Usability Study of Ambulatory Gait Analysis Prototypes

by

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Abstract

The goal of this thesis was to explore the usability of on-foot sensors for ambulatory gait analysis. Using a human factors engineering approach, two different ambulatory gait analysis prototypes were assessed in two separate studies. The first study was conducted with student participants in a university setting and the second study was conducted in-situ with neurorehabilitation patients at Bridgepoint Hospital. The usability and patient experience of the prototypes were assessed, and based on these findings a set of recommendations was developed. These issues and recommendations are detailed in this thesis and are expected to inform the design of future iterations of the prototypes.
Acknowledgements

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Many thanks to Dr. Tammy Sieminowski for her support throughout the Bridgepoint Study—without her confidence in the project, the study would not have been possible. Her insights into the inner workings of neurorehabilitation and in-hospital gait analysis were exceedingly helpful as was her assistance in finding participants for the study. Thanks as well to Elizabeth Hanna at Bridgepoint Hospital for her support and help throughout the recruitment and consent process.

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1 Introduction

1.1 Context of this Research

How people walk has been linked to a wide variety of health outcomes. Clinicians and researchers are often interested in detailed measures of human gait that can be used in applications as diverse as evaluation of orthotics, assessment of falls risk, and assessment of recovery from stroke.

Traditionally gait analysis has been carried out in special purpose labs, but it has been too expensive and time consuming to carry out on large numbers of people. A gait study can cost as much as $2,000 for a single patient, the cost of gait laboratory equipment can be as high as $300,000, and studies can be extremely time consuming (Simon, 2004). Thus, there is a need for a more convenient and cost effective method of analyzing gait.

In the past decade accelerometer-based systems have been developed for ambulatory gait analysis outside the lab. These systems have been mostly designed to wear on the foot or ankle although research has also been done on systems attached to other parts of the body. These existing systems pose various usability and human factors related issues. The research reported below aimed to identify key usability issues and design recommendations for shoe-based sensors developed by the Yasumura-Lab at Keio University in Tokyo, Japan and by the Interactive Media Lab at the University of Toronto.
1.2. Introduction

Gait analysis based on shoe-mounted sensors has the potential to revolutionize measurement of health status in a number of areas. Shoe-based sensors have the potential to not only measure gait more accurately and efficiently but to allow it to be measured continuously over time, giving insight into trends.

The research conducted for this thesis explores the usability of shoe mounted accelerometer sensors as a means to measure changes in gait. Through two separate studies, key recommendations and preliminary findings were obtained to inform future research in this area.

The value of a convenient and cost effect gait analysis system can be seen with the following example. Gait has been found to improve during stroke rehabilitation (Goldie, Matyas, & Evans 1996; Buurke et al., 2008). As such, clinicians at Bridgepoint Hospital often use gait analysis when assessing patients. Bridgepoint Hospital is a health care organization that provides neurorehabilitation services that care for patients recovering from a stroke or acquired brain injury in Toronto, Ontario. Patients usually stay from one to six months (T. Sieminowski, personal communication, March 18, 2010).

Currently at Bridgepoint Hospital, Berg Balance Scores and the Community Balance and Mobility Scales are used to measure patients’ balance and gait. These measures are taken at intervals, and trends may be difficult to determine when there are large time intervals present. As well, these tools are not used consistently between physicians or patients (T. Sieminowski, personal communication, March 18, 2010). The use of a non-invasive and inexpensive sensor that quantitatively measures a patient’s
gait and balance may be useful for clinicians in determining a patient's progress during neurorehabilitation. In addition, more frequent updates on a patient’s balance and gait status may help clinicians make decisions regarding additional gait rehabilitation and intervention.

The goal of this thesis is to assess shoe-based gait systems from a user's perspective and to provide design recommendations for the use of these gait systems in a hospital setting.

The research questions this report aims to answer are:

- Is it feasible to use shoe-mounted gait sensors in a clinical setting?
- If feasible, how can ambulatory gait analysis prototypes be used in a clinical setting (with respect to the efficiency and satisfaction aspects of usability)?
- What are appropriate design guidelines for foot-mounted gait analysis sensors?

This thesis report details the methodology and results and findings and how they inform future research and design of shoe-based gait sensor packages.

1.3. Roadmap of the Thesis

Chapter 2 provides a review of relevant research literature concerning gait analysis, systems for gait analysis, and methods of evaluation.

Chapter 3 discusses the study at Keio University. This study, hereafter referred to as the Keio Study, made use of a sensor package developed by a student at the Yasumura-Lab. The sensor package went through various stages of redesign, and a
A preliminary study was conducted using one iteration of the sensor package. This study made use of mimicked gait and varied ground conditions as a fast and efficient way to assess the sensors.

The study at Bridgepoint Hospital, referred to as the Bridgepoint Study in the remainder of this document, is discussed in Chapter 4. This study was conducted using a sensor package developed by a student of the Interactive Media Lab at the University of Toronto. The selection of the sensor package was informed by the results of the Keio Study. The participants of this study were neurorehabilitation patients at Bridgepoint Hospital. Chapter 5 details the findings and recommendations for the Bridgepoint Study. These include the participant reaction and feedback on the design of the sensor packages and recommendations to address usability and patient experience issues encountered during the study.

The thesis document concludes with Chapter 6, which outlines the contributions of this work, provides a summary of the limitations and challenges faced during the two design studies, and discusses future work.
2 Literature Review

This chapter reviews past research concerning gait analysis methods and measures, foot-based sensor packages, and usability engineering in medical product design.

This review also covers traditional gait analysis and new research being conducted in the field of ambulatory gait analysis.

2.1 Traditional Gait Analysis and Measures

Many balance assessment tools have been developed to measure a patient’s gait and balance. Current tools generally fall into three categories:

“(i) Comprehensive medical assessments performed by geriatricians or nurse practitioners in the out patient or nursing home setting
(ii) Nursing fall risk assessments completed in hospital and nursing home settings
(iii) Functional mobility assessments completed by physical therapists or physicians in an outpatient setting.” (Perell, 2001, page M762).

During clinical gait assessment, clinicians study a patient’s gait, and make qualitative and quantitative assessments, including whether or not the gait is normal. These assessments are often unreliable and difficult to compare across visits (Bamberg, Benbasat, Scarborough, Krebs & Paradiso, 2008).
2.1.1 Gait Measures

When assessing gait, many different measures may be taken, these include:

- **Step Length**: The measurement of the distance between the heel strike of one foot and the heel strike of the other foot. It has been shown to decrease with age (Laufer, 2005).

- **Step Width Variability**: A measure of the variability of the distance between the outer edges of the feet during a step. It has been found that subjects with extreme step width variability at a normal walking speed are more likely to have a history of falls (Brach, Berlin, VanSwearingen, Newman, & Studenski, 2005)

- **Single Leg Stance Time**: Measures the ability to stand with a narrowed base of support. Single-leg stance time has been found to decrease significantly during the seventh and eighth decades of life (Wolfson, 2001).

- **Gait Speed**: has been used as a simple measure of gait. It has been shown to decrease with age (Laufer Head, 2006; Krishnamurthy, 2006).

2.1.2 Gait Analysis Tools at Bridgepoint Hospital

The balance assessment tools in use by physicians at Bridgepoint Hospital are detailed below. The three most common assessment tools used by physicians at Bridgepoint Hospital are the Berg Balance Score, Community Balance and Mobility Scale, and Six-Minute Walk. These tools are used to supplement physician assessment of patient progress during neurorehabilitation.

**Berg Balance Score**

The Berg Balance Score is the method used most consistently at Bridgepoint Health (T. Sieminowski, personal communication, March 18, 2010). The Berg Balance Score is
assigned based on fourteen observable balance items (please refer to figure 2.1).
Each item is given a score between 0 and 4, and the fourteen scores are summed to
determine an overall balance score. Scores between 0-20 roughly indicate wheelchair
bound; 21-40 roughly indicates walking with assistance and 41-56 roughly indicates
independent. (Berg, Wood-Dauphinee, Williams, & Gayton, 1989)

Stevenson (2001) found that a 5-7 point change in the Berg Balance score is
necessary to ascertain with 90% certainty that a significant change in balance
performance has occurred in those undergoing cerebrovascular accident
rehabilitation. However, the agreement between the necessary change (in score) and
clinician assessment of change was varied, possibly indicating a lack of
standardization in how clinicians viewed change (Stevenson, 2001).

<table>
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<tr>
<th>Berg Balance Score Balance Items</th>
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<tr>
<td>Sitting unsupported</td>
</tr>
<tr>
<td>Change of position: sit to stand</td>
</tr>
<tr>
<td>Change of position: stand to sit</td>
</tr>
<tr>
<td>Transfers</td>
</tr>
<tr>
<td>Standing unsupported</td>
</tr>
<tr>
<td>Standing with eyes closed</td>
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<tr>
<td>Standing with feet together</td>
</tr>
<tr>
<td>Tandem standing</td>
</tr>
<tr>
<td>Standing on one leg</td>
</tr>
<tr>
<td>Turning trunk (feet fix)</td>
</tr>
<tr>
<td>Retrieving object from floor</td>
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<tr>
<td>Turning 360 degrees</td>
</tr>
<tr>
<td>Stool stepping</td>
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<tr>
<td>Reaching forward while standing</td>
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Figure 2.1 Berg Balance Score balance items. Please refer to the study by Berg et al (1989) for the full
definitions. (Berg et al, 1989, page 308)
Community Balance and Mobility Scale

After patients have achieved a Berg Balance Score above 55-56, clinicians at Bridgepoint Hospital generally begin using the Community Balance and Mobility Scale (CBMS) as a measure of patient balance and gait (T. Sieminowski, personal communication, March 1 2010).

For the CBMS, patients are asked to perform a series of thirteen tasks (please refer to figure 2.2). The tasks varied to allow for the assessment of representative motor skills used within the community. These tasks are done without walking aids (with the exception of descending stairs). For each task, the subject is given a rating between 0 and 5 (5 being the best). (Howe, Inness, Venturini, Williams, & Verrier, 2006).

<table>
<thead>
<tr>
<th>Community Balance and Mobility Scale Items</th>
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<tr>
<td>Unilateral stance</td>
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<tr>
<td>Tandem walking</td>
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<tr>
<td>180 degree tandem pivot</td>
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<tr>
<td>Lateral foot scooting</td>
</tr>
<tr>
<td>Hopping forward</td>
</tr>
<tr>
<td>Crouch and walk</td>
</tr>
<tr>
<td>Lateral dodging</td>
</tr>
<tr>
<td>Walking and looking</td>
</tr>
<tr>
<td>Running with controlled stop</td>
</tr>
<tr>
<td>Forward to backward walking</td>
</tr>
<tr>
<td>Walk, look, and carry</td>
</tr>
<tr>
<td>Step-ups x 1 step</td>
</tr>
</tbody>
</table>

Figure 2.2 Community Balance and Mobility Scale items. Please refer to the study by Howe et al (2006) for the full definitions. (Howe et al, 2006, page 892)

Six Minute Walk

The six-minute walk is another test performed by clinicians at Bridgepoint Hospital.

This test is performed with less consistency than the Berg Balance Score. In this test,
the patient’s distance travelled is measured after a six-minute walk. Low distance indicates a need to search for causes of gait impairment (Enright, 2003).

2.2 Gait Analysis Systems

Physicians have traditionally used gait and posture laboratories to measure gait, but as mentioned previously, use of these labs can be prohibitively expensive. As technology progresses, however, so do the methods for measuring gait. The availability of small sensors that can be worn on the body has led to an increase in wearable gait sensors. These sensors have helped provide more detailed measures of gait and gait disorders (Nutt, Horak, & Bloem, 2011).

A number of gait analysis systems take advantage of emerging sensor technology. A representative sample of gait analysis systems that assess patient gait in a hospital setting are listed and briefly reviewed below. These systems vary widely, from shoe-based systems to floor-based systems.

2.2.1 Laboratory Based Systems

The following systems make use of new technology to collect different quantitative measures relating to gait.

**GAITRite**

Titianova, Mateev, and Tarkka (2004) developed a system called the GAITRite pressure sensor system. This system analyzed pressure footprint data. The GAITRite system made use of a portable walkway with pressure sensitive sensors that measured location of the foot, time of activation and deactivation, and the dynamic pressure of
the foot on the walkway. Measures taken for the study include: peak pressure, peak pressure time, and sectional integration pressure over time. The study found the typical pattern for normal gait peaks at heel strike and push off. Furthermore, the experimenters used the system to determine Functional Ambulation Profile (FAP) scores for the subjects. It was determined that the FAP score was best utilized during unhurried gait studies as a quick, robust measure (Titianova et al., 2004).

The GAITRite system required patients to walk on top of a portable walkway. This limits the tool’s use to be within a hospital or laboratory setting. One goal for on-foot wearable gait sensors is to increase flexibility of use and setting, allowing users to wear the sensors throughout their day and in multiple locales.

**Study of Gait Initiation Using Electromyography, Force Plates and Cameras**

In a study by Henriksson and Hirschfeld (2005), gait initiation was compared between older, physically active subjects and younger subjects. Gait initiation “is a phase of walking during which falls are often provoked” (Henriksson & Hirschfeld, 2005, page 289). Tibialis anterior and lateral gastrocnemius muscles, ground reaction forces and step lengths were analysed. The authors used electromyography to record the muscles, four force plates to measure ground forces, and a two-camera optoelectronic system to measure step length. The study found that older subjects had significantly shorter step lengths, slower reaction time, and used more vertical force in the swing leg than younger subjects. The results of the study suggest that aging “leads to alterations in weight bearing and ankle muscle activation in relation with gait initiation” (Henriksson & Hirschfeld, 2005, page 295).
Intelligent Gait Detection System (AR-SVM)

A study by Lai, Begg, Taylor, & Palaniswami (2008) developed an intelligent gait detection system. The purpose of this system was to identify patients at risk of falls for preventive intervention. Subjects walked on a treadmill while toe clearance data were collected using a motion analysis system for a minimum of 10 minutes. These data were input into the AR-SVM system. The first stage of the system models the variability in the data using an autoregressive model. The coefficients are then labeled as healthy gait or tripping falls gait. In the second stage, a Support Vector Machine (SVM) classifier is used to recognize healthy and tripping gait. After the system was trained with an initial set of pre-classified data, the resulting model could be used to determine the gait type associated with a new set of data. The results of the study showed that the model could detect a subject’s gait patterns in less than a minute. The results also showed that there “exists an inter stride relationship distinguishing those at risk of tripping from the healthy” (Lai et al., 2008, page 1771).

