.4	22.3	8.8

**Table 9** Visit 2: CHART summary scores for 3 domains: physical independence, mobility, and occupation scores, n=5

<b>Variable</b>	<b>Physical Independence</b>	<b>Mobility</b>	<b>Occupation</b>
Mean +/-	83.8 +/- 32.1	71.6 +/-	83.4 +/-
SD		30.9	33.8

The average MFIS score for the V2 subjects was 13.0 +/- 5.2 (n=5). SF-36 and CHART scores for the V3 subjects are presented in Tables 10 and 11.

**Table 10** Visit 3: SF-36 summary scores for 10 domains: physical functioning (PF), social functioning (SF), role physical (RP), bodily pain (BP), general health (GH), and physical composite score (PCS), n=3

Variable	PF	SF	RP	BP	GH	PCS
Mean +/-	21.7	87.5	50.0	51.3	44.0	29.2
SD	+/- 7.6	+/- 12.5	+/- 50.0	+/- 42.4	+/- 16.4	+/- 12.2

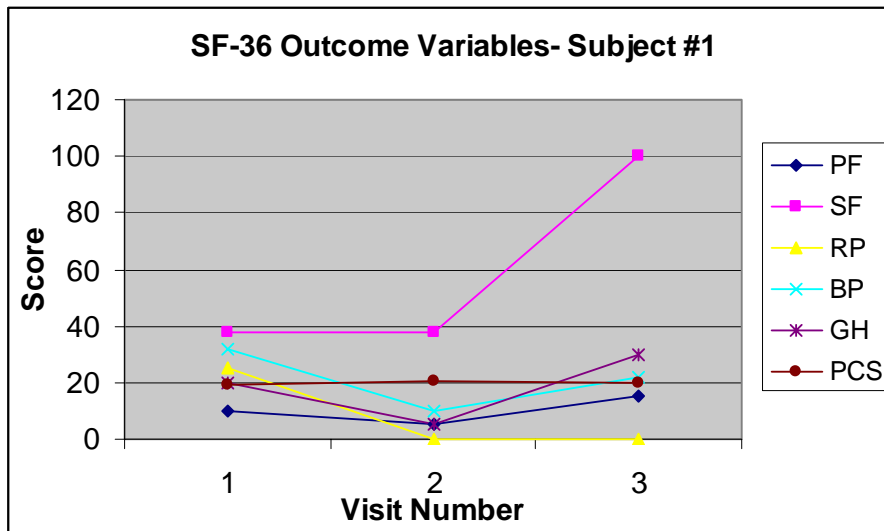
**Table 11** Visit 3: CHART summary scores for 3 domains: physical independence, mobility, and occupation scores, n=3

Variable	Physical Independence	Mobility	Occupation
Mean +/-	98.5 +/- 0.5	87.0 +/- 16.1	100.0 +/- 0.0
SD			

The average MFIS score for the individuals who completed V3 was 10.7 +/- 4.5 (n=3).

Figure 8 is a representative graph of one subject's rate of change in health related quality of life at baseline (between V1 and V2) and after intervention (between V2 and V3).

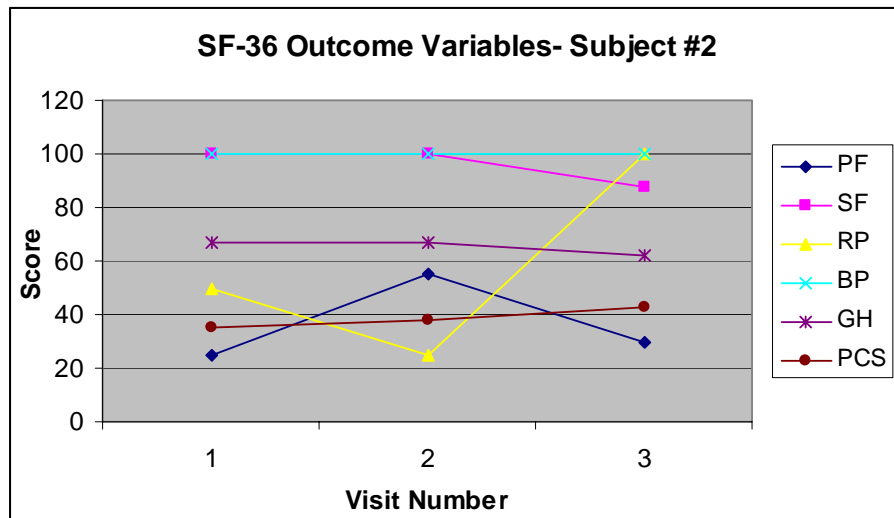
**Figure 8.** SF-36 over three visits for Subject # 1



Note: The # of weeks between V1 and V2= 20; the # of weeks between V2 and V3= 27;  
 Example graph for the progression of SF-36 domain scores, physical functioning (PF), social functioning (SF), role physical (RP), bodily pain (BP), general health (GH), and physical composite score (PCS), over the three visits for subject #1

Taken together with datalogger mobility monitoring data, this subject used her new mobility device almost daily, between 5-6 days out of the week, in addition to maintaining daily ambulation. On the other hand, Figure 9 represents another subject’s rate of change in health-related quality of life over the 3 visits.

Figure 9. SF-36 over three visits for Subject #2



Note: The # of weeks between V1 and V2= 12; the # of weeks between V2 and V3=13; Example graph for the progression of SF-36 domain scores, physical functioning (PF), social functioning (SF), role physical (RP), bodily pain (BP), general health (GH), and physical composite score (PCS), over the three visits for subject #2

This subject reported rarely using her new mobility device, and datalogger monitoring showed she only used the chair approximately 3 days a week.

#### 3.4.2.4. Static Fatigue Testing

All individuals who completed the strength testing portion of the protocol completed the static fatigue testing. Variable summary scores are displayed in Tables 12, 13 and 14 for visit 1, 2 and 3, respectively.

**Table 12** Visit 1: Static Fatigue Index (SFI) means +/- standard deviations for knee flexion, knee extension, ankle DF, hip flexion, elbow extension, and elbow flexion, n=6

<b>SFI variable</b>	<b>Knee Flexion</b>	<b>Knee Extension</b>	<b>Ankle DF</b>	<b>Hip Flexion</b>	<b>Elbow Extension</b>	<b>Elbow Flexion</b>
Mean +/- SD	37.5% +/- 12.9	21.3% +/- 2.5	87.1% +/- 13.7	53.1% +/- 23.4	22.3% +/- 11.9	30.7% +/- 10.5

**Table 13** Visit 2: Static Fatigue Index (SFI) means +/- standard deviations for knee flexion, knee extension, ankle DF, hip flexion, elbow extension, and elbow flexion, n=2

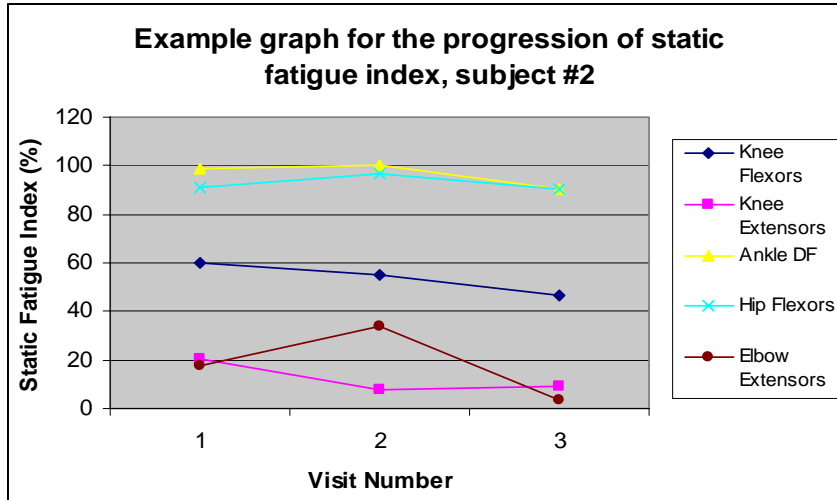
<b>SFI variable</b>	<b>Knee Flexion</b>	<b>Knee Extension</b>	<b>Ankle DF</b>	<b>Hip Flexion</b>	<b>Elbow Extension</b>	<b>Elbow Flexion</b>
Mean +/- SD	56.9 +/- 2.1	8.75 +/- 1.5	51.4	57.95 +/- 54.7	39.9 +/- 8.0	50.1

**Table 14.** Visit 3: Static Fatigue Index (SFI) means +/- standard deviations for knee flexion, knee extension, ankle DF, hip flexion, elbow extension, and elbow flexion, n=1

<b>SFI variable</b>	<b>Knee Flexion</b>	<b>Knee Extension</b>	<b>Ankle DF</b>	<b>Hip Flexion</b>	<b>Elbow Extension</b>	<b>Elbow Flexion</b>
Mean	46.5	9.1	90.4	90.4	3.5	3.5



**Figure 10** Example graph for the progression of static fatigue index of the knee flexors, knee extensors, ankle dorsiflexors (DF), hip flexors, and elbow extensors for subject #2



*Note: Data missing for elbow extensor SFI at V2. Therefore, elbow extensors are not graphed.*

### 3.4.2.5. Electromyography

Table 15 demonstrates single subject muscle fatigue data as determined by power spectral density analysis, obtained through a fast-fourier transformation. This subject transitioned from ambulation to the use of a scooter. Elbow flexor and elbow extensor muscle fatigue increased after mobility device intervention. However, lower extremity muscles, knee extensors and ankle dorsiflexors, actually showed a decrease in median frequency, and therefore, a decrease in muscle fatigue after mobility device intervention between V2 and V3.

**Table 15** Example progression of Power Spectral Density across three visits, n=1

Muscle	V1 Slope (Hz/ sec)	V2 Slope (Hz/ sec)	V3 Slope (Hz/ sec)
<b>Knee extensors</b>	0.16	0.18	-0.04
<b>Ankle dorsiflexors</b>	-0.31	-0.87	-0.42
<b>Elbow flexors</b>	-0.11	-0.28	-0.86
<b>Elbow extensors</b>	-0.41	-0.27	-0.37
<b>PStot</b>	-0.17	-0.31	-0.42

#### **3.4.2.6. Mobility Monitoring**

All ambulatory subjects (N=9) completed pedometer mobility monitoring for the seven days following V1. The average recorded pedometer steps/day was 1813.1 +/- 765.9 (range: 240.0-2744.4 steps/ day).

For the two individuals who were non-ambulatory at the time of inclusion into the study, dataloggers were mounted on their manual chairs after V1 to get an idea of their daily activity. After one week of monitoring daily wheelchair use, the average daily distance traveled was 79.7m and 950.7m for each of the subjects. When considering the total distance traveled over one week, these two individuals traveled 557.9 m and 6655.0 m at an average speed of 0.12 and 0.21m/sec, respectively.

### **3.5.DISCUSSION**

MS has the potential to severely debilitate and functionally impair any individual. Hopefully, the devastating effects of MS will one day be prevented. Until then, efforts should be focused on improving the individual's everyday functioning, and ultimately, their quality of life. It was the aim of this research to provide initial evidence of the physical and psychosocial changes that are commonly seen as they transition in their primary means of mobility. We intend for this information to be useful to consumers and their clinicians in the selection and timing of mobility device prescription. Furthermore, we believe an account of some of the difficulties encountered with conducting this type of longitudinal mobility research in this type of population will be useful for designing and implementing similar future research designs. To the best of our

knowledge, ours was the first study of its type to attempt to provide some indication of what individuals can expect as they transition to an increased reliance on AT.

### ***3.5.1. Subject Recruitment***

The difficulties we encountered regarding subject recruitment was not unique to our study, and, therefore, was not surprising. Subject participation rates in clinical trials have been shown to range from 3-20% (Chang et al, 2002). Studies have investigated the characteristics of individuals who are willing to participate in clinical trials. Such characteristics included: wanting to get the best available care, the belief that participation in the study would help fight their illness, and the fear that their condition would get worse without treatment (Schwartz and Fox, 1995). Therefore, according to these studies, it is likely that individuals were not highly motivated to participate in this study, since they received no direct benefit or therapeutic intervention.

Another reason for difficulty in recruiting subjects for this study is because of the strict inclusion/exclusion criteria. Not only were there ten different inclusion/ exclusion criteria, but furthermore, individuals had to be recruited into a narrow window of time after receiving a prescription for a new wheeled mobility. This introduced a number of issues regarding subject inclusion into the study, including scheduling conflicts with work, school, and taking care of the children. Furthermore, because inclusion into the study needed to take place at or near the time of mobility device prescription, when many individuals were facing issues of acceptance of their disease progression. As previously mentioned, for those unfamiliar with regular AT use, a wheelchair or scooter may represent increasing disability and decreased independence.

Therefore, psychosocial factors may have also limited individuals from being willing to participate in the study.

In addition to the difficulties we encountered with subject recruitment, subject attrition was very high (50%). Two individuals were ultimately withdrawn because they decided they no longer needed to transition to wheeled mobility. The relapsing-remitting component of MS contributes to much of the variability in symptom presentation for individuals. As individuals' symptoms become inactive, they may feel they no longer need to transition to the use of a wheelchair or scooter. However, this is likely to be a temporary resolution of symptoms, and the individual may find him/herself in a position of needing the mobility device in the near future.

Finally, we anticipated that the time of wheelchair delivery would range between two months and four months. However, for the six subjects who participated in V2, the average delivery time was almost 17 weeks. This does not include two individuals who are still included in the study, who applied for a new wheelchair 5 and 7 months ago, and have still not received their new mobility device. Interestingly, in a study by Jedeloo et al, (2002) authors found that delivery time was an important factor in explaining the level of satisfaction of individuals receiving a new wheelchair. Increasing the time between follow-up visits increases the likelihood for subject withdrawal.

### ***3.5.2. Functional Testing***

According to Lerner-Frankiel et al (1986), 1.2 m/s can be considered a functional walking speed. Cross-sectional analysis of ambulatory ability in individuals who completed V1 testing revealed that these individuals, when asked to walk as fast as they are able, still do not reach functional

walking speeds. In fact, their mean velocity was just over half as fast as what is considered to be functional, both when asked to ambulate as fast as they are able, and when they walked at their normal walking speed.

Despite the fact that these individuals are not functional ambulators, anecdotal evidence has shown that individuals often resist the transition to wheeled mobility as long as possible, with the belief that relying on a wheelchair will increase the rate of decline in their ambulatory ability. That is, they feel that if they no longer rely on ambulation as their primary means of mobility, they will lose what walking ability they have. While we were only able to collect longitudinal data on 3 subjects, our data indicates this is not likely to be the case.

Schwid et al (2000) showed that a change of 20% or greater in the time to complete the T8 is needed to consider there to be a functional change in ambulatory ability. For the three subjects who completed the T8 over all three visits, the average change in time to complete the T8 between V1 and V2 was 11%, and the average change in the time to complete the T8 after mobility device intervention (between V2 and V3) was 8%. Therefore, there was not a functional change in ambulatory ability, even after individuals transitioned to primarily the use of a power wheelchair for mobility. Although this is only preliminary data, with a small sample size, it does support our original hypothesis that a transition to the use of a wheelchair will not lead to a clinically significant decrease in ambulatory ability. Further research should be done to more conclusively describe the change in functional ability after the transition in primary means of mobility. This information could prove to be very valuable to individuals and clinicians when faced with mobility decisions.

When considering the manual wheelchair propulsion trial, individuals tested were not able to propel a manual wheelchair at a functional speed, and propelled an average of 0.63 m/s. This measure is limited by the fact that none of these individuals tested had experience propelling manual wheelchairs. Therefore, their propulsion speed might have increased if they were experienced manual wheelchair users. On the other hand, these findings are consistent with the findings of Fay et al, (2004), that showed that manual wheelchair users with MS, when asked to propel a manual wheelchair at their normal propulsion speed, pushed their wheelchairs at an average speed of 0.67 m/s.

The typical clinical progression of mobility intervention moves from ambulation to some type of ambulation aid to the use of a manual wheelchair, and finally, the use of a power wheelchair as a last resort. Our results reveal that the transition to the use of a manual wheelchair in chronic disorders may not always be the optimal choice of wheeled mobility when the use of walking aids fail, since these individuals are not functional wheelchair users. It is possible that the direct transition to the use of powered mobility may prove to result in better functional outcomes for this population. This is an important area of investigation for future studies.

### ***3.5.3. Maximal Voluntary Contraction***

Comparisons may be made in the lower extremity strength of individuals with MS who are about to transition in their primary means of mobility with reported lower extremity peak torques of individuals categorized as “fallers”. Gehlsen & Whaley (1990) and Whipple, et al (1987) both showed that a significant difference exists in the lower extremity strength of elderly individuals classified as “fallers” or “non-fallers”.

In our study, individuals with MS who are waiting to receive a new mobility device had even lower knee extension, knee flexion, and ankle dorsiflexion peak torques (66.1N, 20.8N, and 12.2N respectively) than individuals classified as “fallers” from Whipple et al (1987). In fact, when our subjects were asked whether or not they had fallen in the last month, all but two of them said they had fallen at least once. One individual reported having fallen over twenty times. Taken together, this data indicates that many individuals with chronic disorders who are about to transition to the use of wheeled mobility are already at high risk for falls. It can be argued that these individuals should have considered a transition to a wheeled mobility at an earlier stage in order to prevent the risk of injury and further impairment. Future research should seek to identify benchmarks that would alert clinicians of the need to consider a transition to wheeled mobility in individuals with MS.

We were unable to collect sufficient longitudinal data across the three visits to make a statement about whether or not declines in strength are accelerated by the transition from ambulation as a primary means of mobility to primarily the use of wheeled mobility. Only one subject completed strength testing for all three trials. However, for this individual, in all muscles except the ankle dorsiflexors, muscle strength actually increased after a transition to the use of a scooter. This supports our hypothesis that a change in the primary means of mobility will not necessarily lead to an increase in the rate of decline in muscle strength.

It has been shown that static fatigue is not significantly associated with strength of the same muscles (Schwid et al, 1999), and therefore, this was another important data point to collect. This is especially true given the fact that it is fatigue that so commonly interrupts participation in

daily activity in persons with MS (Krupp et al, 1988). At V1, our subjects showed mean declines in motor output between 21.3% for the knee extensors, and 87.1% for ankle dorsiflexors. While the SFI of the knee extensors in our population is comparable to that seen in the ambulatory subjects with MS from Schwid et al (1999) (28.0%), the SFI of the ankle dorsiflexors in our sample population is much greater than seen in their population (31.6%). Future investigations should seek to determine how changes in lower extremity muscle endurance contribute to decreased function in this population, and how mobility device intervention affects motor fatigue.

When we considered the change in the rate of muscle fatigue as determined by electromyography, for the subject tested over the three visits, we found that a transition from ambulation to the use of a scooter may not necessarily lead to decreased lower extremity muscle endurance, as might have been expected. In fact, the subject tested actually demonstrated decreased knee extensor and ankle dorsiflexor fatiguability after transitioning to the use of a scooter. However, this subject reported using her scooter infrequently. Therefore, it is possible that her continued daily ambulation helped to maintain her lower extremity muscle endurance. Future studies should seek to describe more specifically the change in muscle fatiguability after a transition to wheeled mobility.

#### ***3.5.4. Questionnaires***

It has been previously shown that transitioning to the use of powered mobility results in not only increased mobility, decreased pain and decreased discomfort but also quality of life benefits (Davies et al, 2003). Another study showed that the transition to powered mobility enables self-



controlled mobility and decreased dependence on others for assistance (Buning et al, 2001). This ultimately results in improved social participation. Furthermore, it has been shown that non-ambulatory individuals with MS who rely on a combination of manual wheelchair and powered mobility participate in social activities almost twice as much as individuals who rely only on a manual wheelchair or who use a manual wheelchair, yet retain some ability to ambulate (Ambrosio et al, 2003). These findings serve as a modest example of the impact AT can have in the lives of individuals with MS. Our preliminary studies further support these findings.

We hypothesized that, not only would a transition to the use of a wheelchair or scooter lead to minimal increases in the rate of muscle strength decline, but would also lead to an increase in health-related quality of life. Ultimately, the increases in quality of life resulting from the mobility device intervention are a result of how often the individual is using their wheelchair. While we were unable to collect a sufficient number of longitudinal subject data to perform correlations, our preliminary data shows this to be the case. In the individual who regularly used her wheelchair almost daily, an improvement in a majority of domain scores considered was evident. On the other hand, for the individual who was prescribed a scooter, but reported not using it regularly after receipt, improvements in quality of life scores were not as evident. These findings support our original hypothesis, and demonstrate a need for further investigation as to the correlation between mobility device use and improvements in health-related quality of life.

#### ***3.5.5. Future studies/ considerations***

Although this study, to date, has collected fewer than expected subjects, it has highlighted the need for continued future research in the area of mobility transition in individuals with MS and

other chronic disorders, and has raised many important questions. Why does there seem to be such a large percentage of undiagnosed high blood pressure in this population? Why does it seem to take so long to receive a new wheelchair after it has been prescribed, and how does the variability of symptom presentation in a population such as MS affect the willingness of insurance companies to reimburse for assistive technology? These are all topics rarely investigated, which, considering the widely acknowledged significance of mobility on quality of life in individuals with MS, lends to questions in and of themselves. How many investigators desist from conducting longitudinal mobility research in populations such as MS because of difficulties and barriers as exemplified in our study? Along these lines, how many grant agencies fail to fund longitudinal rehabilitation studies in populations with MS because they are well aware of the difficulties with subject recruitment and attrition? As an example, one prominent organization specifically devoted to the cause of MS funds approximately 35 million dollars for research in MS. A majority of research monies are allocated to more therapeutically-based trials, with only approximately 1.8% granted to rehabilitation-based research.