2.2.2 Shoe-Based Systems

While the technological improvements of laboratory based systems are promising, these systems are still less convenient than shoe-based systems that do not require dedicated space. There has been considerable progress in the past decade in shoe-based gait measurement systems.

GaitShoe

The GaitShoe was developed by Bamberg, Benbasat, Scarborough, Krebs and Paradiso (2008), with the first prototype being developed at the MIT Media Lab in 2003. This system uses “three orthogonal accelerometers, three orthogonal
gyroscopes, four force sensors, two bidirectional bend sensors, two dynamic pressure sensors and electric field height sensors” (Bamberg et al., 2008, page 413). The sensors were attached to a shoe for patients to wear. Data analysed included: initial heel-strike and toe-off timing (using force sensors), pitch, velocity and stride length (using accelerometers), and final heel-strike and toe-off timing. GaitShoe was useful in recognizing the difference between healthy gait and the gait of a Parkinson’s disease patient (Bamberg et al., 2008).

The GaitShoe made use of many sensors attached to the shoe. However, the device design required an insole to be added to the shoe, and bands to be worn around the ankle. These additions to the shoe may make it difficult for users to wear their own shoes, and may be time consuming to attach to the shoe. In addition, the GaitShoe costs almost $1000 for a pair of shoe sensors (Bamberg et al., 2008). This cost may be prohibitive for most users.

eShoe

A system called eShoe was developed by Jagos and Oberzaucher (2008). This system was designed to determine a patient’s risk of falling as well as to provide rehabilitative support. The eShoe system measures gait parameters to detect “worsening gait pathologies” (Jagos & Oberzaucher, 2008, page 1302) that may lead to future falls. The eShoe makes use of force sensitive resistors, accelerometers and gyroscopes embedded into the sole of a shoe. The eShoe was designed to be cost effective and useful over long periods of time. (Jagos & Oberzaucher, 2008). There have been no subsequent publications on the eShoe since 2008.
Micro-Electro-Mechanical System (MEMS)

A study by Gafurov, Helkala and Sondrol (2008) used perpendicularly placed accelerometers to measure data in the vertical, backward-forward and sideways directions. The device was attached to the subjects at the ankle. The system worked comparing the gait cycles of users (Gafurov et al., 2008).

The MEMS system used the gait data as a means to identify an individual biometrically. While the study was able to identify between subjects, it did not try to uncover traditional gait parameters that would be helpful in gait analysis.

Study of Dynamic Gait Instability Index Using a Plantar Pressure Measurement System

A study by Biswas, Lemaire and Kofman (2008) used a commercial plantar pressure measurement system to determine a dynamic gait instability index of subjects. Six parameters were used to calculate the index: anterior-posterior motion, medial-lateral motion, maximum lateral position, cell triggering, stride time and double support time. The results of the study showed anterior-posterior motion, medial-lateral motion, maximum lateral position, and cell triggering was the best combination of parameters to differentiate between different gait conditions (Biswas et al., 2008).

While this system showed promise, the F-scan plantar-pressure measurement system used to collect the data may be too cumbersome for practical use in a clinical setting. The system uses insoles that are placed inside the shoe. The insoles are connected to cables that are connected to a data logger strapped to the small of the user’s back (Tekscan, 2012). It may be difficult to attach this to patients for a long period of time.
Although the shoe-based gait measurement systems vary a great deal in form factor and function, all of them require significant changes to the user’s shoe or attachment to the ankle. The changes to the shoe, particularly in-soles, can have an effect on the comfort and flexibility of a user’s shoes. The attachment of hardware to the user’s ankle requires extra effort for users as the equipment is separate from the users’ typical articles of clothing. Furthermore, these systems require either a facilitator to attach the equipment or the user must be taught how to properly attach the equipment.

In spite of the many prototypes developed for ambulatory gait analysis, a gait analysis solution that is cost-effective, minimally invasive and convenient is not yet available.

2.3 Usability Engineering for Healthcare Products

The gait sensor systems reviewed in the preceding sub-section focused on the data and technology used to assess gait. While these are essential components of any medical device design, it is also important to consider the human element. Designing products for use in a healthcare setting poses a unique problem. There are many different users that will interact with healthcare products and the setting of use can be a very stressful and busy environment.

2.3.1 Evaluation Methods

Usability is of great importance in a hospital setting. Evaluation of new systems and technology is essential to ensure that the tool meets the needs of the users and its context of use. Evaluation, if done at early enough in the design cycle, can inform and improve future iterations of the design.
In iterative design, prototypes are built and assessed using representative users (Nielsen, 1993). The results gleaned from these assessments can be used to inform future iterations of the design.

**Usability Testing**

Rosenbaum and Chisnell (2000) recommend that exploratory usability testing be performed at the onset of the evaluation cycle of iterative product design. The goal is to “identify and understand user problems” (Rosenbaum & Chisnell, 2000, page 6-571), and not to collect detailed data. Subsequent testing delves deeper into the usability of the product and assesses whether the problems encountered in the first round of testing have been addressed. Virzi (1992) found that 80% of usability issues can be found with only four or five study participants.

**Usability Testing in Medical Device Design**

Through a series of case studies conducted by Anderson, Wagner, Bessesen, and Williams (2012) it was found that usability testing plays an important role in medical device design. In all cases studied, usability testing yielded important changes and recommendations to designs that would not have been found otherwise. In particular, a case studied found that it is ideal to perform usability testing with patients. These patient usability tests found issues that did not arise when the device was tested with a dummy in place of a patient (Anderson et al., 2012). Thus, usability assessments with actual patients may be needed to collect realistic usability data.
Usability in Context

While usability analysis is traditionally performed in a laboratory setting, research has found that the context of testing has impact on the results of usability studies. A review performed by Trivedi and Khanum (2012) found that both the physical and social context of use were important aspects of usability evaluations. In fact, approximately 80% of the work surveyed indicated an impact from context on the outcome of the study. Furthermore, Rosenbaum and Chisnell (2000), found that “ethnographic research provides critically important information about user communities” (page 6-571).

Based on the literature above, it became clear that usability assessments, especially of medical devices that would be used by patients, require testing to be carried out in context, and with representative end users of the product. Context, in this case, refers to the users of the system, the task, equipment and the environment the device in which the device is being used (ISO, 1998).

2.4 Summary of Literature Review

Gait analysis is an important aspect of the assessment of a patient’s progress during neurorehabilitation. Physicians at Bridgepoint Hospital make use of several established tools for assessing gait. However, these tools are not used consistently across physicians or on a regular basis with most patients. There is a need for a more convenient and less effortful method for measuring gait of patients.

Laboratory systems for gait analysis require dedicated space and dedicated equipment. Current shoe-based systems require significant changes to a user’s current footwear and may be prohibitively expensive. The goal of this thesis was to
explore the usability of a portable method for measuring gait. After carrying out the first round of usability testing in a university environment, a contextual usability testing approach was used where the assessment of gait analysis prototypes was carried out on patients, in a medical setting.
3 Keio University Sensor and Design Study

As part of this research, two design studies were conducted. The original goal was to do a preliminary usability study of the Keio sensor package at Keio University in Japan to collect preliminary gait and usability data prior to conducting another study in Toronto with representative users of the gait system. This section explores the Keio Study and the eventual progression to the IML Study.

Prior to the selection of the Keio sensor package (used in the Keio Study), the Ubisense Real Time Location system was explored as a potential system to be used for gait analysis. The next sub-section outlines this work, and why the Ubisense system was not used for subsequent studies.

3.1 Ubisense Pilot Study

A pilot study was conducted to investigate whether the Ubisense Real Time Location system could be used to measure gait. This system utilises RFID chips and sensors to determine a position in three-dimensional space. Generally used on factory floors, this system can be used to triangulate the position of a piece of equipment or human resource (Ubisense, 2012).

Professor Alex Mihailidis, a professor at the University of Toronto in the Department of Occupational Science and Occupational Therapy, and the Institute of Biomaterials and Biomedical Engineering, installed the Ubisense system for his research group and kindly made the facility available to me for my research. The system was set up in a
room with four sensors, one in each corner of the room. In collaboration with Professor Mihailidis and Jennifer Boger, a pilot test was conducted using the Ubisense system.

During the pilot test, the researcher and another student researcher both wore the RFID tags in the room and walked for approximately 4 metres in a straight line. The researchers made several attempts at recording data with the sensors in different attachment configurations. These included:

- Inside his or her socks at the ankles
- Attached to his or her legs below the knee
- Tied inside his or her shoes

The system was set to record once every timeslot, with a single timeslot being 27.023 ms. The system used the four sensors to triangulate the location of the tags within the room. At the same time, a screen displayed the tag location within the room.

It was found that while the system was able to show approximately where a tag was in the room at a given time, the system did not provide enough detail to differentiate between the two legs of the researchers or to obtain useful gait measures. Furthermore, the position data were often skewed by the presence of metal objects in the room. Thus, it was concluded that the Ubisense system would not be a feasible tool for measuring gait.

Based on the findings from the Ubisense Pilot Study and the literature review, it became clear that a more convenient gait measurement system should be explored. This led to the collaboration with the Yasumura-Lab at Keio University in Tokyo, Japan discussed in the next subsection.
3.2 Keio Design Study

The first of the two design studies took place at Keio University, Shonan Fujisawa Campus in Tokyo, Japan. This study was done in collaboration with students from the Yasumura Laboratory. A Yasumura Laboratory student, Shota Matusda, developed a series of accelerometer sensor packages. One iteration of these sensor packages was used in this design study. This subsection discusses the development of the sensor packages, and the results and recommendations that came from the study.

There were two primary purposes of the Keio Study. The first was to ascertain whether different gait types could be differentiated based on acceleration data alone. The second purpose was to do an initial usability assessment of shoe based sensors, with recommendations being used in subsequent research. For this study, accelerometer packages were designed and created by Shota Matsuda. The equipment package that he developed will be referred to as the Keio sensor package in the following discussion.

Using the prototype from the first iteration of the Keio sensor packages, a design study was conducted at the Keio University campus with Keio University students. This study was useful as it helped the researchers create a list of design requirements and recommendations. The results of this study yielded insight into the limitations of the prototype and study design that led to improvements in the subsequent study.

3.2.1 Participants
The preliminary set of experiments took place using 6 participants: 5 male and one female between the ages of 25 and 55. Five of the six participants were university
students and the sixth participant was a university professor. All participants had no pre-existing gait problems and had corrected-to-normal vision.

3.2.2 Equipment

The Keio Study was performed using the first iteration of the Keio sensor package. Subsequent iterations evolved from this first sensor.

The first iteration of the Keio sensor package was designed to wrap around a participant’s existing shoes Velcro straps. Accelerometers were attached to the Velcro straps, and wires led up to the circuit board that was affixed to a battery pack. Participants carried the circuit board and battery pack in their hands while walking as shown in Figure 3.1.
Figure 3.1 Diagram of the Keio sensor package attached to a user. The accelerometers are strapped to the participant’s feet, and the circuit board and battery pack are in the participant’s hand. (Diagram by Isabel Foo)

During the study, the feet and legs of the participants were videotaped so that the acceleration data could be synchronized with the participant’s gait during data analysis. The participants also walked alongside a tape measure so that distance and speed could be determined.

The data from the sensors were recorded onto a Secure Digital (SD) card, and could be downloaded onto a computer with a custom-built tool (refer to Appendix A for a screen shot of the tool). The hardware used in this study is shown in Figure 3.2.
3.2.3 Experimental Design

In order to assess different types of gait in different conditions, the participants were asked to walk across two surfaces (one flat, one inclined) and to mimic common gait problems: “limping”, “shuffling”, and “bent over”. The fourth condition of the study required participants to walk as they would normally across the surfaces. A schematic representation of the postures used in the four experimental conditions is shown in Figure 3.3.
To ensure that all of the participants had a similar understanding of the different types of gait to mimic, and to overcome any possible language barriers, each participant viewed videos showing the different gait types (refer to Appendix B for a list of the videos).

The participants walked for approximately one minute for each condition (two walking surfaces, four walking types) and during this time, the researcher (AK) recorded the participants' legs and feet with a video camera. The participants were told to walk at a comfortable pace. The participants all walked along the flat surface first, and the inclined surface second. The order for each type of gait for each surface was randomised for each participant.
3.3 Results

The data collected by the Keio sensor package was raw accelerometer data. Video recordings were also collected. The video data and accelerometer data were synchronised and these data were analysed to determine if different gait measurements could be recognised.

3.3.1 Preliminary Data Analysis

A preliminary analysis of the data from this study was performed to determine whether acceleration would be a useful measure to pursue.

Video data were coded using heel strike and toe off events. These event time stamps were compared against the accelerometer data. The data strongly suggested the existence of gait related patterns and features. Figure 3.4 shows a graph of accelerometer data versus time. The graph shows an increase in accelerometer activity around the same time key gait events occurred (heel strike and toe off).
3.3.2 Usability Issues

Several usability issues emerged from this study that helped inform future design iterations.

**Cumbersome Cables**

The accelerometer cables, used to attach the sensor to the participants’ shoes, were cumbersome. The participants had to take extra care to not trip on the cables and may have made them more hesitant in gait. The healthy gaited participants had no issue after some practice with the device. It is recommended, however, that future iterations should be wireless to eliminate the extra effort to avoid the cables while walking.
**Hardware Attachment**

The main component of the sensor package, the circuit board and battery pack, did not attach to the participant. Thus participants were required to hold onto the two separate devices (attached to each other by a thin wire), while walking. While this did not pose a large problem with the healthy participants used in this first study, it might add unnecessary effort for others walking with less healthy gaits. Furthermore, having the participant hold the sensor package and battery pack would be cumbersome during long-term gait analysis, and users would probably not be willing to carry the hardware in their hands for an extended amount of time.