This study provides both substantive and methodologic information. It suggests that individuals may be able to experience the quality life benefits associated with a transition in their primary means of mobility, without compromising muscle strength and ambulatory ability. From a methodological perspective, the data demonstrate difficulties with recruitment for this type of population and obstacles in the retention of subjects throughout the study. None-the-less, the benefits to be gained from this type of investigation may prove to be very valuable to clinicians and those who are considering a transition to wheeled mobility.

### 3.6.CONCLUSION

There is much work that remains to be done to investigate the consequences of a transition in the primary means of mobility in people with MS, and in people with other chronic, progressive conditions. Along these lines, studies should investigate strategies for improving patient participation in clinical trials such as this. It is the responsibility of investigators to document and try to address barriers to recruitment in this population, as we have done here. This would help to evaluate more efficiently the efficacy of treatment interventions and allow for faster translations of research from the laboratory to the clinic.

This investigation provided preliminary data to test the model we predicted. We believe that many individuals with MS are delaying a transition in their primary means of mobility because of a fear that an increased reliance on wheeled mobility may result in decreased independence and an increased deconditioning. We hypothesized that, while a transition to wheeled mobility may lead to an accelerated rate in the decline of strength and a decreased in ambulatory ability, these effects would be outweighed by an increase in quality of life and participation in daily activities. Even with a modest sample size, we found a tendency that individuals retained functional ambulatory ability as well as muscle strength and endurance, while concomitantly experiencing improvements in psychosocial parameters. Future research should seek to solidify these findings, and relay them to populations such as MS who are often faced with difficult decisions regarding mobility transition. This type of research has the potential to empower individuals by allowing them to make more informed decisions while having a clearer picture of what they can expect after a transition in their primary means of mobility. Researchers should

confront the research design and recruitment difficulties, recognizing the importance of this area of investigation.

### **3.7.ACKNOWLEDGEMENTS**

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### **Suppliers**

Biodex system, Biodex Medical, Shirley, NY

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#### **4. A COMPARISON OF MOBILITY DEVICE DELIVERY WITHIN THE VETERANS ADMINISTRATION FOR INDIVIDUALS WITH MULTIPLE SCLEROSIS AND INDIVIDUALS WITH A SPINAL CORD INJURY**

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#### 4.1.ABSTRACT

**Background:** Individuals with MS generally report a lower level of satisfaction with their mobility device when compared to individuals with SCI. Given the association between mobility and quality of life in this population (Aronson, 1997), this may help to explain the disparity in overall health-perceived quality of life. The purpose of this study was to: 1.) investigate the demographic differences between individuals with MS who are issued a wheelchair through the Veterans Health Administration (VHA) and 2.) describe the differences in wheeled mobility prescription within the VA for these two populations. **Methods:** The VHA National Patient Care Database and the National Prosthetics Patient Database were merged to obtain demographic and wheelchair distribution information for all veterans with SCI and MS in 2000 and 2001. **Results:** 7076 veterans with SCI or MS received wheelchairs in the three years investigated, 2154 of which had descriptive information about the type of wheelchair issued. Of these 2154 entries, we found that individuals with MS were less likely to receive the higher quality (based on weight and adjustability) wheelchairs (manual or power) when compared to individuals with SCI. **Discussion/ Conclusions:** The disparity in wheelchair prescription within the VA for these two populations may help explain the reported differences in AT satisfaction.

Key Words: Wheelchairs, Multiple Sclerosis, Spinal Cord Injury, Assistive Technology

## 4.2.INTRODUCTION

Approximately 13.1 million people use assistive devices in the US (LaPlante, 1992) for mobility, communication, and assistance with activities of daily living. According to the US Technology-Related Assistance of Individuals with Disabilities Act of 1988, Assistive Technology is defined as “any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities” (USGov, 1998). While technological advancements have allowed for a much more sophisticated array of assistive devices available, the effectiveness of the technology is only as good as the fit between the user and the technology to achieve the desired goal (Scherer, 1998). The match between the person and the technology is dependent on the specific needs of the individual, based on functional limitations and disability, and the ability of the technology to compensate for these needs.

Despite the increasing number of people using AT, and consequently, an increased need for appropriate matches between the user and the technology, there have been remarkably few studies investigating the process by which AT are issued to consumers. With this in mind, the Veterans Health Administration (VHA) began tracking AT issued to all veterans, and making this database available to researchers. The National Prosthetics Patient Database (NPPD) consists of all the orthotic, prosthetic and sensory devices distributed to veterans across the United States, including the first time the device was issued, any repairs and replacements. This database was started in October of 1997, and became available to the research community in

October, 2000 (Downs, 2000). This database provides valuable information regarding the distribution of assistive technology to veterans with a wide variety of diagnosis.

According to SCI-Info-Pages (2005), there are 11,000 spinal cord injuries (SCI) each year in the US. One study of 14 men and women with a newly acquired spinal cord injury (SCI) asked the subjects to rate their satisfaction with assistive technology one month after discharge from acute rehabilitation (Scherer and Cushman, 2000). This study found that 64.3% of the respondents indicated that they were “Satisfied” with their assistive technology. Cook et al (1981) showed that a majority of individuals with SCI studied 5 years post injury were functioning comparably to uninjured control counterparts in terms of life satisfaction and self-perceived adjustment. Cushman and Hassett (1992) studied 43 people with SCI 10 and 15 years post injury and collected data on subjects’ perceived quality of life. They found that most subjects saw their life as comparable to, or somewhat better than that of age matched peers. Siosteen et al (1990) concluded that people with adequate resources had lives as fulfilling as those of a matched group of non-disabled persons. Again, however, these findings are diagnosis specific. As the diagnosis and symptom presentation becomes more complex and unpredictable, such as is the case in multiple sclerosis (MS), it is likely that satisfaction of the user with the technology is more difficult to achieve.

There is a large body of literature that focuses specifically on various aspects of quality of life in people with MS. One study by Nortvedt and colleagues (1999) demonstrated that people with MS had markedly lower scores on all quality of life dimensions when compared to the general population. Moreso, Lankhorst et al (1996) revealed a substantial deterioration of quality of life

measures in individuals with MS when compared to other patients with chronic illnesses. Correlates for a decreased quality of life in this population exist in the areas of fatigue, physical disability, neurological impairment, depression, and anxiety, to name a few (Merkelbach et al, 2002; Janardhan, & Bakshi 2000; Fruehwald et al 2001).

One correlation of particular interest has been seen between quality of life and mobility (Aronson, 1997; Everts and Karnilowski, 1996). It has been reported that 85% of the patients with MS reported gait and motor disturbances as their chief complaint (Baum & Rothschild, 1983). One out of two persons with MS will require the assistance of another person for everyday mobility (Baum & Rothschild, 1983). Among individuals with MS, 4% use crutches, 12% use walkers or canes, and 40% use a wheelchair (Baum and Rothschild, 1983). Of the individuals with MS who use a mobility device, it has been shown that 61% use a manual wheelchair, and only 8.2% used a power wheelchair (Finlayson et al, 2001). However, because the database used in this study involved people in Canada with MS, which has a different system of healthcare and AT reimbursement, it cannot necessarily be generalized to the US. Another study by Perks et al, reported that 59% of individuals in Scotland with MS state their current wheelchair does not meet their mobility needs (Perks et al, 1997). Wheeler and colleagues found that, when compared to other wheelchair users, individuals with MS are particularly skeptical, critical, and questioning about explanations given by health care providers regarding mobility selection (Wheeler et al, 1996).

It is evident that the satisfaction of assistive devices by individuals with MS is very different than the satisfaction with assistive devices by individuals with SCI. Although these two diagnoses are



very different, and symptom presentation may vary greatly between the two, once the decision to transition to a wheeled mobility device is made, all individuals are equally entitled to a wheelchair that will best meet their needs. Based on clinical observation, we hypothesize that too many individuals with MS are using low-grade depot-style wheelchairs as their primary means of mobility. This is particularly disturbing considering that depot wheelchairs are intended for temporary use only (for example, during a rehabilitation hospital stay)(Cooper 1995), and have been shown to have markedly decreased half-lives, when compared to lightweight and ultralight wheelchairs (Fitzgerald et al, 2001).

The first specific aim of this study was to characterize the demographic characteristics of individuals with MS and individuals with SCI who received a wheeled mobility device as represented in the VA NPPD. The second specific aim was to compare the wheeled mobility devices issued to individuals with MS and individuals with SCI. Specifically, we investigated the differences in the types of manual and power wheelchairs and scooters issued to these groups of veterans. “Developing an understanding of what assistive devices these persons [with MS] possess, and what factors predict this possession may assist occupational therapists in thinking critically about how they work with this population and what service gaps may exist.”(Finlayson et al, 2001).

## 4.3.METHODS

### *4.3.1. Study Design*

This study used a retrospective design to analyze two combined years of data, 2000 and 2001, from two different Veterans Health Administration (VHA) databases, the National Patient Care Database (NPCD) and the National Prosthetic Patient Database (NPPD). These databases were merged to create a unique database with unique identifiers. That is, individuals were included into the system only once, even if they received more than one wheelchair over the course of the two years investigated. The NPCD was used to obtain demographic information for individuals, including date of birth, gender, race, and primary diagnosis. The NPPD is a database that holds a record of the assistive devices issued to veterans. For this study, we investigated NPPD information on the type of wheelchair issued and on the “create date” (see Table 16 for operational definitions of variables.) Prior to obtaining the databases, an honest broker linked the two databases while maintaining patient confidentiality, as per the Health Insurance Portability and Accountability Act of 1996 (HIPPA) regulations. In linking the data between the two databases, data sets were de-identified and patient IDs were scrambled. A SAS statistical package was used to extract only those variables investigated from the original databases, and a new database, containing only information from veterans with MS or veterans with SCI, was created. This study was approved by the VA Pittsburgh Healthcare System Institutional Review Board.

**Table 16.** Operational definitions of variables

<b>Variable</b>	<b>Definition</b>
<i>Age</i>	Age on the day that the wheelchair was ordered and put into the system
<i>Race</i>	According to six NPCD race categories: Hispanic Black, Hispanic White, American Indian, African American, Asian, and Caucasian, and a seventh category for “unknown.”
<i>Gender</i>	Male/ Female
<i>Type of Wheelchair</i>	Based on K-codes of medicare system for classification- See Table 2
<i>Create Date</i>	Date that the wheelchair was ordered
<i>Diagnosis</i>	Primary diagnosis related to wheelchair use based on ICD-9 coding

#### **4.3.2. Data cleaning**

The process for cleaning the data of the merged database is described in Hubbard, S (Hubbard S, 2004). Briefly, the number of entries for each variable was based on the total number of entries minus missing values for that variable. Age was calculated as the time in years between the *create date* and the *birthdate*. If more than one diagnosis was recorded for a veteran, the diagnosis most likely to contribute to the use of a wheelchair was considered the primary diagnosis. From these, all individuals with MS or a SCI were included in the dataset. If a veteran had both a SCI and an MS diagnosis, they were grouped into the individuals with MS, since MS may be considered a type of spinal cord injury. Individuals with SCI were identified if they were issued an ICD-9 code indicating a specific diagnosis with a SCI level, such as “C1-C2 spinal cord injury.” Both individuals with tetraplegic and paraplegic SCI were included in the SCI group.

For type of wheelchair, authors used a new ranking system of eight wheelchair classes in order to simplify the medicare K-codes (HCFA Common Procedure Coding System (HCPCS). Available at: <http://www.hcfa.gov/medicare/hcpcs.hmt>) used to describe type of wheelchair issued taken

from Hubbard (2004). The new ranking system was based on wheelchair function, weight, and adjustability. Table 17 describes the grouping used to classify each of the wheelchair types. If the same individual received a wheelchair in 2000 and/or 2001, only the wheelchair for the first year was used, in order to have a dataset comprised of unique entries.

**Table 17.** Wheelchair classifications

<b>Code</b>	<b>Type of Wheelchair</b>	<b>Description</b>
K0001= manual wc- depot	M1 (1)	>36 lbs, non-adjustable; “depot” wheelchair
K0002= manual wc- hemiplegia		>36 lbs, non-adjustable, lower seat only; depot wheelchair
K0003= manual wc lightweight		<=36 lbs, non-adjustable; lightweight, depot wheelchair
K004= manual wc lightweight	M2 (2)	<34 lbs, adjustable seat/back height, some adjustment in axle; high strength, lightweight; rehabilitation wheelchair
K0005= manual wc ultralight	M3 (3)	<30 lbs., adjustable seat/back height/axle/camber; ultralight wheelchair
K0010= power wc	P1 (5)	Non-adjustable, seat height only, standard weight non-programmable controls
K0011= power wc	P2 (6)	Miscellaneous power wheelchairs
K0014= power wc	P3 (7)	Custom power wheelchairs, other motorized wheelchair base
E1230= scooter	S1 (8)	scooter

### ***4.3.3. Statistical Analysis***

#### **4.3.3.1. Specific Aim 1: Demographic characteristics**

Descriptive statistics were used to compare demographic information between the two groups, including the number of entries per diagnosis. Means +/- standard deviations were used to describe the age of each group, and frequency counts were used to describe gender and race/ethnicity. All variables were tested for normal distribution. An independent samples t-test was used to compare the ages of the two groups.

In order to increase the power of our analysis, we compressed the race variable into two general groups, white and minority (Hispanic Black, Hispanic White, American Indian, Black, Asian and unknown). A Chi-Squared analysis was used to compare the distribution of races among the two groups.

#### **4.3.3.2. Specific Aim 2: Comparison of devices**

Frequency counts were used to describe the number of manual wheelchairs, power wheelchairs, and scooters issued to each group over both years. Frequency counts were also used to describe the types of manual wheelchairs, power wheelchairs, or scooters issued.

To investigate whether there is a significant difference in the type of wheelchair, manual, power, or scooter, issued to veterans with MS and veterans with a SCI, we used a one-way Chi-Squared analysis. Groups were considered significantly different at  $p < 0.001$ . This p-value was selected as an indicator of significant difference between the comparison groups since the sample size for this study was large. With a large sample size, there is an increased likelihood to observe

statistically, but not clinically significant differences. We attempted to minimize this by using a strict cut-off point for significance.

#### **4.4.RESULTS**

According to our database, a total of 7,076 veterans with either a SCI or MS received wheelchairs between 2000 and 2001; however, because of missing data, we were only able to evaluate the types of wheelchairs issued to 2154 veterans. The remaining 4922 veterans received wheelchairs, but we did not have enough information on the type of wheelchair they received to include them in the analysis. Statistical analysis comparing race, gender, age and diagnosis of the individuals with incomplete information versus the entries used in our analysis revealed there was no significant difference between the two groups.

##### ***4.4.1. Specific Aim 1: Demographic characteristics***

There was no significant difference between the group of data entries that were eliminated from the analysis because they did not have a classifiable wheelchair and the group that we analyzed. Of veterans considered, there were a total of 791 veterans with SCI, 90 of which had tetraplegia due to SCI. There were 1363 veterans with MS.

#### 4.4.1.1. Age

Ages for all veterans included in our analysis who received wheelchairs in 2000 and 2001 ranged between 20.6 years and 100.2 years, with a mean age of 54.4 +/- 12.8 (Table 18). An independent samples t-test indicated that there was a significant difference (p=0.000) between the ages of the SCI group and the MS group.

#### 4.4.1.2. Gender

Males made up 92.3% of all individuals with either MS or SCI who received a classifiable wheelchair. For each of the two groups, males also represented the majority of individuals who received wheelchairs (Table 18).

**Table 18** Age distribution for the two comparison groups, SCI and MS

<b>Group</b>	<b>Age Mean +/- SD</b>	<b>Gender % Male</b>
<b>SCI (n= 791)</b>	52.8 +/- 14.0	98.0
<b>MS (n=1363)</b>	55.3 +/- 12.0	88.9

#### 4.4.1.3. Race

White veterans made up 67.9% of veterans with SCI and 85% of veterans with MS. There was a significant difference (p=0.000) in the race distributions of whites and minorities between the two diagnoses.

**4.4.2. Specific Aim 2: Comparison of devices**

Individuals with a SCI received approximately the same number of manual wheelchairs as power wheelchairs (49.8% and 43.7%, respectively) (Table 19). Scooters were the least frequently prescribed mobility device at only 6.4% of all devices issued to veterans with a SCI (Table 19). For veterans with MS, manual wheelchairs were the most commonly issued mobility device (44.7%), followed by power wheelchairs (33.7%), and finally scooters (21.6%). A one-way Chi Squared analysis revealed there was a significant difference for each of the frequencies of manual wheelchairs, power wheelchairs and scooters issued to veterans according to diagnosis.

**Table 19** Compares the percentage of manual wheelchairs, power wheelchairs and scooters issued among the two groups

Group	Number Manual Wheelchairs		Number Power Wheelchairs		Number Scooters		Total number wheelchairs
	N	%	N	%	N	%	
SCI	394	<b>49.8</b>	346	<b>43.7</b>	51	<b>6.4</b>	791
MS	609	<b>44.7</b>	460	<b>33.7</b>	294	<b>21.6</b>	1363
<b>Total</b>	1003	<b>46.6</b>	806	<b>37.4</b>	345	<b>16.0</b>	2154

*Note: Percentages given as percent of total number of wheelchairs prescribed for each diagnosis. \* denotes statistical significance at  $p < 0.05$*

When comparing the type of manual wheelchair issued, ultralight wheelchairs were the most common type of wheelchair issued to individuals with a SCI (Table 20). For this same group, a depot wheelchair was the least frequently prescribed type of manual wheelchair. On the other hand, ultralight wheelchairs were the least frequently prescribed wheelchairs to individuals with MS, with only 14.0% of all wheelchairs issued being ultralight. Individuals with MS were more



likely to receive a lightweight wheelchair or a depot wheelchair. In fact, 39.2 individuals with MS who received manual wheelchairs were issued depot chairs.

**Table 20** Distribution of four classes of manual wheelchairs issued to SCI and MS groups

<b>Type Manual Wheelchair</b>	<b>SCI</b>		<b>MS</b>	
	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
<b>M1</b>	101	<b>25.6</b>	239	<b>39.2</b>
<b>M2</b>	126	<b>32.0</b>	285	<b>46.8</b>
<b>M3</b>	167	<b>42.4</b>	85	<b>14.0</b>

*Note: Percentages given as percent of total number of manual wheelchairs issued for each diagnosis*

For individuals in the MS group, scooters were the most common type of powered mobility device prescribed (Table 21). For individuals in the SCI group, however, a customized power wheelchair was the most common type of powered mobility issued. On the other hand, only 15.5% of the individuals with MS were issued a customized power wheelchair.

**Table 21.** Compares the distribution of powered mobility in the two groups

<b>Type Powered Mobility</b>	<b>SCI</b>		<b>MS</b>	
	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
<b>S1</b>	51	<b>12.8</b>	294	<b>39.0</b>
<b>P1</b>	126	<b>31.7</b>	189	<b>25.1</b>
<b>P2</b>	76	<b>19.1</b>	154	<b>20.4</b>
<b>P3</b>	144	<b>36.3</b>	117	<b>15.5</b>

*Note: Percentages given as percent of total number of powered mobility issued to individuals for each diagnosis.*

## 4.5.DISCUSSION

To the best of our knowledge, this is the first study to compare assistive technology prescription between individuals with MS and individuals with SCI. This is an important area of investigation, given the satisfaction with AT between these two groups is so different (Cook et al, 1981; Scherer and Cushman, 2000; Perks et al, 1997). For an individual with mobility impairments, AT can greatly affect their ability to participate in activities of daily living, and ultimately their quality of life. A better understanding of the AT distribution and prescription may provide valuable insight as to why quality of life scores are so different between individuals with MS and individuals with SCI.

### *4.5.1. Specific Aim 1: Demographic characteristics*

Based on the fact that there were no significant differences in the demographic characteristics of the group of data entries that were eliminated from the analysis and those included in the analysis, it is likely there was no selection bias based on data entry.

According to Hubbard (2004), the average veteran receiving a wheelchair from the VA is a white, 69 year old male with chronic obstructive pulmonary disorder/ congestive heart failure (COPD/CHF). Individuals with MS and SCI made up 3-4% and 6-8% of the total population of veterans receiving wheelchairs in the database, respectively (Hubbard, 2004). According to our study, the average age of individuals with MS and SCI was statistically significantly different. However, because the difference in the mean ages and standard deviations was not more than

three years, this difference is not clinically significant. Furthermore, there was no clinically significant difference in the mean ages of our samples and that of the general population of veterans receiving wheelchairs, which is approximately 55-56 years old (Hubbard, 2004). The average age of an individual with a SCI is 31 years old and the average age of diagnosis of MS is 37 years old.

Our gender distributions are consistent with the overall distribution of US veterans, since the majority (95.2%) is male ([http://www.cacvso.org/641,4,Slide 4](http://www.cacvso.org/641,4,Slide%204)). Among the general population, the ratio of males to females with SCI is 4:1 (<http://www.emedicine.com/pmr/topic182.htm> ). However, in the general population, female individuals with MS outnumber male individuals with MS by 2.6:1 ([http://health.yahoo.com/health/ceters/women/\\_19238199.html](http://health.yahoo.com/health/ceters/women/_19238199.html)). This may help explain why males with MS made up approximately 10% less of the population when compared to males with SCI.