Consequently, it was recommended that the battery pack and circuit board be attached to each other and that the package be secured to a belt clip. The belt clip can be used to attach the device to the belt or pants of users, thereby eliminating the need to hold onto the device. This allows for the device to be securely attached to the user with minimal effort. In order to account for the varying heights of participants, the belt attachment should be designed such that any slack in cable length can be contained within the attachment. In this way, the extra cable length resulting from shorter participants would be hidden (and will reduce the chance of tripping), and extra cable length required for taller participants would be easily accessible.

**Accelerometer Strap**

The thickness of the Velcro strap was noticeable when wearing the device, and may have affected how participants walked. Furthermore, because the strap came between the participants' shoes and the ground, it reduced the traction of the shoe on the ground. This could become a tripping hazard and it is recommended that the attachment mechanism not wrap around the shoe. The strap can be made to attach to
only the top portion of the shoe (e.g. using the laces), thereby reducing the need to wrap the strap around the foot.

Each of these issues severely impacted the usability and patient experience of the Keio sensor package. Because of this, further research was performed using a different set of sensors. Based on the issues identified during the Keio Study, the aforementioned recommendations were developed. Furthermore, three key design requirements arose from the usability issues identified. These requirements fed directly into the Bridgepoint Design requirements and IML sensor package evaluation (see following chapter). These included the need for the package to be:

- Wireless
- Firmly attached to the user’s foot, to avoid shifting of the device
- Minimally noticeable when worn (both in weight and size), so that users could go about their day-to-day life with minimal interruption and without affecting gait

3.4 Limitations of the Study

This study had a number of limitations and challenges, which are described in this section.

3.4.1 Mimicked Gait Impairments

This study required participants to view gait impairments in videos and mimic these impairments. This mimicking may not have been accurate, especially as participants likely had varying degrees of experience with each gait type. None of the participants in the study had acting experience and thus it cannot be assumed that their renditions of each gait were particularly skillful.
The “normal” gait portion was not performed under “normal gait” conditions. Participant gait may have been affected because they were being video-taped and had the sensors attached to their feet. This may have changed their “normal” gait, and affected the results. The participant’s were also observed to be adjusting gait speed to accommodate for the researcher video-taping their feet and to keep pace with the camera. This may have also affected gait.

3.4.2 Participants and Setting

The participants used for this study were all students of Keio University. They were all healthy and had no gait impairments. As such, they were not the intended users of a gait assessment device and were not assessed in a healthcare setting.

3.5 Subsequent Iterations

The Keio sensor package underwent two further iterations. These new iterations were designed and developed by Shota Matsuda.

3.5.1 Second Iteration

The second iteration of this package separated the one package into two. The sensors were redesigned by Shota Matsuda to fit within the lining of house slippers as shown in Figure 3.5.
These prototypes, however, would be difficult to use in a clinical setting such as Bridgepoint Hospital as patients are able to wear whatever footwear they desire. As well, the inclusion of the sensor package in the lining of the top of the slipper limited the amount of space within the slipper for the user’s foot.

3.5.2 Third Iteration

The third iteration of the sensors was designed with the goal of mass production. Printed Circuit Boards (PCBs) were designed by Shota Matsuda. These circuit boards were printed with conductive paths for the circuits. While the ease of mass production of the PCBs was promising these subsequent iterations of the Keio sensors were eventually discarded in favour of the IML sensor package.
3.6 Discussion

The purpose of this study was to investigate the utility of acceleration as a means to measure gait and usability of the gait sensors. Based on the experiment conducted, some periodic data could be observed and it appeared that the gait data followed the same general patterns found in the video data. Because of the usability problems associated with this device and the availability of a more advanced prototype developed by someone in the same lab as the researcher, subsequent research was conducted using the IML sensor package (instead of the second and third iteration of the Keio sensor package).
4 Bridgepoint Hospital Study

The second study was conducted at Bridgepoint Hospital in Toronto. This study used sensor packages developed by Phil Lam of the Interactive Media Lab at the University of Toronto. The primary goal of this study was to assess the usability of the devices in a realistic context. This study was conducted in collaboration with Dr. Tammy Sieminowski, an attending physician in the neurorehabilitation unit at Bridgepoint Hospital. The Bridgepoint Study aimed to overcome the limitations of the earlier Keio study (reported in the preceding chapter) by making use of actual users and by conducting the study in context.

4.1 Study Design

The researchers worked together with Dr. Sieminowski to recruit neurorehabilitation patients at Bridgepoint Hospital. These patients were targeted as they were recovering from stroke or other brain injuries that affected gait. As the patients were residential and undergoing rehabilitation on a daily basis, it was assumed that gait would undergo marked changes throughout the hospital stay.

Neurorehabilitation patients were screened and those deemed eligible for the study were asked to provide consent to participate. The devices were attached to the existing footwear of each consenting participant for a period of 24 hours, up to two times per week for up to six consecutive weeks (depending on the patient’s admission and discharge date). During this time, the researcher assessed the usability of the sensor package as well as the patient experience. Ethics approval was granted
through the Joint Bridgepoint-West Park-Toronto Central Community Care Access Centre Research Ethics Board and the University of Toronto (Administrative Approval #25475) (refer to Appendix F for the Ethics approval documents).

In addition, consenting participants’ hospital charts were checked for primary diagnosis, admission date, discharge date, history of falls, balance scores (Berg Balance Scores, 6 minute walk scores, Community Balance and Mobility Scale scores). The purpose of collecting this information was to understand the condition of the study participants.

4.2 IML Sensor Package

The original intent was to make use of the Keio sensor package in a study with patients in a clinical setting. However, the opportunity to use another set of sensors arose. The IML sensor package were developed by Phil Lam, a student of the Interactive Media Lab. The sensor package was originally designed for use in measuring dragon boat paddler work output using accelerometers. However, modified versions of these sensors could be applied for use in gait analysis as well. This sensor package was selected for use since it appeared to avoid some of the usability issues associated with the Keio sensor package, the convenience of having the sensor designer located nearby for troubleshooting, and due to of the increase in sensors in the sensor package.
4.2.1 IML Sensor Package Requirements

Based on the literature review, a discussion with Dr. Sieminowski, and the knowledge gleaned from the Keio study, a set of requirements for the IML sensor packages were developed. These requirements outlined how the sensor package should work and perform and what attributes it should have. The requirements are categorized into several groups: hardware requirements, user requirements for researchers and user requirements for patients.

The user requirements were divided into two separate groups of users. The researcher user group refers to the users that would be administering the gait analysis system. This includes the physicians, clinicians, researchers, and physiotherapists. The patient user group refers to the patients who are the end-users of the sensor package.

The subsequent usability and patient experience testing assessed the IML sensor packages against these requirements.

<table>
<thead>
<tr>
<th>Hardware Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>The sensor package battery must last at least 24 hours</td>
</tr>
<tr>
<td>The data from each foot should be easily synchronized</td>
</tr>
<tr>
<td>The sensor battery should be easy to charge</td>
</tr>
<tr>
<td>The sensor should be easy to calibrate</td>
</tr>
<tr>
<td>The sensor package should be wireless</td>
</tr>
</tbody>
</table>

Figure 4.1 Hardware requirements for gait analysis system

<table>
<thead>
<tr>
<th>User Requirements for Researchers</th>
</tr>
</thead>
<tbody>
<tr>
<td>It should be easy for users to see when the sensor is turned on, turned off, and recording data</td>
</tr>
<tr>
<td>It should be easy for users to see when the battery needs to be charged</td>
</tr>
<tr>
<td>It should be easy to download the data collected</td>
</tr>
</tbody>
</table>

Figure 4.2 User requirements for researchers for gait analysis system
User Requirements for Patients

<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>The sensor package should be able to attach to a variety of shoes</td>
</tr>
<tr>
<td>The sensor package should be easy and quick to attach and detach from shoes</td>
</tr>
<tr>
<td>The sensor package should not require any permanent changes to shoes</td>
</tr>
<tr>
<td>The sensor package should be minimally noticeable by the user when worn</td>
</tr>
<tr>
<td>The sensor package should attach firmly to the user's shoes and not require the user's effort in carrying it</td>
</tr>
<tr>
<td>The sensor package should be able to withstand day-to-day use</td>
</tr>
<tr>
<td>The sensor package should be easily sanitized</td>
</tr>
<tr>
<td>The sensor package should not impede the user’s ability to walk</td>
</tr>
<tr>
<td>The sensor package should be as inconspicuous as possible, so as not to affect the user’s walking</td>
</tr>
<tr>
<td>The sensor package should not affect the safety of the user</td>
</tr>
<tr>
<td>The sensor package should be light enough that its weight does not affect the user’s walking or comfort</td>
</tr>
</tbody>
</table>

4.2.2 IML Sensor Package Design

The IML sensor package was designed to collect data from a collection of (3D) accelerometers and a gyroscope. The sensor packages were used to log and store data, and these data were subsequently transferred to a computer. In addition to accelerometers and gyroscopes, the device contained a real-time clock that facilitated synchronization of the data collected separately from the two feet. Data was collected at a frequency of 100 hertz. Please refer to Appendix C for more details on the IML sensor package hardware.
There were several benefits to using the IML sensor package over the Keio sensor package:

- The new sensor package was designed to attach to the tops of shoes.
- The new package contained more sensors than the package used in the Keio Study. The Keio sensor package used a 3-axis accelerometer, while the IML sensor package made use of a 3-axis accelerometer as well as a 2-axis gyroscope. This allowed for the collection of more data.
- The IML sensor packages were more energy efficient and could last longer on one charge than the Keio sensor packages. This allowed for longer intervals of data collection thereby making the usability test more representative of the real life application of the sensors.
- The IML sensor packages were wireless, which avoided the tripping hazard that existed with the Keio sensor packages.

4.2.3 IML Sensor Package Casing Design
Custom casing was designed by Phil Lam to house the sensor package and attach to participants’ shoes for this study. The casing was designed such that researchers could see the LED through the casing and could interact with the USB port by opening the cap of the casing. This USB port allowed for quick and easy download of data and charging of the battery (refer to Appendix D for more images of the package casing).
The casing was designed to fit on many different types of shoes. The six holes allowed for lacing to shoes and a flap underneath the package allowed the sensor to slide on top of non-laced shoes (for example: loafers).

In order to collect data, the sensors first had to be calibrated with the current time (to allow for subsequent synchronization between the feet). This calibration was done with
a custom built program that allowed the researcher to check that each sensor was working properly, and to set the sensor time to that set by the computer clock (refer to Appendix E for a screen shot of the calibration program).

After data were collected, the data could be downloaded to a computer by means of a USB cable.

4.3 Pilot Testing

Prior to the commencement of the study at Bridgepoint Hospital, a short pilot study was conducted to test how well the device casing would attach to shoes and withstand normal use. The researcher wore the sensor package over a period of 48 hours. The device was affixed firmly to tennis shoes using the laces and lace holes on the casing.

The researcher found that the sensor packages did not greatly impede movement of the foot during the time they were worn. The researcher was able to bend her foot as usual, and did not feel any discomfort from the sensors.

After having performed a pilot test, and having found that the sensor packages could withstand the rigour of two days of continued use without damage to the sensors or discomfort to the user, the research continued with Bridgepoint Hospital participants.

4.4 Participants

The four participants were recruited from the Neurorehabilitation patient population at Bridgepoint Hospital. Bridgepoint Hospital provides active and slow stream neurorehabilitation for patients who have experienced a stroke, subarachnoid
haemorrhage, or other traumatic brain injury. All patients arrive with new neurologic deficits, some of which may impact their gait and mobility. Over the course of neurorehabilitation, patients work with physiotherapists and occupational therapists to improve mobility.

The mean age of patients at Bridgepoint Hospital is 61 yrs (SD 18.2, range [18,93]). The mean length of stay is 47 days (SD 25, range [0,148]). The ratio of diagnoses is: stroke (53.0%), traumatic brain injury (16.4%), subarachnoid hemorrhage (5.7%), subdural hematoma (3.7%), and other (21.1%). (T. Sieminowski, personal communication, May 1, 2010)

The study participants were recruited from the two neurorehabilitation units at Bridgepoint Hospital (3-East and 7-West). The participants were, at the time of study:

- Admitted to Bridgepoint Hospital for neurorehabilitation
- Older than 18 years of age
- Capable of consent to personal care decisions
- Able to communicate in English
- Ambulating independently (with or without gait aids)

Potential participants were identified by Dr. Sieminowski based on the inclusion criteria. After being identified, Dr. Sieminowski explained the research project and left a consent to contact form with the patient. Patients who agreed to being contact by the researcher then submitted their forms to a third-party who gave the forms to the researcher. Based on the received consent to contact forms, the researcher established contact with the potential participants to obtain informed consent.
Dr. Sieminowski was not informed as to who consented to participate to avoid conflicts in the patient/physician relationship and care. Please refer to the research ethics documents in Appendix F for the consent forms used and a thorough description of the consent process.

Participant data collection ranged from two to four weeks, based on the length of patient stay. Because of the limited number of sensors and the need to charge the sensors between each use, the data were gathered from each consenting participant once per week (depending on sensor availability).

4.5 Results

Due to difficulty recruiting consenting participants, the study was limited to four participants.

This difficulty was primarily due to three reasons:

- The consent process was lengthy due to the fact that it required the physician to first assess and identify potential participants and to then obtain consent to contact before the researcher was able to initiate the second stage of the consent process. As a result, some patients were discharged before consent could be obtained or before an adequate amount of data could be collected.
- Patients expressed concern over participating in the study as they did not want to be distracted from their rehabilitation activities.
- Some patients expressed concern over the device design itself, as they did not want to attract too much attention to their feet.
Of the four patients who participated in the study, data were collected for three of them. This was because one participant dropped out of the study after the gait sensors caused too much discomfort. This participant’s discomfort is discussed further in Chapter 5. For the other participants, data were collected for a range of 2 to 4 weeks, once each week. During the weeks that the participants were in-patients, the student researcher would visit to attach the sensor and collect data.

The participant’s went about their day-to-day lives while wearing the sensor packages. Typical daily events include attending rehabilitation appointments, taking walks around the hospital and surrounding area, and socializing with other patients at Bridgepoint Hospital. There was insufficient data about activity to analyse against the collected data. Future studies should explore the daily schedules of participants to gather more insight into activities during data collection.

4.5.1 Participant Sensor Activity

The sensor package was designed to turn off after several seconds without movement. Thus, it was possible to ascertain when the sensor was in use.