#### ***4.5.2. Specific Aim 2: Comparison of devices***

Chi Squared analysis revealed that there was a significant difference in the general types of wheeled mobility (manual wheelchairs, power wheelchairs and scooters) issued to individuals in the two groups. While there was approximately equal number of manual and power wheelchairs issued to individuals with a SCI, manual wheelchairs were the most common category of wheeled mobility issued to individuals with MS. A recent study conducted in our laboratory investigated the efficacy of manual wheelchair propulsion in individuals with MS (n=15) who use a manual wheelchair as their primary means of mobility (Fay et al, 2004). This study found that individuals with MS were unable to maintain a functional speed of wheelchair propulsion

when compared to control counterparts. Kinetic analysis revealed that with each propulsive stroke of the wheelchair, individuals with MS imparted a force in the opposite direction of forward propulsion, essentially working against themselves every time they pushed the chair. This would lead to increased energy expenditure during wheelchair propulsion. This is especially significant in this population, for whom fatigue is a major limiting factor (Krupp et al, 1988). It is therefore possible that many individuals with MS are being issued manual wheelchairs, even though it is not a functional means of mobility. This study is limited by the fact that the database provides no information regarding disease progression for the individuals with MS. It is a well-known fact that symptom presentation, and consequently, mobility limitations are extremely varied among different individuals with multiple sclerosis. Furthermore, this study is limited by the fact that it only considers two years of data. Future studies should compare the differences in mobility device prescription between the two groups over an extended period of time.

When we considered the individual types of manual wheelchairs, individuals with SCI were most likely to receive an ultralight wheelchair. On the other hand, only 14% of individuals with MS who were issued a manual wheelchair received an ultralight chair. Research has shown that ultralight wheelchairs are the best quality of wheelchair in terms of cost effectiveness and strain on the upper extremity of the user. Specifically, although ultralight wheelchairs are the most expensive type of manual wheelchairs, they have been shown to have higher number of wheelchair propulsion cycles per dollar than either depot or lightweight chairs (Fitzgerald et al, 2001), and last 13.2 times longer than depot wheelchairs (Cooper et al, 1996). Furthermore, ultralight and lightweight wheelchairs tend to experience repairable component failures, as

compared to depot wheelchairs, which tend to experience frame failures (Cooper et al, 1996). These wheelchairs also offer the adjustability needed to minimize the risk for upper extremity injury in individuals who rely on a manual wheelchair as their primary means of mobility. Boninger et al, (2002) showed that optimal horizontal and vertical positioning of the wheelchair axle decreases the forces imposed on the upper extremities during wheelchair propulsion. Therefore, the dichotomy in the types of manual wheelchairs issued to individuals with SCI and individuals with MS is important. It is possible that individuals with MS are issued a poorer quality (heavier and less adjustable) of manual wheelchair because clinicians anticipate the progression of this dynamic disease. Clinicians may view the use of a manual wheelchair as an intermediate step in the progression to an increased reliance on AT for mobility. With this in mind, it is not surprising that a majority of individuals with MS state that their manual wheelchair does not meet their mobility needs (Perks et al, 1997). It is also possible that, since many individuals obtain prescriptions for a manual wheelchair as a means to alleviate some of the daily fatigue, they don't use the wheelchair as their primary means of mobility, and are therefore issued a lower quality of wheelchair. Ironically, this may lead to an increase in the fatigue symptoms they are attempting to overcome, since depot and lightweight chairs are heavier than ultralight chairs, and therefore, would require an increased effort and energy expenditure.

Our results revealed that individuals with MS are also less likely than individuals with SCI to receive a better quality of power wheelchair. While individuals with SCI were most likely to receive a customized power wheelchair, individuals with MS were most likely to receive a scooter. It can be argued that scooters are perceived as less of a symbol of disability when

compared to standard power wheelchairs. Because of the unpredictable course of MS, it may be more difficult for individuals with MS to accept their increased reliance on AT for daily mobility. They may view transitioning as a sign of ‘giving up’. A scooter may offer a means to alleviate fatigue symptoms resulting from ambulation, without the self-perception of increased disability. The psychosocial impact of accepting a transition in the primary means of mobility, particularly in individuals with MS, may provide very useful information for the wheelchair selection process.

This study is limited by the fact that the NPPD does not provide information about the individual’s physical capabilities or functional impairments, therefore making it difficult to appraise the efficacy of device prescription in these populations. In the general population, fifty-two percent of individuals with a spinal cord injury (SCI) are considered paraplegic and 47% quadriplegic (<http://www.sci-info-pages.com/facts.html>). However, in the NPPD database for 2000 and 2001, once all the missing data were filtered, only 90 individuals with tetraplegic SCI remained in the analysis, indicating that we likely did not capture all veterans with tetraplegic SCI. It is possible that clinicians coded veterans with tetraplegic SCI as another primary diagnosis besides definitive SCI, such as “quadriplegia or quadriparesis”. This diagnosis was not included into the analysis, since it is possible that quadriplegia resulted from another pathology besides traumatic SCI, like MS. Along these lines, it is more likely that tetraplegic SCI is accompanied with other secondary diagnosis, such as respiratory problems, which may have been used as the primary diagnosis for the clinician imputing the patient information. Therefore, there may be some discrepancies in the classification of SCI when clinicians are inputting the primary diagnosis into the database. The under-representation of veterans with tetraplegic SCI is

likely to have led to an underestimate of the number of power wheelchairs that were issued to veterans with SCI. This would further widen the gap between the general types of wheeled mobility device (manual wheelchair, power wheelchair or scooter) issued to veterans with the two diagnosis. This study reveals that there exists a need for future reliability studies in ICD-9 coding as it relates to wheelchair prescription within the VA.

Finally, these results are specific to a veteran population with SCI and MS, and, because of differences in funding policies and patient demographics, are not generalizable to the general SCI and MS populations. A previous study has shown that individuals who have public insurance, such as Medicare and Medicaid, receive a lower quality of wheelchair when compared to individuals who have private insurance (Hunt et al, 2004). The type of insurance confounder was removed from this study since all veterans received their assistive technology from the VHA. However, it is likely that veterans receive a higher overall quality of wheelchair than individuals in the general population, especially those with public insurance, because of the increased purchase flexibility of the VA. This is not the case when comparing the type of wheelchairs issued among veterans within the VA system, and individuals receiving their wheelchair from a Model Spinal Cord Injury Systems (MSCIS). According to Hunt et al, (2004), 97% of all the manual wheelchairs issued were ultralight.

Along these lines, the quality of wheelchair issued is dependent on the facility in which the individual is being issued their new device. Ideally, a wheelchair will be prescribed by a team of the consumer and rehabilitation professionals working together, such as would be found in an MSCIS setting (Hunt et al, 2004). Such rehabilitation professionals include a physiatrist, a

physical or occupational therapist, and a rehabilitation engineer/ assistive technology specialist. Because of the acute nature of a SCI, individuals are more likely to receive a prescription for their new mobility device through a team as described. On the other hand, because MS is a chronic, progressive disease, symptoms often have a slow onset, and, because of this, individuals may not have the same access to assistive technology specialists for their wheelchair prescription. None-the-less, the benefits to be gained through the use of the most appropriate wheeled mobility apply to all individuals, regardless of disability.

#### **4.6.CONCLUSIONS**

Our study reveals that there is a disparity in the types of wheelchairs distributed to veterans with a SCI and MS. Individuals with MS are less likely to receive ultralight wheelchairs when they are issued a manual wheelchair, and, when considering powered mobility, they are less likely to receive programmable, customizable power wheelchairs. Instead, individuals with MS are most likely to receive a scooter.

Based on these findings, effective solutions for optimizing the provision of AT devices among veterans with MS should be further investigated. Future studies should seek to identify standards of care for issuing mobility devices to this population of individuals, with a complicated and unpredictable clinical course.



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**5. Proposal of: THE EFFECT OF EARLY MOBILITY DEVICE INTERVENTION ON QUALITY OF LIFE AND PARTICIPATION IN INDIVIDUALS WITH MULTIPLE SCLEROSIS: A RANDOMIZED CONTROLLED CLINICAL TRIAL**

**5.1.INTRODUCTION**

We propose that, because of a lack of research in the area of mobility device prescription for individuals with MS, clinicians and wheeled mobility users themselves often have a difficult time knowing if and when is the best time to switch to a new mobility device. Furthermore, when the decision to switch has been made, mobility device selection is difficult. Currently published evidence supporting the importance of research in the area of mobility device delivery for individuals with multiple sclerosis has been cited throughout this document.

Through a series of 3 studies considering: 1. the characteristics of ambulatory individuals with MS who are about to transition to a new form of wheeled mobility, 2. muscle strength, muscle fatigue and quality of life changes that accompany a transition in primary means of mobility for individuals with MS and 3. the type of wheeled mobility devices commonly issued to veterans with MS, we have demonstrated that individuals with MS are already ambulating at non-functional ambulation speeds, demonstrating sedentary levels of physical activity, and have compromised levels of quality of life and participation in daily activities at the time that they decide to transition to wheeled mobility. We also found in a pilot study that the expected

declines in strength and muscle fatigue may not necessarily occur after this transition. Finally, once a transition to an increased reliance on mobility device is made, veterans with MS seem to receive an inferior quality wheelchair when compared to veterans with a spinal cord injury. Taken together, we hypothesize that if a transition to wheeled mobility is made at an earlier stage in their disease progression, and if the wheelchair issued is prescribed to specifically match the needs of the user, individuals with MS will experience an improvement quality of life and participation.

### **5.2. Work Completed to Date/ Continuing Work**

In order to provide more conclusive preliminary evidence of a need for an earlier transition in persons with MS, the two projects entitled “Correlates of ambulatory ability in persons with multiple sclerosis who are about to transition to a new primary means of mobility” and “Preliminary evidence of a need for an earlier transition in ambulatory individuals with multiple sclerosis: a methodological report” will be continued with protocol changes. The protocol changes will be geared to address recruitment difficulties encountered, and to implement recommendations for improving chances for increased subject participation.

The overall study design will follow that described in the methodological report, and testing will take place over 3 visits (V1-V3). Participants will continue to be recruited through the Center for Assistive Technology (CAT) of the University of Pittsburgh. A project co-investigator will approach clients of the CAT who have demonstrated an interest in participating in research studies. The co-investigator will explain the testing procedure, and will consent the client, if they agree to participation. As described in chapter 3, all individuals with a chronic, progressive



disorder (including all those diagnoses leading to a decline in mobility status, and excluding those resulting from cardiac conditions, orthopedic, or other conditions which would preclude strength testing) who have a referral for a new form of wheeled mobility will be included. Even though we will no longer include the strength-testing portion of the protocol with the extension of this study, we will include the individuals with the same inclusion and exclusion criteria, so that the data can be pooled. Transitions considered will include ambulation to manual wheelchair, ambulation to power wheelchair/ scooter, or manual wheelchair to power wheelchair/scooter. In addition, individuals transitioning from ambulation to the use of a power assist wheelchair or from a manual wheelchair to a power assist wheelchair will be included. We have decided to include this type of mobility device transition since clinical observation has revealed that individuals with MS with mobility impairments are increasingly transitioning to the use of power-assisted wheelchairs as their new primary means of mobility. Other inclusion/exclusion criteria as previously described will remain the same.