The figures below show the proportion of each day (between 9:00 am and 5:00 pm), that the sensor package was in use for each of the participants. The graphed figures show the days where data was available for the participants between 9:00 am and 5:00 pm. The proportion of use varied greatly between participants. This may have been because some participants owned multiple pairs of shoes and may have worn the shoes with the sensor packages less frequently.
Figure 4.6 Sensor activity graph for participant 2 over an eight-hour period.

Figure 4.7 Sensor activity graph for participant 3 over an eight-hour period.
Figure 4.8 Sensor activity graph for participant 4 over an eight-hour period.

There is potential for this measure to be used in future work in determining whether a patient’s activity has increased over time. These data may be able to tell researchers whether or not a participant is moving their feet throughout a day, and researchers can then infer whether their overall activity has increased or decreased over time.

4.5.2 Participant Medical Histories

After the participants were discharged from the hospital, their medical histories were reviewed for original diagnosis and changes to gait during their stay at Bridgepoint. Participant data were mined to determine how physicians measured gait changes throughout their neurorehabilitation stay. The relevant chart extractions for the participants are tabulated below.

The three most common gait assessment tools that are used by physicians at Bridgepoint Hospital, as discussed in Chapter 2, are the Berg Balance Score, the Community Balance and Mobility Score and the Six Minute Walk. The reports regarding gait were inconsistently recorded for the three participants. This inconsistency in
recording, as well as the lack of detail in recording gait information made these data difficult to use.

The health record forms had fields for the following gait-relevant information:

- In room walk: referring to a patient’s ability to walk around the room
- Bed mobility: referring to a patient’s ability to move off the bed independently
- Ambulation and locomotion ability: referring to a patient’s overall ability to walk independently
- Ambulation support provided: referring to ambulation support tools used (for example: canes or walkers)
- Fall occurrence: referring to incidents of falls
- Fall prevention strategy: referring to strategies used to prevent falling (for example: rubber soled shoes to prevent slipping)

As demonstrated by the participant summaries below, most of these data were not collected consistently.

**Participant 1**

Participant 1 agreed to participate in the study but quickly withdrew because the sensors were too uncomfortable to wear. As a result, this participant’s medical data were not accessed.

**Participant 2**

Participant 2 was diagnosed with malignant neoplasms of the brain. This participant was recorded as having independent locomotion throughout his or her stay at
Bridgepoint and required no supports. This participant had no fall occurrence score throughout. His or her health record did not include any gait patterns, gait scores, or other relevant gait information.

<table>
<thead>
<tr>
<th>Throughout stay</th>
<th>Ambulation ability</th>
<th>Independent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locomotion ability</td>
<td>Independent</td>
<td></td>
</tr>
<tr>
<td>Ambulation support</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Fall occurrence</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

Figure 4.9 Summary of Participant 2’s Gait Related Records

**Participant 3**

Participant 3 was diagnosed with a stroke. At first, this participant used a single point cane but no longer required this cane after November 25, 2010. This participant had no fall occurrences and was considered to be independently ambulatory throughout their stay.

As a falls prevention strategy for this participant, the hospital ensured that the participant wore rubber-soled shoes and positioned the bed to minimize falls risk. The health record did not include any gait patterns, gait scores, or other relevant gait information.
Participant 3

<table>
<thead>
<tr>
<th>Date</th>
<th>Ambulation support</th>
<th>Bed mobility</th>
<th>Fall occurrence</th>
<th>Fall prevention strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 18</td>
<td>Single point cane</td>
<td>Independent</td>
<td>None</td>
<td>Rubber soled shoes, bed position</td>
</tr>
<tr>
<td>November 25</td>
<td>No support needed</td>
<td>Independent</td>
<td>None</td>
<td>Rubber soled shoes, bed position</td>
</tr>
</tbody>
</table>

Figure 4.10 Summary of Participant 3’s Gait Related Records

Participant 4

Participant 4 was admitted for a fracture to the base of the skull and other unspecified injuries to the head. The participant’s records stated that on November 3, the participant was able to walk independently in the room, and ambulation ability in the corridors was independent, except that a manual wheelchair was used for ambulation support. By November 4, participant 4 was recorded as using a single point cane for ambulation support. His or her health record did not include any gait patterns, gait scores, or other relevant gait information.
Overall, the level of detail of the charts was low, making it difficult to ascertain minor changes in the participants’ gait during their stay at Bridgepoint. It should be noted that there were no Berg Balance Score, gait patterns or gait scores noted for any of the three participants throughout their stay at Bridgepoint.

Of the participants studied, only two participants appeared to have had any change in their gait during their rehabilitation. Participant 4 went from requiring a wheelchair for ambulation support to needing only a single point cane. This change in the chart appears within a few hours of the original note. As one of the inclusive factors for the study was that the patient be able to ambulate independently, the participant was not considered for the study until after the change in their ambulation support needs. Participant 3’s ambulation changed from needing a single point cane to not needing any supports at all during their rehabilitation. Participant 2’s ambulation was unchanged during his or her stay at Bridgepoint Hospital.
5 Findings and Recommendations

The study took place over six weeks at Bridgepoint Hospital. While the original intent of the study (and the REB approved study protocol), was to collect only gait analysis data, several usability and patient experience issues arose. As the attachment and detachment of the sensor packages took some time, the researcher ended up spending a considerable amount of time with each participant (up to twenty minutes for each data collection visit). During these visits, the participants would chat about their experiences with the IML sensor packages and how they felt it affected their day to day lives. These issues, along with other patient experience, usability and process issues identified through research observation are documented below.

Future studies should account for this unexpected source of qualitative data and include this in the human subjects protocol.

5.1 Patient Attitude and Experience

Participant attitudes towards the project and interest in participating in the study both varied considerably. Some potential participants expressed concerns about the safety, conspicuity, and operation of the device. In addition to these concerns, the long consent process and lengthy documentation made it difficult to recruit participants for an adequate amount of time.
5.1.1 Bright LED

As previously mentioned, each sensor package made use of an LED to indicate when the sensor was properly programmed and when it was recording data. While this device feedback was useful for the researcher during the programming process, the LED did not have an obvious benefit for participants. The LED was distracting for some participants and attracted unnecessary attention. Participants commented on the brightness of the LED, and how distracting it was in dark rooms.

Another participant commented on how easily the LEDs became activated. In a few cases, disturbances to the area around the sensor packages would cause the LED to turn on (as the sensor package was activating itself based on perceived movement). Several times, this occurred when the participant was not wearing the sensor packages at all, but was in fact, in bed. In these cases, another person had walked close to the sensor packages and may have nudged them, causing them to turn on. In dark rooms, the bright flashing light was alarming and distracting. This situation caused unnecessary hardship for the participants participating in the study and those sharing their room (at times up to four other patients).

It is interesting to note that these issues with the LED conflicted with one of the previously identified requirements. While the LED was an important feature for the research-user, it was not necessary for the patient-user, and in fact, was found to be an issue when in use. It is important to differentiate between the needs of the two types of users, and iterate the design accordingly.

One purpose of the LED was to indicate to researchers if the device was malfunctioning and required fixing. If, however, the device malfunctioned during use, the participant would not be equipped to remedy the situation, and any information
from the LED would not be useful. In one case, a participant expressed concern when the LED of one of the sensors turned off after having been hit by a falling object. This concern likely created a negative experience during the study, which could have been avoided if the sensor had been designed without the LED, or with an LED that was less prominent or that was less prone to activation based on random events in the environment.

Clearly the sensor package feedback should be designed to be less obtrusive. As the LED made the sensor package too noticeable and may have impacted the way subjects behaved, it is important that the design of the location of the LED be considered in future iterations. One recommendation would be move the LED from the top of the device and place it on the bottom instead, or, as a “quick-fix” to turn the sensor within the casing and calibrate it upside down. The LED was only useful to the researcher when calibrating the device, after which any feedback given would not be useful until the sensor was back in the laboratory. Thus, it is not necessary that the LED be visible while the sensor package is in use.

It was observed that the lighter coloured casings (for example: white and lime green), tended to leak more light than the darker casings (for example: black and blue). Because of this, some participants preferred the darker casings – as they were less conspicuous. Participants found that when they were wearing the device at night, for example: in dark hallways and rooms, the light would be very bright and distracting. This, in turn, could have affect the participants’ gait. Because the darker coloured devices were more opaque, the light would be less bright. If the LED cannot be eliminated, it is recommended that dark, opaque casings be used to minimize light leakage.
5.1.2 Attitudes about Device Appearance

Some participants expressed concerns over the conspicuity of the device. They did not like the fact that the sensor was clearly visible on their shoes and expressed concern about others noticing and asking questions about them. The sensor packages were especially evident when the colour of the device contrasted with their shoes. One participant requested that the researcher only attach dark coloured sensors as they were less noticeable.

A number of devices were created in varying colours. Because of technical issues with some of the devices, it was often impossible to use matching colours on the same participant. This caused some concern for some participants who did not like the appearance of mismatched devices.

In future iterations, care should be taken to make the sensors as inconspicuous as possible. This can be done by making the casing the same colour as typical shoes (for example: white and black for sneakers, brown for loafers, etc) and minimizing the variety of casing colours (so that there will be more casings of each colour).

5.1.3 Communication Aids: Consent Process and Patient Education

The lengthy consent process meant that it took several weeks to obtain informed consent from participants, the lengthy process in addition to the wordiness of the documentation may have influenced the number of participants who agreed to participate in the study.

The participant sample for this study consisted of in-patients undergoing neurorehabilitation. As these patients stayed in the hospital for an average of 6 weeks,
many developed close relationships with other patients. Some participants were eager to show off the device to their friends, and would have benefited from more information about the devices.

In future studies, the experimenter should prepare friendlier documentation to provide to potential participants. The long consent form may have been too text heavy for potential participants to digest properly and may have been overwhelming to potential participants. The consent form should make use of visual aids, including informational graphics, to convey information in a more consumable manner. Images of the sensor packages on a pair of shoes will help potential participants visualise how the sensor package would fit onto their own shoes, and aid in his or her understanding of the impact of the experiment on their day-to-day routine.

Some participants had difficulty filling in the consent form of the documentation, and required clarification on the wording and checkbox to check. Future consent forms should make use of larger font, and more obvious check boxes to ensure participants have a clear understanding of which sections need to be filled out and what each question is asking.

Documents that contain less text and were more easily consumed may seem less daunting and overwhelming to potential participants, and this may aid in the recruitment process.
5.2 Usability Issues

In addition to these issues affecting patient experience, a number of usability issues were identified during the Bridgepoint Study. These issues affect how easily the researcher was able to attach the sensors and collect the necessary data. The issues are outlined below with related design recommendations for future iterations.

5.2.1 Inflexible Casing

In order to protect the electronics, the device was housed inside a stiff plastic casing. While this casing protected the electronics, it also made it difficult to fit snugly on top of participants’ shoes. One participant had to withdraw from the study almost immediately as the stiff plastic casing dug into his or her feet when he or she attempted to walk to assess the fit of the sensor package and this resulted in too much discomfort.

The device was designed such that the long edge of the sensor package ran parallel to the participants’ foot. While more aesthetically pleasing, this caused problems when trying to bend or flex the foot. As the sensor package was attached to the shoe, where it lay along the top of the foot differed depending on the shoe type. This became an issue when the sensor attached closer to the toes of the foot versus closer to the ankle. This issue became apparent when attempting to attach the sensor package to loafer-like shoes. The sensor package attached closer to the toes, and the rigidity of the casing inhibited bending of the foot.

The participant that withdrew from the study was wearing narrow slip-on loafers. The sensor seemingly attached easily by sliding into the loafer opening, such that the bottom lip of the sensor casing was inside the shoe. However, upon walking, the
participant found that the sensor made any foot movement physically uncomfortable and immediately asked that the sensors be removed.

This discomfort was caused by two factors:

1. The shoes were slip-on loafers with no laces or other attachments. Thus, the shoe needed to be tight enough for the patient to wear without their foot slipping. Because the shoe was already form-fitting, there was little extra room inside the shoe. The added volume of the bottom half of the casing within the shoe took up too much space, and caused the shoe to be too tight.

2. The loafer opening was closer to the toes than the opening of other shoe types (for example: sneakers that lace up higher up the foot). As such, the sensor was placed further down the foot where more bending occurs during walking. Because both the sensor and casing are inflexible, this inhibited the participant’s movement and caused pain as the edge of the sensor package dug into the top of the participant’s foot with each bend.

It is important that the sensor packages fit as comfortably as possible on participant’s shoes. The sensors should have little if any effect on how participants walk. If the sensor causes discomfort or pain, the gait of the participant can be affected which will skew the data collected. Thus, it is important that future iterations include necessary design changes that maximize the comfort of the sensors for more types of footwear.

There are several recommendations that could help to avoid physical discomfort:

1. The entire sensor package can be made much shorter so that it does not impede bending, or, as a “quick-fix” the long edge of the sensor package should be placed perpendicular to the foot. This way, the shorter width of the
sensor would run along the top of the foot, and this will impede foot bending less.

2. The sensor package could be designed to sit higher off the shoe, allowing for more space between the sensor package and the shoe to allow more flexibility in movement.

3. The sensor package could be design to be flexible, bending with the foot as it bends. If this change is made, it is important that the bend be as fluid as possible to avoid any extra effort to bend the foot.

5.2.2 Sanitation

The Bridgepoint Study took place in a hospital setting. The patients in the hospital were recovering from various conditions. As such, it was of utmost importance that proper sanitation be considered.

The casing used on the IML sensor package for the Bridgepoint Study was designed to use porous material. This made cleaning and proper sanitation difficult. The researcher took care to spray the device down with alcohol after each use, but this technique was not ideal.

There were problems with the alcohol spray method used:

- As the electronics were affixed permanently to the casing, there was a risk that the electronics would get damaged from the alcohol spray.
- The casing contained many bends and fold. The alcohol spray may not reach all surfaces of the casing because many of them were difficult to reach.
It is recommended that in future iterations, the casing be designed so that the sensor may be removed to facilitate thorough cleaning of the casing and that the casing be made of a material that may be fully immersed in liquid to be cleaned. Fully immersing the casing in cleaning liquid ensures that small bends and folds are covered by the cleaning solution and properly sanitized.