V1 testing will take place either at the CAT, on the same day of wheelchair prescription, or at the participant's home, within two weeks of wheeled mobility prescription. V2 testing will take place either at the CAT, on the day of wheelchair delivery, or again, at the participant's home, within two weeks of device delivery. Finally, V3 testing will take place at the participant's home, at a time interval equal to that between V1 and V2, +/- 2 weeks.

The testing protocol will be shortened so that it may easily be conducted at the CAT or at the participant's home. Therefore, the protocol will consist of functional testing, questionnaires and mobility monitoring. All testing should take approximately one hour.

Functional testing will include the fast trial timed 8-meter walk test and the normal walking speed 8-meter walk test. The functional wheelchair propulsion trial will be eliminated from the protocol since it will be difficult to conduct in many subjects' homes. If the subject does not have an area of the home in which they will be able to safely perform the ambulation testing trials, this portion of the testing will be eliminated. In addition to recording the type of mobility device used to complete the trial, the investigator will record the type of surface in which the trial was completed, and the surface will be the same over the three visits, when possible.

Questionnaires to be completed by the participants will include an intake questionnaire to obtain subject demographics and information about their diagnosis, the SF-36, the CHART and the MFIS. As a part of the intake questionnaire, participants will continue to be asked if they had fallen in the last month, and if so, how many times. In addition, they will be asked to describe what they believe to be the primary reason for their fall(s), if any.

Using a pedometer and a datalogger, both ambulation and wheeled mobility device use will continue to be monitored in the week following research testing.

### **5.3. Randomized Controlled Clinical Trial**

The purpose of this investigation will be to test the effect of an early mobility device intervention in persons with MS on quality of life measures. We hypothesize that a transition to a powered mobility device at a level when functional ambulation is first compromised and when self-

reported fatigue limits daily participation in persons with MS will lead to an increased quality of life.

### ***5.3.1. Study design***

We will recruit 40 subjects in the Pittsburgh area.

### ***5.3.2. Inclusion Criteria***

- MS as diagnosed by the McDonald criteria (McDonald et al, 2001)
- Individuals who ambulate slower than 0.8 m/sec as determined by the timed 25 foot walk test (T25FW)
- Individuals who do not already have a powered mobility device
- Individuals who score of 12 or below on the Modified Fatigue Impact Scale (MFIS)
- Must have some means of transporting (f.g. wheelchair lift) and disassembling powered mobility device
- Between the ages of 18 and 65 years

### ***5.3.3. Exclusion Criteria***

- MS exacerbation within 3 months prior to visit 1
- Any other diagnosis besides MS that is responsible for a decline in their functional mobility

The T25FW and the MFIS will be used as inclusion criteria since we have previously shown that they relate to average number of daily steps and daily participation, respectively. For the T25FW, 0.8m/sec was used as a cut-off since it has been previously shown that functional walking speed is 1.2m/sec- the time needed to cross a street intersection (Lerner-Frankiel et al,

1986), and this value is expected to decrease by approximately 30-34% with age (Samson et al, 2001). An MFIS score of 12 was used since the mean MFIS score of the individuals who participated in our previous study (Chapter 2) was 13 +/-3. We hypothesize that at the time these individuals were included into the previous study, their fatigue was already at a level that significantly limited their daily participation. Since the EI group will receive a mobility device intervention at a time earlier than would typically occur, and therefore, are likely to be without home and vehicle wheelchair modifications, an inclusion criteria was established that only those individuals with a means of transporting or disassembling their new powered mobility device will be included. This will include having a car or van lift, someone available who is able to help disassemble the wheelchair and put it into the vehicle, and/ or access to public transportation. This will preclude the likelihood that participants do not use their new mobility device based solely on the fact that they do not have a means to functionally use the new wheelchair. In addition, no participant will be included in the study if they have had an MS exacerbation within the last 3 months. This is to minimize non-representative baseline measurements as a result of a recent flare-up in symptoms. Along these lines, if a participant has an exacerbation while included in the study, the exacerbation will be noted in the chart, however, this individual will continue in their participation. If the participant's data appears to be an outlier, exacerbation symptoms will be treated as a confounder.

We will use a randomized controlled clinical trial for this study. Ambulatory individuals with MS will be recruited at the physician's office by a clinical coordinator, who will consent subjects into the study, with their approval. Subjects will be screened for eligibility, and the clinical coordinator will ask them to perform the T25FW and to complete the MFIS. We have

previously shown that the T25FW and the MFIS are quick and easy-to-use surrogate tools that may be used to estimate daily physical activity and participation in persons with MS (Please see Chapter 2). Therefore, we will use these tools as benchmarks for when a transition to the use of a wheeled mobility device may be indicated. Those individuals meeting the inclusion/ exclusion will be randomized into one of two groups, the early mobility intervention group (EMI) and the normal mobility intervention group (NMI). Randomization will be carried out using computer-generated numbers to assign each subject to one of the two groups. Only the clinical coordinator will know to which of the two groups the subject was assigned. The investigators obtaining outcome measurements will not know to which intervention group the subject was assigned.

Individuals randomized into the NMI group will receive a normal standard of care, in which the physician will determine if and when a mobility device is indicated. The EMI intervention group will be referred to an assistive technology specialist to receive a new powered mobility device (Figure 1). All testing will either take place at the Center for Assistive Technology (CAT), or at the participant's home. Participants will complete testing over three visits:

- *Baseline testing* (upon receipt of new wheeled mobility device for EMI participants, and upon inclusion into the study for NMI participants),
- *Visit 2*- two months after baseline testing, and
- *Visit 3*- one year after baseline testing.

Two months was chosen as the time frame for the second visit testing since it will provide information about how well the individuals in the EMI group are adjusting to the use of their new wheelchair. One year was chosen as the time frame for the third visit since it is expected

that individuals will be accustomed to using the new wheeled mobility device, and will have a regular pattern of use.

For each visit, testing will be completed as follows:

1. Functional ambulation
2. Questionnaires
3. Mobility monitoring

#### ***5.3.4. Special Considerations***

Certain considerations will be taken in order to control for external variability that may contribute to measurement error. These are:

- When possible (ie. testing performed at the CAT), room temperature will be constant throughout testing of all subjects (i.e.  $70^{\circ}\text{F} \pm 2^{\circ}\text{F}$ )
- Examinations will be performed at the same time of day for all subjects (between 10AM and 12PM)
- Subjects will be asked to avoid strenuous activity the day of testing

#### ***5.3.5. Outcome Measurements***

##### **5.3.5.1. Functional ambulation**

The timed 25-foot walk (T25FW) will be used as a clinical measure of ambulatory impairment. The T25FW or similar tests have been used in several studies looking at gait impairment in MS (Schwid et al, 1997), and has been shown to provide meaningful information about impairment in this population (Schwid et al, 1997). Subjects will ambulate a straight 25-foot, level surface course as fast as they are able, using whatever type of ambulatory aid they feel is necessary (the

same ambulation aid will be used during each visit). Subjects will be encouraged to walk with the least amount of assistance possible. The type of ambulation aid will be recorded, and will be the same for each visit testing. Subjects will wear a pedometer during this portion of the testing (see mobility monitoring below).

#### **5.3.5.2. Questionnaires**

*Fatigue:* The Modified Fatigue Impact Scale (MFIS) (Fisk, 1994a; Fisk, 1994b) is a shortened version of the 40-item Fatigue Impact Scale (FIS) questionnaire designed to assess the problems in patients' quality of life that they attribute to their symptoms of fatigue. Therefore, it measures fatigue severity more directly than the Fatigue Severity Scale (Krupp, et al, 1989), another commonly studied questionnaire we considered. The FIS has separate subscales in which patients rate the impact of fatigue on physical (10 items), cognitive (10 items), and psychosocial function (20 items). In the initial validation studies, FIS subscales had good internal consistency, and each subscale demonstrated worse fatigue in MS and CFS patients than hypertensive controls (Fisk et al, 1994b). There was no association between FIS and EDSS scores, suggesting that the FIS was measuring fatigue rather than neurologic impairment/disability. A shortened version of the FIS, the MFIS, (eliminating 19 redundant items) has been incorporated into the MS Quality of Life Inventory, recommended for monitoring in clinical and research settings by the Consortium of MS Centers and the National MS Society.

*Quality of Life:* All subjects will assess their quality of life using the SF-36 Health Survey, widely acknowledge as the "Gold Standard" for generic measure of health status (Freeman et al, 2000)(Appendix 4). This survey measures the functional effect of an illness as perceived by the

patient, and is one of the most commonly used measures of quality of life (Nortvedt et al, 1999). *The key variables of the SF-36 to measure change in health-related QoL over time will be those measuring physical components (physical function (PF), social functioning (SF), role physical (RP), bodily pain (BP), general health (GH), and the physical composite score (PCS).* We have shown that, when compared to the general population, these domains tend to be lower in individuals with MS who are about to transition in their primary means of mobility (Chapter 2). The internal consistency, reliability, and validity of this survey as a measure of health status in multiple sclerosis have been confirmed (Freeman et al, 2000; Ware et al, 1993). Furthermore, the SF-36 has been shown to be sensitive to early changes in MS (Canadian Burden of Illness), and was predictive of EDSS scores after one-year (Nortvedt, MW et al, 2000). Therefore, this outcome measure will provide valuable information regarding perceived health status by the subject. However, limitations, such as floor and ceiling effects, as well as poor responsiveness for change, have been demonstrated in individuals with MS (Freeman et al, 2000). For this reason, it has been recommended that this tool be used in conjunction with other measures (Freeman et al, 2000).

*Participation:* The Craig Handicap Assessment and Reporting Technique (CHART) is a 27-question outcome tool used for measuring quality of life in terms of participation in everyday activities as well as in social activities (Whiteneck et al, 1992). *The key variables of the CHART to be considered are the mobility and the occupation summary scores.* These summary scores will be used to measure change in daily participation over time, since, when compared to the general population, these domains measuring physical functioning have been shown to be lower



in individuals with MS who are about to transition in their primary means of mobility (Chapter 2).

*Impact of Assistive Device:* The benefits of an assistive technology device may only be as great as the satisfaction and acceptance of the device by the individual. With this in mind, the Psychosocial Impact of Assistive Device Scale (PIADS)(Day & Jutai, 1996) will be administered to the subjects one week after AT delivery, and then again at T3. The PIADS is designed to measure the impact of the assistive device within three domains including: competence, adaptability, and self-esteem (Appendix 6). The reliability coefficient and the split-half reliability of the PIADS are high (Cronbach's alpha= .95 and Guttman split-half= .89, respectively)(Day and Jutai, 1996). An extra question will be added asking subjects to estimate average daily use (in hours) of the newly acquired mobility device.