Another recommendation is to cover the IML sensor package with an antimicrobial coating. These coatings have been found to decrease microbial activity on medical instruments (Eby, Luckarift, & Johnson, 2009).

5.2.3 Charging

In order to minimize the size of the device, a very small battery was used in the sensor package. While power-saving techniques were employed (e.g. the device went into “sleep mode” when not in use), the battery was depleted after approximately 24 hours of use.

When charging the battery and downloading data from the device, the entire device had to be removed from participants’ shoes. This required frequent visits by the researcher. As the participants had busy rehabilitation schedules, there were only limited windows of time each morning that the researcher could visit the participants to attach and detach the sensors. As such, the necessity to return every 24 hours to attach and detach the sensors meant that less data were being collected as only a limited number of participants could be attended to on each visit.
There are several potential recommendations for this issue:

1. The sensor can be programmed to turn off automatically at night, so that slight movements on the ground (e.g. others walking about in the room) will not cause the device to turn on to record data. This will also help to alleviate the issue encountered with the bright LED causing distraction in darken rooms when not in use.

2. The sensor can be designed such that the battery is detachable and removable, so the researcher only needs to switch batteries to keep the device recording. This will speed up the data collection process as it eliminates the need to calibrate a new set of sensors each time the battery is drained.

3. The sensor can collect data at a lower frequency to reduce power-consumption and increase usage time.

5.2.4 Removable Pieces

The casing was designed such that a cap could be removed so that the device could be switched on and off. Unfortunately, as the cap was attached and detached, the attachment mechanism would become weaker, resulting in a looser fitting cap as the casing was used and re-used.

This resulted in the cap becoming loose and falling during data collection. Some participants expressed concern and distress when the cap became loose as it was often difficult for the participant to bend over and re-attach the cap themselves.

It is recommended that future casings be designed with material that will not wear with use, or that the cap be eliminated entirely and that the on/off switch be moved to a
location that is accessible without the removal of a cap. Fewer removable pieces will lower the likelihood that pieces become loose or lost during use.

5.2.5 Device Attachment

The participants that participated in the Bridgepoint Study were all undergoing neurorehabilitation. Neurorehabilitation patients typically wear footwear that they find comfortable. This turned out to be footwear that could be easily worn and removed as participants were frequently moving in and out of their beds.

As a result, a variety of shoe types were worn by the participants. The following survey of shoe types was performed by Dr. Sieminowski, and the pictures are used here with her permission Figures 5.1 to 5.4 show examples of patient footwear worn by neuro-rehabilitation patients.

The device casing was designed to be attachable to many different types of shoes. In practice, most types of shoes proved difficult to attach. Of the consenting participants, the most successful attachment method found was tying the sensors to laced cross trainers.
Flip Flops and Sandals

Figure 5.1 Sandals and Flip flops worn by patients at Bridgepoint Hospital (Image credit: Dr. Tammy Sieminowski)

Flip flops and sandals posed a difficult problem as there is little material on the top of the shoes to which sensor packages could be attached. In addition to the difficulty that would be encountered in attaching the sensor package, the lack of material would have sanitation issues as the sensor package would make direct contact with the participant’s foot.

In the case where there is not enough material for the sensor to attach to the top of the shoe, one recommendation is to attach the sensor package to attach to the bottom of the shoe on the sides of the sole, and suspend over the top of the foot. This can be done using clips. In this way, the sensor package will have minimal contact with the skin, and the sensor package can be firmly attached to the shoe.
Cast and Shoe

Some patients wore different footwear on each foot. In these cases, a sensor might only be successfully attached to one shoe. The gait data collected from only one shoe are not as meaningful as data collected from two shoes. Furthermore, it may be difficult to analyze data between two different types of shoes as the shoe type could affect the gait of the patient.
Slip on Mules

Figure 5.3 A Variety of Slip-On Mules worn by patients at Bridgepoint Hospital (Image Credit: Dr. Tammy Sieminowski)

Many patients preferred mule like shoes such as the ones pictured above. These shoes could be slipped on and off easily, and did not require the patients to bend over and use their hands. These shoes would pose problems for attachment of the sensor packages. As the front half of the shoe must be tight enough that the foot does not slip off during walking, there would no be enough room in the shoe to attach the sensor package. Similar to the problems encountered with Participant 1, the casing would make the shoe too tight and make bending of the foot more difficult.

This issue can be addressed in a similar manner to the issue of flip-flops and sandals. The sensor package can be attached to the soles of the shoe at the side of the shoe using clips. The sensor package can then sit on top of the slip-on mule securely.
Cross Trainer Running Shoes

![Cross Trainer Running Shoes](image)

Figure 5.4 Cross Trainer Running Shoes worn by patients at Bridgepoint Hospital (Image Credit: Dr. Tammy Sieminowski)

We confirmed that running shoes were best as the lacing allowed for the sensor package to be attached on top of the shoe, and the attachment flap fit neatly beneath the laces and over the tongue of the shoe. No part of the sensor went into the shoe, so it did not make the shoes too tight. As well, because no part of the sensor came in contact with the participants’ feet, it maintained a higher level of cleanliness. The sensor package could be tied to the shoes with a bit of slack, thereby not inhibiting the bending or movement of the foot. As well, because the top of the shoe sits higher on the foot (where less bending occurs during walking), the sensor did not further impede movement.

While the cross trainers were the easiest to attach, there were still some usability issues present. The sensor package casing can be re-designed so that fewer holes need to be laced through to make the lacing process faster. Further research should be conducted to investigate the ideal lacing technique. Experimentation may be done to
determine which slots the laces should go into for maximum stability and comfort and to minimize lacing time. This lacing technique should then be printed directly onto the sensor package to make it easier for researchers and physicians to remember how to lace the sensor properly. Another implication of a standard, repeated lacing technique is that the data should be more consistently captured as the stability from the sensor package attachment should remain largely unchanged between consecutive attachments.

It is obvious from this quick survey of footwear that there is no one solution for all shoe types. As patients are likely to wear any number of shoe types, it is important to have a design that accommodates many shoe types. It is clear that one design will not work for all shoes because of the varying levels of success achieved attaching the sensor packages to the different types of shoes encountered.

An overall recommendation is for future iterations to design different types of sensor casing that each accommodates a different shoe type. These variations, as discussed in the recommendations above, can be specific for each type of shoe allowing for a closer, more comfortable fit for each type and eliminating losses in comfort and fit that occur when trying to make one casing design fit on a diverse variety of shoes.

5.3 General Recommendations

The primary goal of this study was to assess the usability of the current sensor package design. This was done through an assessment of both the participants’ and researcher’s use of the sensor package. In addition to the recommendations outlined
above for each individual issue encountered, a set of recommendations was created that would improve patient experience and usability as a whole.

5.3.1 Expediting the Lengthy Data Collection Process

The current data collection process includes 8 steps. This long, involved process made it difficult to deploy more than one pair of sensor packages each day (because of the limited availability of the patients). Streamlining this process would save experimenter time, and allow for more data collection.

![Diagram of data collection process]

Figure 5.5: Current Programming Process

Calibration and Set Up

The first three steps of the process involve the calibration and set up of the sensor package. These three steps can be combined into one step to save time. The device made use of internal clocks to synchronize steps between pairs of devices. As such, the device clocks had to be set prior to installation of the sensor on patient shoes. This was time consuming, as each device had to be calibrated individually. Future iterations can change the interface and allow for simultaneous calibration to reduce the redundancy of tasks and save time for the researcher.
In the current process, the researcher must also make a note of which sensor will go on which foot (left or right), and what time the sensor was attached to the participant’s shoe. The time measurement is done to ensure that subsequent data analysis is only performed on relevant gait data, and not on data collected prior to device attachment.

Future iterations of the sensor package may reduce these steps by integrating that data into the device itself. A simple button or switch can be added to create a time stamp at the time of the button press eliminating the need to manually note the start time. The sensor packages can be permanently assigned to either the right foot or the left foot, eliminating the need to note which foot the sensor package was attached to.

**Data Download**

The device download steps can be streamlined by allowing for simultaneous download of the data. This way, the researcher does not have to sit and wait for the data to download from one device before beginning the process for the second device. The data from the two devices will eventually need to be combined into a single file for analysis, so if this step is performed during the data download process, there will be a time savings both during the download stage and during the analysis stage.

If these recommendations are implemented, the device calibration and download process can be reduced to five steps (please refer to figure 5.6 for the recommended process). With fewer steps, there is reduced likelihood of forgetting a step. As well, the addition of increase automation will reduce the time necessary to program the sensor package.
5.3.2 Gait Feedback

During the Bridgepoint Study, some participants expressed interest in the data that was collected from their shoes. These participants wanted to know whether their gait was noticeably improving and whether the sensor packages could detect the changes. This showed that participants were interested in measuring their own neurorehabilitation and had an interest in following their progress during their stay.

Future iterations of the device could include functionality that allows participants to have more involvement in the measurement of their gait. This could include simple output from the device itself or giving participants access to gait data after it has been downloaded and analysed. Giving the participants feedback and some ability to interact with the device itself may help participants become more involved in their own care.
5.4 Challenges and Limitations of the Study

5.4.1 Limited Sample Size

The pilot test was performed on only one participant (the student researcher), as a result, the issues encountered may have been more limited than if more participants were used during the pilot testing.

The main challenge faced during the Bridgepoint Study was the limited number of study participants. This was due to a number of factors, including those outlined above. As well, the lengthy consent process and time constraints caused challenges in data collection.

Obtaining Consent

It was time-consuming to identify and obtain consent from patients. In some cases, it took longer than a week to obtain consent.

The process, outlined in Figure 5.7, required six steps before the researcher was able to start the data collection. Because of the varied length of stay for most of the patients, this lengthy process made it difficult to start collecting data with enough time left in the patient stay to collect a suitable amount of data.

![Figure 5.7: Lengthy Consent Process](image-url)
Time Constraints

The busy schedule of Bridgepoint patients made it difficult to find individual participants outside of a 15-minute window each weekday morning. Because of the amount of time required to attach and detach the sensors, it was difficult to visit more than one participant each morning. Changes to the calibration and attachment of the sensors could help mitigate this issue.

5.5 Comparison of Sensor Packages

For this thesis, two separate sets of sensor packages were used to collect gait data. These two packages differed in several ways, and each had strengths and weaknesses to their compatibility in a naturalistic setting. The IML sensor packages made use of more sensors than the Keio Sensors.

Future work should be done using the IML sensor packages. The usability issues of the IML sensor packages and device calibration and data collection process can be addressed in future iterations to eventually achieve a device and system that will help physicians measure and assess the gait of their neurorehabilitation patients.
6 Conclusion

Traditionally, gait analysis is performed only periodically throughout a patient’s rehabilitation. There are many difficulties in establishing a more rigorous gait measurement system that may be used in hospital settings. The primary purpose of this thesis was to determine if on-foot gait sensors would be practical in a hospital setting. Patients undergoing neurorehabilitation are very busy and move a great deal throughout the day. The Bridgepoint Study aimed to determine if the IML sensor package would work in a hospital setting with busy and active patients.

During the Bridgepoint Study (described in chapter 4 and 5), it was found that existing gait assessment tools were not used consistently on patients. So, it could be difficult to understand and assess a patient’s gait improvement over time. Furthermore, based on discussions with Dr. Sieminowski, it emerged that the gait test or tool used by most physicians generally depended on their own personal preference and previous professional experience. This may cause issues in determining a patient’s gait changes as different assessment tools may be used at different points in their neurorehabilitation.

It became clear that there was a need for a gait assessment system that would be consistent across patients and throughout an individual patient’s stay at Bridgepoint Hospital. A possible solution would be a gait assessment system that provided quantitative measures of gait. These measures could be compared across a patient’s stay at Bridgepoint, making it easier for a physician to assess that patient’s improvement over time.
The Keio study made use of mimicked gait and different ground conditions to determine if the sensors were sensitive enough to ascertain changes in gait. This method allowed a quick assessment of gait analysis prototypes prior to more extensive hospital studies.

The methodology employed for the Bridgepoint study helped the researcher gain insight into the patient experience and usability issues of the sensors. By visiting the participants twice weekly (once for attaching the sensors, and once for detaching the sensors), the researcher was able to glean important information on how the participants interacted with the sensors.

The use of the gait sensors in a neurorehabilitation setting proved to be more difficult than in a controlled setting. The lengthy patient identification and consent process made it difficult to gather data from any one participant for longer than a few weeks.

6.1 Summary of Contributions

The main contribution of this thesis was the evaluation of two separate sensor packages for ambulatory gait analysis. This included:

1. The Keio Study
   a. Evaluation of the sensor package and identification of usability issues
   b. Design recommendations based on the evaluation
2. The Bridgepoint Study
   a. Evaluation of the sensor package and identification of usability issues
b. Recommendations for the design of ambulatory gait analysis sensors to be worn by neurorehabilitation patients

During the first study, at Keio University, a set of usability issues was identified. These findings informed the requirements used to assess the ambulatory gait analysis package design identified for the Bridgepoint Study.

The hospital setting used in the second study allowed the research to identify a list of usability and patient experience issues that would have been hard to find in a laboratory setting. Many of these issues were of high severity, and some impeded the ability to use the sensor package at all. Without testing the sensor on a variety of patients, with many different types of shoes and in various stages of neurorehabilitation, these issues may not have been identified.

Based on what was learned in the two studies, a set of recommendations was created to address each of the issues encountered. These recommendations can feed into future iterations of the design and improve the usability and patient experience of on-foot gait assessment sensors.

6.2 Summary of Challenges and Limitations

The Keio Study and Bridgepoint Study both had associated challenges and limitations. In order to save time and expense, the Keio Study was performed using students as subjects – these students mimicked gait impairments while the Keio Sensors collected gait data. As the subjects were not actually patients with real gait impairments, their feedback would have been different from the actual intended users of the device.
Furthermore, the students were asked to mimic gait impairments after viewing videos of gait impairments. This mimicked gait may not have been as accurate as if the subject’s did suffer from the gait impairments, and this may have also affected the results.

The Bridgepoint Study, performed with real patients during their neurorehabilitative stay at Bridgepoint Hospital avoided both these issues. The participants were all intended users of the devices. As well, these participants were asked to walk normally – and did not need to mimic gait impairments.

The biggest challenge faced with both the pilot study and the Bridgepoint Study was the limited sample size. The Bridgepoint study in particular found a number of usability and patient experience issues with the current sensor package. This information led to the development of a set of recommendations that will feed into future research.

6.3 Future Work

The overall goal of this thesis was to ascertain whether on-foot gait sensors could be worn and used in a hospital setting. It was found that while some issues did arise, as a whole, most participants had a positive experience with the gait sensors. These issues and recommendations that arose from the Bridgepoint and Keio studies will help inform future design iterations.
6.3.1 Data Analysis
Future work can be done on the signal processing of the collected gait data. The collected data sets will be large, and work will need to be done to clean up these data and analyze the data for gait parameters that can help assess a patient’s gait.

6.3.2 Focus on Researcher Experience
In addition to addressing the issues identified in the Bridgepoint study, further study can be done into the overall experience of using gait sensor packages. This study focused on the patient experience when using the gait sensors – future studies could focus on the researcher experience. It is important that all users of the device have a positive experience with no usability problems. These future studies could address the device calibration, data download and data output of the gait sensors.

6.3.3 Involve Patients in their Own Care
Future work can also explore how feedback concerning the gait measurements can be presented to patients in a way to engage them in their own neurorehabilitation. Some participants expressed an interest in seeing how their gait measurements changed over time, and would have benefited from seeing gait data visualised in a consumable and meaningful manner while they were still at Bridgepoint Hospital.
Making gait analysis cheaper and more convenient is a step towards greater patient self-efficacy. In diabetes management, it has been found that involving patients in their own health monitoring (such as blood glucose monitoring), can result in dietary changes (McAndrew et al., 2011) and a decrease in diabetes related morbidity for type 2 diabetes patients (Martin et al., 2006). Similar work can be done using gait monitoring to explore whether involving patients in their own gait monitoring can positively affect progress and outcome.
By making gait data accessible to patients, work can be done to involve patients in their own care. Anderson et al. (1995) have shown that patient empowerment is associated with improved blood glucose control in patients with diabetes.

The feedback from gait analysis monitors can give participants a tangible connection to their own progress, and this may help motivate them to work on their own rehabilitation.
References


8 Appendices
Appendix A: Keio Sensor Package Screen

Screenshot of custom interface for downloading data from Keio sensor package. The table on the left lists raw accelerometer values against a timestamp. The graph on the right charts raw accelerometer data.
Appendix B: List of Gait Videos

These videos were shown to participants during Keio Study for gait mimicking:

Shuffle gait: http://www.youtube.com/watch?v=ylHZWO17W70


Appendix C: IML Sensor Package Hardware Details

Schematic diagram of the IML sensor package hardware

- **Sensors**
  - IMU
    - 3-Axis Accelerometer
    - 2-Axis Gyroscope
  - Microcontroller

- **Peripherals**
  - Real-time clock
  - MicroSD Card
  - Power management
  - USB Interface
  - Sensor calibration hardware
Appendix D: Additional Views of IML Sensor Package Casing

Additional views of the IML sensor package casing

(Image credit: Phil Lam)
Appendix E: IML Sensor Package Calibration Program

Screenshot of calibration program used for IML sensor package programming.
Appendix F: Research Ethics Approval and Documents
Re: Ambulatory Gait Analysis

Dear Dr. Heslegrave,

Please find below our clarifications and modifications for the protocol submitted for full Board review of the project entitled “Ambulatory Gait Analysis”. We also request to extend the termination date of the study to June 30 2011 to coincide with the ethics proposal we have submitted to the University of Toronto and to account for any problems we may encounter in developing the sensors.

The modifications that have been made are as follows:
1. The protocol and consent forms now state that subjects will wear the sensors twice a week for six weeks.
2. The measurement package to be used includes both five degree of freedom accelerometers (x, y, z, yaw, and roll) and gyroscopes. We will add an intermediate step between raw data and gait analysis where the sensor data is interpreted in terms of the trajectory of the foot in space. Thus, instead of looking for points of interest in accelerometer data and estimating the likelihood that they correspond to certain features of gait, we’ll identify deterministic values such as where the foot stopped moving when it was on the ground, and how long the stride was. Three measures of particular interest (based on past research on gait disability, aging, and falls risk) that we plan to measure are: vertical acceleration from a foot flat position; stride length variability; stance width.
3. In the Information Letter, the contact information for the Student Researcher has been added.
4. The description for gait has been simplified to “how you walk” in the consent forms.
5. The information that will be taken from the chart (“proper medical diagnosis, reason for your stay at Bridgepoint Hospital, history of falls, admission and discharge date, and balance scores from your balance tests at Bridgepoint Hospital”) has been added to the consent form.
6. The signature line for the person obtaining consent has been added to the form.

Thank you,

Anita Ko
Master of Applied Science Candidate
Interactive Media Lab, Mechanical and Industrial Engineering, University of Toronto
anitako@mie.utoronto.ca
416 318 6606

Enclosed:
REB application
Application for access to retrospective data for research
Study protocol
Operational impact form
Curriculum vitae of the Principal Investigator (attending physician on neurorehabilitation units) at Bridgepoint Health, co-investigator and student researcher
JREB ID NUMBER: (office use only)

Joint Bridgepoint-West Park – Toronto CCAC Research Ethics Board (JREB)
Research Application

congruent with the Toronto Academic Health Sciences Council
Human Subjects Research Application

All sections of this application MUST be completed before it will be considered for REB review. If not applicable, indicate “N/A”. Unless indicated, the Research Ethics Board Application questions must be completed in the space provided. A complete application must be submitted to each site where this research will take place. A separate protocol must also be included with the application.

SECTION I: GENERAL INFORMATION

1. PRINCIPAL INVESTIGATOR NAME:

| Title: Dr. | Last Name: Sieminowski | First Name: Tammy |

2. FULL STUDY TITLE:
Ambulatory Gait Analysis

3. SOURCE OF FUNDING:

| Sponsor Name: |
| Sponsor Protocol Number (if applicable): |
| Granting Agency Name: |
| Internal Funding: |
| Other: |

☐ Funding obtained  ☐ Funding applied for (expected date of decision):

☒ No funding required (explain):
The sensors will be paid for using Professor Chignell’s NSERC Discovery Grant

4. INVESTIGATORS:

A. PRINCIPAL INVESTIGATOR

| Title: Dr. | Last Name: Sieminowski | First Name: Tammy |
| Dept/Div: Medicine | Program: Neurorehabilitation |
| Telephone: 416-461-8251 x1969 | Pager: 416-714-8262 | Fax: n/a |
Street Address: 14 St. Matthews Road  
Line 1  
Line 2  
City: Toronto  Province: Ontario  Postal Code: M4M 2B5  Email: TSiemino@bridgepointhealth.ca

**PRINCIPAL INVESTIGATOR AGREEMENT** - I assume full responsibility for the scientific and ethical conduct of the study as described in this REB application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects and any other relevant regulations or guidelines. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and experienced or will undergo appropriate training to fulfill their role in this project.

Signature of Principal Investigator  
Date

**B. CO-INVESTIGATOR(S):**

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Institution</th>
<th>Dept/Div/Program</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chignell</td>
<td>Mark</td>
<td>University of Toronto</td>
<td>Mechanical and Industrial Engineering</td>
<td></td>
</tr>
<tr>
<td>Ko  (Student researcher)</td>
<td>Anita</td>
<td>University of Toronto</td>
<td>Mechanical and Industrial Engineering</td>
<td></td>
</tr>
</tbody>
</table>

**C. STUDY COORDINATOR OR RESEARCH ADMINISTRATIVE CONTACT FOR THIS APPLICATION (if not the PI):**
Not Applicable ☐

<table>
<thead>
<tr>
<th>Title: Ms.</th>
<th>Last Name: Ko</th>
<th>First Name: Anita</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone: 416 318 6606</td>
<td>Pager: n/a</td>
<td>Fax: 416-978-7753</td>
</tr>
</tbody>
</table>
| Street Address:  
Line 1 5 King’s College Road | | |
| Line 2 | | |
| City: Toronto  Province: Ontario  Postal Code: M5S 3G8  Email: anitako@mie.utoronto.ca |

Indicate to whom correspondence should be mailed: ☐ PI  ☑ Administrative Contact

**D. ON STAFF INVESTIGATOR (for studies initiated outside of this institution)*:**
Not Applicable ☑
Title: Prof.  Last Name: Chignell  First Name: Mark
Dept/Div: Applied Science and Engineering  Program: Mechanical and Industrial Engineering
Telephone: 416-978-8951  Pager: n/a  Fax: 416-978-3453
Street Address: Line 1 40 St. George Street, Room 8171
Line 2 University of Toronto
City: Toronto  Province: Ontario  Postal Code: M5S 2E4  Email: chignell@mie.utoronto.ca
Signature:  Date: 

6. DIVISION/DEPARTMENT/PROGRAM APPROVAL
I am aware of this proposal and support its submission for ethics review. I consider it to be feasible and appropriate. I attest that the principal investigator responsible for this study has the qualifications and expertise to carry out this study in a competent and professional manner.

Name (Print)  Div./Dept./Program (Print)  Signature  Date

7. STUDY PERIOD:
Expected Start Date: June 2010  Total Study Duration: 6 months

8. INVESTIGATOR CLASSIFICATION
Staff Research: □ YES ☒ NO
Student Research: □ Post-Doctoral ☒ PhD □ Master’s □ Undergraduate □ Resident/Fellow

Note: Where an investigator is a student/trainee, it is expected that the supervisor will be the Principal Investigator. If the supervisor is not on staff at the research site, check with your institution regarding who may be the PI.

Other (specify):

9. PRIOR ETHICS/SCIENTIFIC/SCHOLARLY REVIEW

<table>
<thead>
<tr>
<th>Application submitted to (check all that apply):</th>
<th>Ethics Review and Approval Status (check all that apply and indicate date where applicable):</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Bridgepoint/West Park/Toronto CCAC</td>
<td>Application To Be Submitted</td>
</tr>
<tr>
<td>[ ] Other Institutions in the Toronto Area</td>
<td>☒</td>
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<tr>
<td>[ ] Baycrest Centre for Geriatric Care</td>
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<tr>
<td>[ ] Bloorview MacMillan Children’s Centre</td>
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<tr>
<td>[ ] Centre for Addiction and Mental Health</td>
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<tr>
<td>[ ] Hospital for Sick Children</td>
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<tr>
<td>[ ] Mount Sinai Hospital</td>
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<tr>
<td>[ ] St. Michael’s Hospital</td>
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<tr>
<td>[ ] Sunnybrook and Women’s College Health Sciences Centre</td>
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<tr>
<td>[ ] Toronto Rehabilitation Institute</td>
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<tr>
<td>[ ] University Health Network</td>
<td>☒</td>
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<tr>
<td>[ ] Other (Specify )</td>
<td>☒</td>
</tr>
</tbody>
</table>

*Include all relevant correspondence related to ethics review (i.e., REB review letter, replies, approval letter). If applying to more than one site, indicate which will be the primary site for ethics review:

A. Has this proposal received prior scientific peer review? □ YES ☒ NO

If YES, indicate where and attach any relevant reviewer comments.

If NO, refer to institutional instruction page regarding possible review requirements.

B. Is this protocol associated (e.g. extension, roll over) with a previously approved study at this institution? □ YES ☒ NO

If YES, indicate:
Name of Principal Investigator: 
REB file number: 

10. MATERIAL TRANSFER AGREEMENT
Is there a material transfer agreement (MTA) involving human material for this study? (This refers to an agreement for transfer of biological materials (e.g., tissues, cell lines) from the institution to another institution or other entity.)

☐ YES  ☒ NO

If YES, attach a copy.

11. INVESTIGATIONAL DRUGS OR DEVICES
Not Applicable

A. Does this study involve any of the following (check all that apply):
☐ Investigational New Drugs
☐ Investigational Biologics
☐ Investigational Natural Health Products (NHP)
☐ Investigational Medical Devices
☐ Approved drug for a new indication (e.g., new age-group, disease entity)?

B. If the study involves any of the above:
Is “No objection” or authorization letter from Health Canada attached?

☐ YES  ☐ NO

If no, has a Clinical Trial Application (CTA) been submitted (or will soon be submitted) to Health Canada?

☐ YES  ☐ NO

If pending, provide date of submission: 

Health Canada “No Objection” file #: 

If “No objection” letter or authorization is pending, forward approval letter to the REB office as soon as it is available.

C. Provide FDA IND number (drug studies) or PMA number (device studies):

☐ Not Applicable
☐ Pending (if pending, forward to the REB office when available)

SECTION II: STUDY SUMMARY

NOTE: THIS IS NOT A SUBSTITUTE FOR THE FULL PROPOSAL.

12. ABSTRACT
Must be a summary of study suitable for lay audience.

(Max. 100 words.) This is a quantitative study aiming to investigate the utility of acceleration as an evaluative measure of neurorehabilitation. Participants will wear accelerometer sensors on their shoes one or two times a week for six weeks. The data collected will then be analyzed to determine changes in gait throughout the participants’ neurorehabilitation.
13. **RATIONALE AND HYPOTHESIS/RESEARCH QUESTION**
   Include the significance of the study. (Max 1/2 page)

   Many balance assessment tools have been developed to measure a patient’s gait and balance. Clinicians at Bridgepoint Hospital make use of the Berg Balance Score, Community Balance and Mobility Scale, and Six-Minute Walk to evaluate the gait of neurorehabilitation patients. These tools require a dedicated testing area and physiotherapist assessment.

   This research project will explore the use of accelerometers as a tool to quantitatively evaluate changes in gait during neurorehabilitation. Accelerometers may be attached to patients’ shoes to measure the acceleration in their gait as they go about their day-to-day activities. The purpose of this study is to assess whether or not the acceleration data may be used to gauge changes in the patients’ gait.

   If acceleration is found to be a good measure of change in gait, it may eventually be used as a tool to measure a patient’s progress through their neurorehabilitation.