#### **5.3.5.3. Mobility Monitoring**

Since we have previously shown that the effect of a transition to the use of wheeled mobility on quality of life seems to be dependent on amount of device use (see Chapter 3), we will monitor the EMI group's ambulation and wheeled mobility device use for one week after each testing session. We will measure the amount of ambulation and mobility device use at each time point. *The key variable for both of these measures will be distance traveled in steps/day and in meters per week, respectively.*

After completing all testing, each subject will be given a pedometer. The subjects will be asked to record the pedometer value each night. The pedometer will provide the distance each subject

walks in a day. Pedometers have been shown to be a valid and cost effective means of monitoring physical activity (Tudor-Locke et al, 2002). Because readings may not always be accurate in people with disabilities (Macko et al, 2002), subjects will wear the pedometer during the T25FW. If inaccurate readings (greater than 10% error) are seen we will ask the subject to repeat the T25FW two additional times and we will create a correction factor to be used when calculating distance traveled for the following week. If needed, this correction factor will be calculated at each visit. Although there may be error in this measure with abnormal gait, this is the most cost effective and least invasive method of determining the amount walked. After one week, the participant will be asked to mail the pedometer to the Human Engineering Research Laboratories (HERL). If the subjects do not wear the pedometer for a day, that day will not be included in the analysis and we will average other days to replace the missing data point and arrive at a total distance traveled.

In addition, we will mount a data logger (Spaeth et al, 2000) on the wheelchair or scooter of the participants in the EMI group, and any wheeled mobility device the participants in the NMI group may receive during their inclusion in the study. The data logger provides total distance traveled in the wheelchair as well as when the distance is traveled. We will phone subjects as described above, and at the end of one week, the subjects will mail the data logger and the pedometer back to HERL.

### **5.3.6. Data analysis**

#### **5.3.6.1. Power Calculations**

Based on means and standard deviations of existing research for the SF-36 (Trefler et al, 2004), and unpublished research completed at our laboratory on changes in social participation as

measured by the CHART, we will have 80% power at an alpha of 0.05 with 20 subjects in each group. We expect to see large increases (change in score by 15 points) in the SF-36 over time.

### ***5.3.7. Threats to the Study***

- Results may be affected by acute exacerbations, changes in pharmacological interventions, or changes in physical activity level during the study period. It is likely these will be randomly distributed among the two groups, such that they do not drastically affect results. During each visit, we will record medications used and ask subjects if they have experienced an MS exacerbation since the last visit (defined as a new or worsening symptom lasting for at least 48 hours in the absence of fever or infectious illness). Any exacerbation will be recorded. Analysis will be performed with and without patients with a change in exacerbation or a change in medication in order to determine whether they significantly alter results.
- There is likely to be variability in daily amount of wheelchair and scooter device usage. This is true both because many of the individuals who participate in the study may not feel they need a new mobility device, and since individuals in the EMI group who receive a powered mobility device will probably not have home and vehicle modifications. We will attempt to control for this by quantifying the average daily usage of the newly acquired mobility device through use of the data logger and a pedometer. If there is a substantial variability between subjects, an ANCOVA will be calculated, using wheeled mobility device distance traveled per day as a covariate. In addition, we will collect information on satisfaction with and acceptance of the device through the PIADS.
- Heterogeneity in the study population may interfere with evaluations. While individuals with MS often present with a wide range of symptoms, increasing between-subject

variability, our ultimate goal is to quantify the effect of early mobility device intervention on quality of life and daily participation. Therefore, we chose to keep the eligibility criteria fairly broad, to observe the full spectrum of changes and provide highly generalizable results.

- Patients assigned to the NMI group may all receive a new wheelchair, and may get their wheelchairs sooner because of participation in the study. Participants will be blinded as to the two different groups, in addition to the evaluator being blinded.

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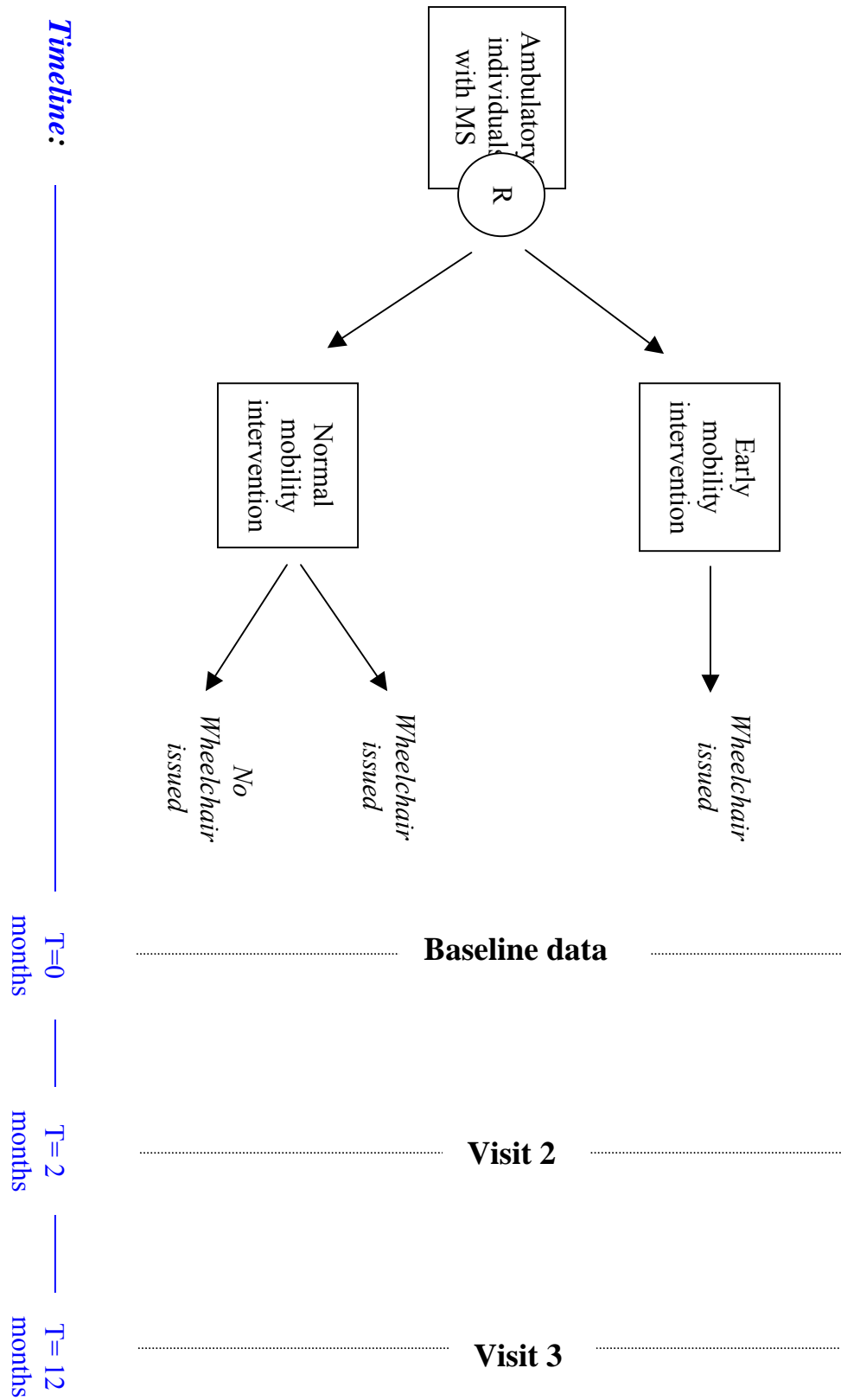
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Figure 11. Project Schematic





## 6. CONCLUSIONS

The Matching Person and Technology Model is composed of three primary components: 1) the technology, 2) the milieu or the environment in which the user will interact with the technology and 3) the technology user him/herself. The effectiveness of the technology is only as good as the fit between the user and the technology to achieve the desired goal (Scherer, 1998). In all too many cases, where these three components don't quite fit, the wheelchair user experiences decreased satisfaction, and may eventually abandon the new chair. Such a "lack of fit" may result from inappropriate technology prescription, poor timing to introduce the intervention, or from the individual being intimidated by certain unknowns involved in acquiring the new device, for example.

Gaps in the adequacy of wheeled mobility device prescription may be attributed to the point of view from which rehabilitation professionals and the users themselves often approach disability. Working from a medicalized perception of disability (The Individual Model of Disability), the cause of the 'problem' is within the individual themselves; a person with a mobility impairment is disabled because they are unable to walk. Therefore, the main purpose of the intervention, in this case, the wheelchair, is to cure the disability, and not to ameliorate social conditions or circumstances. It is inevitable that this will lead to a decreased satisfaction with the assistive technology, since the intervention is not purposed to meet the outcome needs of the user. It is our belief that the wheelchair prescription process for individuals with MS commonly occurs from the Individual Model perspective.

Unlike most individuals with a SCI who report satisfaction with their assistive technologies (Scherer and Cushman, 2000), a majority of the individuals with MS who use a manual wheelchair feel their current wheelchair does not meet their mobility needs (Perks et al, 1997). With this in mind, the association between mobility and quality of life (Aronson et al, 1997) may help explain decreased reported health related quality of life scores between individuals with MS and both the general population (Nortvedt et al, 1999) and those with other chronic disabilities (Lankhorst et al, 1996)

The above findings raise the following questions: Is the decreased satisfaction with AT common to individuals with MS a result of being issued a mobility device of lower quality? Or is it a result of a decreased ability to define when is the best time to transition and what indicators should be used to determine when an individual with MS is in need of a new wheelchair? And finally, is the decreased satisfaction with mobility device use a result of secondary effects of using a wheelchair, such as increased weakness and deconditioning, and consequent decreased functioning? These are all questions we attempted to address in this work. Specifically, we considered the technology (wheelchair), the user, and the interaction between the two.

### **6.1. The Technology**

The first step in our investigation considered the quality of the technology (wheelchair) being issued, and whether a disparity exists in wheelchair types that are issued to veterans with MS and veterans with SCI. We hypothesized that veterans with MS are being issued manual and power wheelchairs that are of a lower quality when compared to veterans with SCI. To test this

hypothesis, we analyzed two consecutive years of data from the Veterans Health Administration National Prosthetics Patient Database (NPPD), which contains information of all orthotic, prosthetic, and sensory devices issued to veterans. From this database, we were able to isolate a group of veterans with MS and a group of veterans with a SCI who had received a wheelchair or scooter in 2000 and 2001. By linking the NPPD with the National Patient Care Database, we were able to obtain demographic information about these two groups of veterans being issued a new mobility device.