14. **STUDY DESIGN**
   (Many of these questions apply to clinical research studies. If any of the items are not applicable to your study, indicate N/A):

   **A. Describe Design/Methodology.**
   Indicate Clinical Trial Phase (I, II, III, IV) where appropriate. (Max 1 page)

   This is a quantitative study that will study changes in gait of neurorehabilitation patients. The neurorehabilitation patients screened and eligible for the study will be asked to provide consent to participate in the experiment. Accelerometer sensors will be attached to the existing footwear of each consenting patient for a period of 24 hours, one – two times per week for six consecutive weeks.

   The student researcher will attach and detach the sensors from the patients' footwear each week. The student researcher will then collect the data for analysis.

   Consenting patients’ medical records will be checked for primary diagnosis, demographic information, history of falls, Berg Balance scores, Six Minute Walk scores and Community Balance and Mobility Scale scores.

   **B. What are the primary outcome measures?**
   - [☐] Not applicable
Measure changes in gait made over the course of inpatient neurorehabilitation

C. List any criteria for premature withdrawal of a subject from the study for safety concerns.
   □ Not applicable
   Patient will be withdrawn from the study if there is any concern expressed by the patient, unit staff, or investigators suggesting the sensor may be adversely affecting the patient’s mobility. The unit staff (RNs/therapists/etc) will be briefed on the study prior to the start, and will be asked to make the Principal Investigator aware of any safety concerns with respect to the sensors.

D. Is a placebo used in this study? □ YES □ NO
   If YES, how is this justified (e.g., no alternative standard treatment available)? Include any provisions in place to reduce risks to subjects assigned to placebo (e.g., increased monitoring, rescue medication). (Max ¼ page)

E. Does the study involve deception or intentional lack of disclosure? □ YES □ NO
   If YES, explain justification and how subjects will be debriefed. (Max ¼ page)

F. Will the subject be withdrawn from or denied usual therapy for any condition in order to participate in the study or be subject to other restrictions? □ YES □ NO
   If YES, explain. (Max ¼ page)

15. SUBJECTS/CONTROLS
   A. How will subjects be chosen (main inclusion/exclusion criteria)?
      If applicable, how was the proposed control group selected? (Max ¼ page)
      The study population will be recruited from the two neurorehabilitation units at Bridgepoint. The principal investigator, who is responsible for the care of these patients, will screen the patients for the student researcher.

      The inclusion criteria are: patient has been admitted to Bridgepoint Hospital for neurorehabilitation, is above 18 years of age, is capable to consent to personal care decisions, is able to communicate in English, ambulates independently (with or without gait aids).

      i. What is the age range of eligible subjects?
         Above 18 years of age.
B. Number to be enrolled at this institution: 15  Total study enrolment: 15

C. Approximate size of eligible population from institution/practice: 75

D. Is sample size justified in the protocol? ☑ YES ☐ NO
   If NO, provide sample size justification.
   (Max ¼ page)

   The sample size of 15 is based on the time and number of accelerometer sensors available and also the size of eligible population. Based on the experience of the principal investigator, there should be approximately 6 to 10 qualified patients at the onset of the experiment, with 1-2 new patients starting neurorehabilitation each week.

16. STUDY INTERVENTIONS or PROCEDURES INVOLVING HUMAN SUBJECTS

   Not Applicable (e.g. observational studies). ☑
   If not applicable, go directly to 16. DATA ANALYSIS.

   A. Usual standard of care.
      Document what is the usual standard of care at this institution for this population.
      Not Applicable ☐
      (Max ½ page)

   B. Changes/additions to usual standard of care.
      Indicate what procedures are to be carried out in the study, that are NOT considered part of the diagnostic, therapeutic "routine" or standard care of the subject or how standard care is altered. Attach a copy of all instruments (i.e., questionnaires, rating scales, etc.)
      (Max ½ page)

   C. What are the additional risks associated with the study as compared to usual standard of care?
      Do not refer to other sections of this form.
      (Max ½ page)

   D. Subject Time Commitments.
      Indicate duration of study visits or extra time commitment (length, number, and frequency of test sessions) for study participation.
      (Max ¾ page)
17. **DATA ANALYSIS**
   Briefly explain what methods will be used to analyse study data. You may refer to protocol for this questions.
   (Max ¼ page)
   The gait data of each participant will be compared over the 6 weeks to gauge changes in gait parameters (e.g. gait speed, stride length, single leg stance time, sway, etc). The changes in gait will also be compared to the patients’ Berg Balance Scores, Six Minute Walk scores and Community Balance and Mobility Scale scores given by their physiotherapists to determine the validity of the gait data.

   The measurement package to be used includes both five degree of freedom accelerometers (x, y, z, yaw, and roll) and gyroscopes. We will add an intermediate step between raw data and gait analysis where the sensor data is interpreted in terms of the trajectory of the foot in space. Thus, instead of looking for points of interest in accelerometer data and estimating the likelihood that they correspond to certain features of gait, we'll identify deterministic values such as where the foot stopped moving when it was on the ground, and how long the stride was. Three measures of particular interest (based on past research on gait disability, aging, and falls risk) that we plan to measure are: vertical acceleration from a foot flat position; stride length variability; stance width.

**SECTION III: ETHICAL ISSUES**

18. **RECRUITMENT AND CONSENT**
   
   Note: Any document to be viewed by the subject (e.g. consent/assent forms, information sheets, recruitment posters/letters) must be included with your submission. Refer to the other materials in this package for more detailed instructions.

   **A. How will potential subjects be identified and/or referred?**
   
   ☒ Healthcare professional
   ☐ Permanent Health Record/Clinical Chart
   ☐ Other Existing Database (specify):
   ☐ Advertisements, including web based recruitment tools (attach a copy if applicable)
   ☐ Other (specify):

   i. Indicate who will identify potential subjects.
   (Max ¼ page)
   Principal investigator who is an attending physician on neurorehabilitation units

   ii. Explain how enrollment in multiple studies is managed in this patient population at this institution.
   Not Applicable ☒
   (Max ¼ page)
B. Explain who will make initial contact with subjects or authorized third party and how (e.g. in person, phone, letter, e-mail/web site). Attach a copy of the script or any written materials if applicable.
(Max ¼ page)

The principal investigator will make initial contact with subjects in person. A permission to contact consent letter will be given to interested patients for them to consider participating in this study. The Principal investigator will be blinded to this response.

C. Describe the consent process. (E.g., Will consent be written, oral, telephone (include script), and who will obtain consent.) If the study population requires special consent considerations (e.g. child, incompetent adult, unable to communicate) you may refer to item E. of this section.
(Max ¼ page)

Patients identified as meeting the criteria will be asked to consider consenting to being contacted by the student researcher and asked to complete an initial consent form. The physician making the initial contact will be blinded to this response, to avoid a conflict of therapeutic relationship. In the case where the patient consents, a third party will collect the response and contact the student researcher. At this point, the final consent form and additional study details will be provided to the patient.

i. How much time will be given to subjects to review the information before being asked to give consent? 1 week

D. Is there a relationship between the subjects and:

Person obtaining consent  □ YES  ☒ NO
Investigator            □ YES  ☒ NO

If YES, explain the nature of the relationship (e.g., physician, employer) and what steps will be taken to minimize a potential perception of coercion.

E. Will this research involve any of the following? (check any that apply):

☐ genetic research  ☐ women of child-bearing potential
☐ tissue samples    ☐ pregnant women
☐ healthy volunteers ☐ children less than 16 years of age
☐ students         ☐ fetal tissue or placenta
☐ staff            ☐ incompetent subjects
☐ prisoners        ☐ borderline incompetent subjects
☐ involuntary subjects ☐ subjects unable to communicate
☐ emergency patients ☐ individuals who may require translation or who are illiterate
☐    ☐ individuals temporarily unable to provide an informed consent (e.g. unconscious, emergency?)

☒ none of the above
The above list identifies research that may require special consideration, e.g. regarding confidentiality, voluntariness, risk or capacity to consent. If the research will involve any of the above attach a summary explaining how the subject’s interests will be protected, how capacity will be determined (if applicable) and how surrogate consent and assent (if applicable) will be obtained. Where inability to provide an informed consent is expected to be temporary, describe what plans are in place to regularly assess capacity and to obtain consent if the individual later becomes capable of providing consent. For subjects who have limited skills in English or are illiterate, attach a summary explaining what special procedures are in place (e.g., translated forms, translator, impartial witness).

19. **RISK/BENEFIT ESTIMATES**

   **A. Potential Benefits to Subjects**
   List anticipated benefits if any. ☒ No direct benefits anticipated.

   **B. Potential Harms (Injury, Discomforts and Inconveniences) to Subjects (including psychological factors):**
   i. Document the risks to subjects involved in this research. ☐ NO known risks
   
   (Max ¼ page)

   No discomfort is anticipated. While the sensors are very small and light, there is a very small chance that they will influence on the patient’s mobility (because of the extra weight on their foot). Depending on the availability of the sensors, there may be cases where patients have only one shoe with a sensor attached. Sensors will be placed to minimize inconvenience with donning and removing footwear. The student researcher will visit the participant to place the sensors on their shoes and to remove the sensor 24 hours later.

   a. For studies involving placebo, washout, or withholding of treatment, indicate risks related to absence of treatment. Not Applicable ☐

   b. Include a summary of the data regarding reproductive risks such as teratogenicity or embryotoxicity of the study drug, any risk with breastfeeding, or risk to men regarding conception. Not Applicable ☒
   
   (Max ¼ page)

   ii. Does participation in this study affect alternatives for future care? (e.g. development of antibodies that could prohibit future treatment with this or similar compounds) ☐ YES ☒ NO
   
   If YES, explain.
   
   (Max ¼ page)

20. **PAYMENTS TO SUBJECTS**

   Indicate what payments, if any, will be provided to subjects: None
☐ Reimbursement for expenses incurred as a result of research. Amount: $ 
Specify (e.g., travel, meals)

☐ Gifts for participation Value: $

☐ Compensation for time Amount: $
If compensation for time will be provided, please justify:

21. **MONITORING**

A. Is there a steering committee? ☐ YES ☐ NO ☒ Not Applicable

B. Is there a plan for monitoring of the study (e.g., sponsor-initiated site visits)? ☐ YES ☐ NO ☒ Not Applicable
If YES, describe:
(Max ¼ page)

C. Is an interim analysis planned? ☐ YES ☒ NO
If YES, describe briefly.

D. Is there a data and safety monitoring board (DSMB)? ☐ YES ☒ NO
If NO, please justify:
The data collected in the study is only identified by unique identification numbers. Patients’ names will not be recorded.

If YES, is it independent of the sponsor? ☐ YES ☐ NO

22. **POTENTIAL CONFLICTS OF INTEREST**

Does the principal investigator or any co-investigators involved in this research study or any member of their immediate family:

☐ Function as an advisor, employee, officer, director or consultant for the study sponsor?

☐ Have direct or indirect financial interest in the drug, device or technology employed (including patents or stocks) in this research study?

☐ Receive an honorarium or other personal benefits from the sponsor (apart from fees for service)?

☒ None of the Above

If any of the above conflicts apply, append a letter to the Chair of the REB, detailing these activities and how they will be managed. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project.
23. **PUBLICATION /DISSEMINATION OF RESULTS**

A. Is there an independent steering committee regarding publication?  ☐ YES  ☑ NO

B. How will the results be communicated to subjects and other stakeholders (e.g. advocacy groups, scientific community)?
Check all that apply:

- ☐ Individual debriefing at end of test session  ☑ Publication (e.g., journal article, presentation)
- ☐ Group debriefing  ☐ No plan
- ☐ Letter of appreciation at end of study
- ☐ Other (specify):

**SECTION IV: FUNDING and CONTRACTS**

24. **BUDGET**

Attach an itemized study budget (applies to full board and expedited review studies).

Do the funds presently available or applied for cover all requirements to conduct the project?  N/A  ☑ YES  ☐ NO

If NO, explain how the shortfall will be made up:

25. **CONTRACT/RESEARCH AGREEMENT**

- ☑ No Contract/Research Agreement Involved
- ☐ Contract/Research Agreement Involved

Name of sponsor/agency:

Has the contract/research agreement been submitted for review and signing (see institution specific instruction page)?  ☐ YES  ☑ NO

A. Liability

i. Is there external (non-institutional) liability insurance?  ☐ YES  ☑ NO

ii. If the subject suffers an injury as a result of participation in the study, who will cover reasonable out-of-pocket expenses to ensure that immediate medical care is provided?

☐ Sponsor  ☐ Institution
☐ Other (specify):

B. Publication Agreements

i. Is there an agreement between the investigator and the sponsor
regarding use, publication or disposal of the data? □ YES □ NO

If YES, does the funding agency or sponsoring company place any restrictions on publication of findings or reporting of interim results? □ YES □ NO

If YES, explain any restrictions.

ii. Does the contract/research agreement permit the disclosure of research results, including SAEs, to stakeholders (subject and/or guardian, sponsor, REB, REBs of other sites, and regulatory agencies) if required to protect the health of subjects? □ YES □ NO

SECTION V: PRIVACY AND CONFIDENTIALITY

26. PRIVACY AND CONFIDENTIALITY

Under the Personal Health Information Protection Act (Bill 31) which came into force in Ontario on Nov. 1, 2004, the following information must be provided to the Research Ethics Board (REB) when requesting approval of research studies involving the collection, use and disclosure of personal health information.

A. Describe all personal health information required to be collected and the potential sources of this information. If subject identifiers will be used on data collection forms (e.g., names, initials, DOB, OHIP #, Hospital ID# etc.), provide justification.

(Max 1/3 page)

No personal identifiers will be collected. Consenting patients’ hospital chart will be checked for primary diagnosis, admission date, discharge date, demographic information (age, gender), history of falls, balance scores (Berg Balance Scores, 6 minute walk scores, Community Balance and Mobility Scale scores).

B. Describe how the personal health information will be used in the research.

(Max 1/3 page)

The personal health information will be used to gauge if accelerometer gait data is a good measure of changes in patient gait. Changes in the Berg Balance scores, 6 minute walk score and Community Balance and Mobility Scale scores will be compared to changes in the acceleration data.

C. If personal health information is to be linked to other information, provide the following details: NA ☒

i) Describe the information that the personal health information will be linked to.

ii) Explain how the linkages will be made.

iii) Explain why these linkages are required.
D. Explain why the research cannot reasonably be accomplished without using personal health information. (Max 1/4 page.)
The purpose of the study is to measure the utility of acceleration as a means to measure gait. The personal health information will be compared with the data from the sensors to gauge how well acceleration can measure changes in gait.