We compared 791 veterans with a SCI with 1364 veterans with MS who received a manual wheelchair, a power wheelchair or a scooter. The average age of veterans with MS was 55.3 +/- 12.0 years and the average age of veterans with a SCI was 52.8 +/- 14.0 years. The majority of veterans, both with MS and a SCI, were white males. While, because of our large sample size, there were statistically significant differences in the ages and races of the two groups, these differences were not clinically significant. We did, however, find clinically significant results when comparing the type of mobility devices most commonly issued to veterans from each group.

Overall, veterans with MS were significantly more likely to receive a scooter than veterans with SCI (21.6% and 6.4%, respectively), and less likely to receive a power wheelchair (33.7% and 43.7%, respectively). There was also a statistically significant difference in the types of manual and power wheelchairs issued. Only 14% of veterans with MS were issued ultralight wheelchairs, as compared to 42.4% of veterans with a SCI. Similarly, 15.5% veterans with MS and 36.3% veterans with a SCI received customized, programmable power wheelchairs.

A suboptimal wheelchair may result in a major disturbance in the individual's daily functioning. From our study, we found that the usability and cost-effectiveness of wheelchairs issued to veterans with MS need improvement. The types of manual wheelchairs commonly issued to veterans with MS do not allow them to adjust the set-up, leading to an increased likelihood for upper extremity injury and increased energy expenditure. Similarly, the types of powered mobility commonly issued to veterans with MS do not allow for customizability to meet their individual needs. Taken together, it can be argued that the mobility technology issued is not meeting the intended goal of allowing the individual to most effectively function in their daily environment.

With the medicalization of disability, individuals with SCI demonstrate clinically measurable mobility limitations, where, clearly, assistive technology is a very appropriate intervention. On the other hand, individuals with MS may oftentimes not be considered as "disabled," since standard tests of strength, spasticity, and sensation are not sensitive enough to detect mobility deficits in this population (Ambrosio et al, 2002) Therefore, the need for assistive technology may not be as readily identified until later in the disease progression.

## **6.2. The User**

The purpose of a wheelchair, as is true for any assistive technology device, is to "increase, maintain, or improve functional capabilities of individuals with disabilities." (US Technology-Related Assistance of Individuals with Disabilities Act of 1988). Therefore, the received benefit of the wheelchair is only as effective as the extent to which it meets the needs of the individual

and allows them to better function in their daily environment. The need for mobility aid must be recognized early enough so that participation in activities and quality of life are not compromised. The second project of this study aimed to describe the individual with MS who is about to transition in their primary means of mobility. From this, we hoped to gain preliminary information about clinical indicators that can be used to identify a need for mobility device use.

Specifically, we investigated walking ability and physical activity at home, while collecting information about their self-reported fatigue, participation in daily activities, and quality of life. To do this, we recruited seven individuals with MS who had a prescription for a new mobility device (manual wheelchair, power wheelchair or scooter), but who had not yet received their new device. Each subject completed a timed 25 foot walk test (T25FW), where they were asked to ambulate 25 feet as fast as they were safely able, using whatever ambulation aid they felt was necessary. They were also asked to complete a series of questionnaires including: the Short-Form36 Quality of Life questionnaire (SF-36), the Craig Handicap Assessment Reporting Technique (CHART) to assess their daily participation in activities, and the Modified Fatigue Impact Scale (MFIS). All the above testing took place at the Human Engineering Research Laboratories. At the end of the testing protocol, subjects were given a pedometer to take home, and were asked to wear the pedometer all day, every day for one week, recording the pedometer reading each night before going to bed.

The average time to complete the T25FW was 13.1 +/- 5.0 seconds (0.61m/sec) and they ambulated an average of 2,047 steps/day. The T25FW correlated significantly with the average daily number of steps. Individuals with MS scored considerably lower on all domains of the SF-

36 when compared to the general population, with exception of two domains which measured emotional and mental health. In these two domains, they actually scored higher than published norms. Similarly, for domains of the CHART primarily measuring physical functioning, subjects scored lower than norms published for the general US population, but only slightly lower when considering cognitive functioning. Self-reported fatigue was not correlated with any of the quality of life variables; however, it was significantly negatively correlated with the mobility and the occupational participation scores of the CHART.

Clinical observation reveals that individuals often fear a transition to wheeled mobility because they fear it will lead to increased deconditioning and consequent increased rate of functional decline. However, from these results, we have found that individuals with MS who are waiting to transition to a new primary means of mobility may already be considered sedentary at the time of mobility device prescription. The T25FW may be a quick and easy clinical tool for estimating physical activity in this population. Furthermore, these individuals have generally lower quality of life scores and a decreased participation in daily activities, when compared to the general population. Given the relationship in self-reported fatigue and participation, the MFIS may also be a valuable tool as a clinical indication of when fatigue is beginning to affect an individual's ability to fully engage in everyday life activities.

Issuing a wheelchair only at the point at which the individual is no longer physically capable of independent mobility also works under the Individual Model framework. Under the Individual Model of disability, individuals with MS may oftentimes not be considered "disabled" because standard tests of strength, spasticity, and sensation are not sensitive enough to detect mobility

deficits. Therefore, if they test “normal”, assistive technology is not indicated until later on in their disease progression. On the other hand, for individuals with SCI, who demonstrate clinically measurable mobility limitations, clearly, assistive technology is an obviously appropriate intervention.

This is flawed because, as seen from this study, at the time a need for mobility device intervention is identified, these individuals have already experienced a decrease in daily physical activity, and a consequent decrease in participation in life activities that may be a result of an increase in their self-reported fatigue. Together, this may help explain the decreased quality of life scores seen in this population.

### **6.3. The Technology/ User Interaction**

When considering the general population of individuals with mobility impairments, there is a relatively large body of research that investigates the technology and the user, when considered separately. However, very little research exists that considers the interaction between the two. The purpose of the third and final project of this study was to investigate the effect of mobility device use on strength, fatigue, and quality of life, over time.

Given the difficulties recruiting and retaining individuals with MS for a longitudinal study, this study considered all individuals with chronic disorders as they were transitioning in their primary means of mobility. Any progression to an increased use of assistive technology (manual wheelchair to power wheelchair use, for example) for daily mobility was considered.

Subjects completed testing over three visits. The first occurred at or near the time when they received a prescription for a new wheeled mobility device (V1), the next at the time that they receive their new device (V2), and finally, after they had been using their new device over a time equivalent to the time between V1 and V2 (V3). Eleven individuals completed and were included in the V1 data analysis, six in V2, and three in V3.

For all three visits, ambulatory ability, physical activity, self-reported fatigue, social participation and quality of life were recorded as described in the second project. In addition, the BioDex System 3 was used to test maximal muscle strength and muscle fatigue was measured for the knee extensors, knee flexors, ankle dorsiflexors, hip flexors, elbow flexors and elbow extensors. Electromyography was also performed to assess the muscle fatigue of the knee extensors, ankle dorsiflexors, elbow flexors and elbow extensors.

Even with a modest sample size, we found a tendency that individuals retained functional ambulatory ability as well as muscle strength and endurance, while concomitantly experiencing improvements in psychosocial parameters that seemed to relate to the amount of new mobility device use. Findings such as these may be helpful to individuals who are faced with mobility device intervention decisions, and may help alleviate common fears that an increased reliance on assistive technology will lead to an increased rate of disease progression.

When considering wheelchair prescription, the medical model has failed individuals with MS. These individuals do not demonstrate the classic profile of an individual with mobility disability. Because of this, many individuals wait to transition to assistive mobility only at a point where



they have a compromised participation in everyday activities and decreased levels of physical activity. Furthermore, when the transition occurs, these individuals tend to receive lower end mobility aids when compared to individuals with SCI. From our results, we have no indication if this trend in prescription is due to attitudes and beliefs of the health care provider, or whether from the individual themselves. Clinical observation has shown that individuals with MS do have a tendency to request assistive technology that they view as less stigmatizing and disabling, such as scooters. However, our final study has provided preliminary evidence to refute these misconceptions. We are finding that wheelchair use, instead of being a disabler, facilitates increased quality of life scores, without resulting in significant decreases in ambulation and strength levels.

#### **6.4. Future Work**

Future studies should seek to further investigate other aspects of the Matching Person and Technology Model in individuals with MS, and specifically, the wheelchair prescription process. For example, it has been shown that individuals who live in wheelchair accessible homes tend to use their wheelchair more often (Hoenig et al, 2002). With this in mind, and considering the potential impact of an appropriate environment on the level of satisfaction with assistive technology, investigating the extent to which individuals with MS are receiving appropriate home modifications for optimal use of their wheelchair is important.

Another area that was not within the scope of this investigation, yet bears great influence on the appropriateness of mobility device prescription is the amount of consumer education/ training on the use of a wheelchair or scooter that is provided to individuals with MS. Training and

consumer education regarding wheelchair use is important given the importance of wheelchair propulsion techniques and set-up on the ability to effectively use a wheelchair (Boninger et al, 2000). Therefore, it is important to investigate the amount of training on the proper use of a wheelchair that individuals with MS receive. Because MS is a dynamic, progressive disease, the introduction of a new mobility device may come slowly, and this may be at the expense of proper instruction on how to best use their new device within their environment.

Based on the findings from these studies, it is our belief that individuals with MS would benefit from a consideration of a transition to a wheeled mobility device at an earlier stage in their disease progression, and from a higher quality of wheeled mobility. The T25FW and the MFIS may be useful tools for clinicians to know when a change to wheeled mobility may be indicated. Furthermore, from a methodological perspective, given the difficulties with subject recruitment in this population, investigators should design research protocols that take into consideration barriers such as encountered in these studies. Recommendations include the use of a full-time clinical coordinator to focus on subject recruitment, and a protocol designed to be conducted within the subject's home to minimize the risk of subject testing cancellation.

These studies, taken together, have shown that the Individual Model has failed to identify individuals who could benefit from mobility device. We propose that wheelchair prescription from a Social Model of disability perspective would be able to sooner identify these individuals by a decreased functional mobility, decreased social participation and decreased quality of life scores. The Social Model of disability, unlike the Individual Model, identifies the individual's limitations as society's failure to provide appropriate services and to ensure that individuals with

disabilities are provided with the necessary provisions to integrate into their community. Therefore, a switch to wheelchair prescription, under the Social Model, has the potential to benefit individuals with MS. It is our belief that drawing from a social model, where outcomes, and not physical disabilities, are of key interest would have two effects: 1) increased quality of the wheelchairs prescribed and 2) mobility device prescription when physical activity levels, participation and quality of life first begin to decline.

In Chapter 5, we described our plans to continue with the longitudinal study (Chapter 3), with protocol modifications based on our own recommendations. Furthermore, we outlined a randomized, controlled clinical trial, designed to test our hypothesis that an earlier transition to wheeled mobility in individuals with MS will lead to a decrease rate of decline in quality of life and daily participation. Together, the studies we have conducted, are currently conducting, and plan to conduct, as outlined throughout this thesis, set up a framework for much needed research in the area of mobility device use in individuals with MS. Finally, it is our hope that the results from these studies will be an impetus for continuing research in the area.

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