E. If consent to the disclosure of the personal health information is not being sought from the individuals to whom the information relates, provide justification as to why it would be impractical to obtain explicit consent.
N/A

F. Describe the reasonably foreseeable harms and benefits that may arise from the use of the personal health information, and how the harms will be addressed. (Max ¼ page)
No foreseeable harms associated with collection of personal health information as no personal identification information will be collected.

The foreseeable benefit is an increased understanding of the utility of acceleration as a means to measure gait.

G. Describe all persons who will have access to the personal health information, their roles in relation to the research and reason for access, and their related qualifications.

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
<th>Qualifications</th>
<th>Role/Reason for Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Tammy Sieminowski</td>
<td>Bridgepoint Hospital</td>
<td>MD, CCFP</td>
<td>Principal investigator/ to determine reason for neurorehabilitation and falls history</td>
</tr>
<tr>
<td>Anita Ko</td>
<td>University of Toronto</td>
<td>BASc, MASc student</td>
<td>Student researcher/ to determine reason for neurorehabilitation and falls history</td>
</tr>
</tbody>
</table>

H. i) Describe the safeguards that will be imposed to protect the confidentiality and security of the personal health information. (Max ¼ page)
Patients will only be identified using a unique patient identification number to protect confidentiality. Electronic files will be protected by passwords. Hard copies of collected data will be kept in a locked cabinet in an office accessible only by the student researcher, co-investigator and principal investigator.

ii) Indicate how long personal health information will be retained in an identifiable form and why.
The data will be destroyed following the completion of the analysis in the fall of 2010.

iii) Who will have access to these data in the future.
Principal investigator, co-investigator and student researcher.
I. Describe how and when the personal health information will be disposed of or returned to the health information custodian.  
(Max ¼ page)

The personal health information will be disposed of by shredding any written materials containing identifiable personal information when the study is complete.

J. Has the investigator applied for approval to another REB?  ☐ Yes ☒ No
If yes, provide the response to or status of the application.

K. Describe whether the investigators’ interest in the disclosure of the personal health information or the performance of the research would likely result in an actual or perceived conflict of interest with other duties of the researcher.
Not Applicable ☒

L. Describe the anticipated public or scientific benefit of this study.
The anticipated public benefit is that improvements and changes in gait can be identified during neurorehabilitation, resulting in the potential for more accurate and personalized neurorehabilitation.
Title: Ambulatory Gait Analysis

Introduction
Bridgepoint Health is a health care organization that provides “patient care, research, and teaching in the specialized field of Complex Chronic Disease prevention and management” (Bridgepoint Health). It is comprised of Bridgepoint Hospital, Bridgepoint Family Health Team, Bridgepoint Collaboratory for Research and Innovation and Bridgepoint Health Foundation.

This study will be done at Bridgepoint Hospital. Bridgepoint Hospital provides short-term care to patients living with disabilities, multiple diseases, as well as those seeking rehabilitation after a sudden illness. The neurorehabilitation service provides care for patients recovering from a stroke or acquired brain injury. Patients usually stay from one to six months (Bridgepoint Health).

This is a quantitative study aiming to investigate the utility of acceleration as an evalutative measure of neurorehabilitation. Participants will wear accelerometer sensors on their shoes one or two times a week for six weeks. The data collected will then be analyzed to determine changes in gait throughout the participants’ neurorehabilitation.

Literature Review
Many balance assessment tools have been developed to measure a patient’s gait and balance. This research project will explore the use of accelerometers as a tool to evaluate changes in gait during neurorehabilitation. Current tools can generally fall into three categories:

“(i) Comprehensive medical assessments performed by geriatricians or nurse practitioners in the out patient or nursing home setting

(ii) Nursing fall risk assessments completed in hospital and nursing home settings
(iii) Functional mobility assessments completed by physical therapists or physicians in an outpatient setting.” (Perell, 2001)

Clinicians at Bridgepoint Hospital make use of the Berg Balance Score, Community Balance and Mobility Scale, and Six-Minute Walk to evaluate the gait of neurorehabilitation patients.

**Berg Balance Score**

The Berg Balance Score is the method that is used most consistently at Bridgepoint Health. The Berg Balance Score is assigned based on fourteen observable balance items (e.g. ability to sit unsupported, changing from sitting to standing, changing from standing to sitting, unsupported standing, etc). Each item is given a score between 0 and 4, and the fourteen scores are summed to determine an overall balance score. Scores between 0-20 roughly indicate wheelchair bound; 21-40 roughly indicates walking with assistance and 41-56 roughly indicates independent. (Berg, Wood-Dauphinee, Williams, Gayton, 1989)

Stevenson (2001) found that a 5-7 point change in the Berg Balance score is necessary to ascertain with 90% certainty that a change in Berg Balance score performance has occurred in those undergoing cerebrovascular accident rehabilitation. However, the agreement between the 5-7 point necessary change and clinician assessment was poor, possibly indicating a lack of standardization in how clinicians viewed change (Stevenson, 2001).

**Community Balance and Mobility Scale**

After patients have achieved a Berg Balance Score above 55-56, clinicians at Bridgepoint Hospital generally begin using the Community Balance and Mobility Scale as a measure of their balance and gait.

Patients are asked to perform a series of thirteen tasks (e.g. unilateral stance, tandem walking, tandem pivot, etc). These tasks are done without walking aids (with the exception of descending stairs). For each task, the subject is given a rating between 0 and
Six Minute Walk

The six-minute walk is another test performed by clinicians at Bridgepoint Hospital. This test is performed with less consistency than the Berg Balance Score. In this test, the patients distance is measured after a six-minute walk. Supplemental measures include blood oxygen saturation and perception of dyspnea during the walk. Low distance indicates a need to search for causes of gait impairment (Enright, 2003)

Clinical Gait Analysis

During clinical gait assessment, clinicians generally study a patient’s gait, and make qualitative assessments. Clinicians study a patient’s gait, and determine if the gait is normal or abnormal. Abnormal gait may then be classified (Krishnamurthy and Verghese, 2006). These assessments are often unreliable and difficult to compare across visits (Bamberg, 2008).

Quantitative Measures

This study will make use of quantitative gait measures to assess the gait of neurorehabilitation patients. Common quantitative measures include:

Heel strike and toe off timing

Step Length

Sway

Sway is the spontaneous motion during standing. Sway is thought to increase marginally during adult life (Wolfson, 2001).

Single Leg Stance Time

Single leg stance time measures the ability to stand with a narrowed base of support. Single-leg stance time should not change between the third and sixth decades, but
decreases during the seventh and eighth decade. (Wolfson, 2001)

**Functional Base of Support (FBOS)**

Functional base of support measures the limits of stability. It is “the percentage of the foot that can be used during backward and forward leaning” (Wolfson, 2001). FBOS should be stable through the sixth decade, after which it decreases steadily. (Wolfson, 2001)

**Gait Speed**

Gait speed has been used as a simple measure of gait. It stays relatively stable until the seventh decade and slows 15% per decade after that. Slowing gait speed may be associated with decreased stride length, single support time (when only one foot is on the floor) and double support time (when both feet are on the floor) (Wolfson, 2001). A study by Krishnamurthy (2006) on gait of non-disabled nonagenarians found that gait velocity was slower for nonagenarians than younger subjects.

**Methods**

**Study Population**

Bridgepoint Hospital provides active and slow stream neurorehabilitation for patients who have experienced a stroke, traumatic brain injury, subarachnoid hemorrhage, etc. All patients arrive with new neurologic deficits, some of which may impact their gait and mobility. Over the course of neurorehabilitation, patients work with physiotherapists and occupational therapists to improve mobility.

The mean age of patients is 61 yrs (SD 18.2, range [18,93]). The mean length of stay is 47 days (SD 25, range [0,148]). The ratio of diagnoses is: stroke (53.0%), traumatic brain injury (16.4%), subarachnoid hemorrhage (5.7%), subdural hematoma (3.7%), other (21.1%).

The study population will be recruited from the two neurorehabilitation units at
Bridgepoint. The principal investigator, who is one of the attending physicians on the neurorehabilitation units, will screen the patients for the student researcher. Patients identified as meeting study criteria will be asked to consider consenting to being contacted by the student researcher and asked to complete an initial consent form (see appendix). The physician making the initial contact will be blinded to this response, to avoid a conflict of therapeutic relationship. A third party will collect the response and contact the student researcher, if the patient consents to being contacted. At this point, the final consent form and additional study details will be provided to the patient (see appendix). Based on the experience of the principal investigator, there should be approximately 6 to 10 qualified patients at the onset of the experiment, with 1-2 new patients starting neurorehabilitation each week.

The inclusion criteria are: patient has been admitted to Bridgepoint Hospital for neurorehabilitation, is above 18 years of age, is capable to consent to personal care decisions, is able to communicate in English, ambulates independently (with or without gait aids). Patient will be withdrawn from the study if there is any concern expressed by the patient, unit staff, or investigators suggesting the sensor may be adversely affecting the patient’s mobility. The unit staff (RNs/therapists/etc) will be briefed on the study prior to the start of the study, and will be asked to make the Principal Investigator aware of any safety concerns with respect to the sensors.

The sample size of 15 is based on the duration of the study, number of accelerometer sensors available, and the anticipated size of the eligible population. Since data will be recording at a high sample frequency for long periods of time the size of the sample should be more than enough to detect changes in gait during the neurorehabilitation period.

Patients consenting to participate in the study will have small sensors secured to the top of their shoes. No discomfort is anticipated. While the sensors are very small and light, there is a very small chance that they will influence the patient’s mobility (because of the extra weight on their foot). Depending on the availability of the sensors, there may be cases
where patients have only one shoe with a sensor attached. Sensors will be placed to minimize inconvenience with donning and removing footwear. The student researcher will visit the participants to place the sensors on their shoes and to remove them 24 hours later.

Patient data will be identified using a unique patient identification number to protect confidentiality. No personal identifiers will be collected. Electronic files will be protected by passwords. Hard copies of collected data will be kept in a locked cabinet in an office accessible only by the student researcher, co-investigator and principal investigator. All data will be destroyed at the completion of the study.

**Research Design**
This is a quantitative study that will study changes in gait in neurorehabilitation patients. The neurorehabilitation patients screened and eligible for the study will be asked to provide consent to participate in the experiment. Accelerometer sensors will be attached to the existing footwear of each consenting patient for a period of 24 hours, two times per week for up to six consecutive weeks.

The student researcher will attach and detach the sensors from the patients’ footwear each week. The student researcher will then collect the data for analysis.

Consenting patients’ hospital chart will be checked for primary diagnosis, admission date, discharge date, demographic information (age, gender), history of falls, balance scores (Berg Balance Scores, 6 minute walk scores, Community Balance and Mobility Scale scores).

**Equipment**
The sensor device measures approximately 20mm x 45mm x 5mm, and will be housed in a plastic casing that is approximately 25mm x 50mm x 10mm. It will weigh approximately 50g, and will be capable of operating continuously for at least one week without human intervention.
The device will be attached to the subject’s shoes via mounting holes, through which the shoelaces can be threaded. This will ensure that the device is securely fastened to the top of the subject’s shoe, positioned so it does not impede activity. Alternately, Velcro straps can be used, for shoes which have Velcro fasteners.

Figure 1: Depiction of accelerometer sensor (in casing) on shoe

**Data Analysis**

The gait data of each participant will be compared over the 6 weeks to gauge changes in gait parameters. The changes in gait will also be compared to the patients’ Berg Balance Scores given by their physiotherapists to determine the validity of the acceleration data.

The measurement package to be used includes both five degree of freedom accelerometers (x, y, z, yaw, and roll) and gyroscopes. We will add an intermediate step between raw data and gait analysis where the sensor data is interpreted in terms of the trajectory of the foot in space. Thus, instead of looking for points of interest in accelerometer data and estimating the likelihood that they correspond to certain features of gait, we'll identify deterministic values such as where the foot stopped moving when it
was on the ground, and how long the stride was. Three measures of particular interest (based on past research on gait disability, aging, and falls risk) that we plan to measure are: vertical acceleration from a foot flat position; stride length variability; stance width.

**Clinical Relevance**
Currently at Bridgepoint Hospital, Berg Balance Scores and the Community Balance and Mobility Scales are used to measure patients’ balance and gait. These measures are taken at intervals, and trends may be difficult to determine when there are large time intervals present. The use of a non-invasive sensor that quantitatively measures a patient’s gait and balance may be useful for clinicians in determining a patient’s progress during neurorehabilitation. In addition, more frequent updates on a patient’s balance and gait status may help clinicians make decisions regarding additional gait rehabilitation and intervention.

**Operations Impact**
None anticipated

**Budget Information**
This project does not involve any monetary cost, The sensors will be paid for through Professor Chignell’s NSERC Discovery grant.

**Project Timeline**
In the case of REB approval, the principal investigator will start screening patients in early June 2010. The student researcher will then contact patients who have consented to being contacted. The student researcher will begin attaching the accelerometers to the footwear of consenting patients in June and July 2010. The student researcher will attach and detach the sensors from the patients’ footwear for 6 consecutive weeks for each patient.
Analysis of the data will begin after all the data has been collected in August. A final thesis report will be submitted in the fall of 2010 as part of the Master of Applied Science degree requirements of the student researcher.
References


Initial Consent Form to Being Contacted

Study: Ambulatory Gait Analysis

Date: _______________

Dear Volunteer,

Thank you for your consideration in participating in my research project. I am currently a Master of Applied Science student in the Mechanical and Industrial Engineering Department at the University of Toronto.

For my thesis project, I am researching how useful it will be to measure how patients walk as a tool to measure neurorehabilitation. This letter is to provide you with information so you may decide whether or not you wish to be contacted by me to participate in my study. Participation is completely voluntary and you are free to withdraw or stop at any time without penalty. Withdrawal of consent will not affect your therapeutic relationship with the health care staff at Bridgepoint Health.

At the end of this letter, you are given the opportunity to indicate if you wish to be contacted by me or to request more information before making a decision. If you agree to be contacted by me or would like more information, please sign and date the form. Please return one signed copy to me and keep the other copy for your reference. If you do not wish to participate, just keep the form.
You are not obligated to participate in my study. By signing this form, you are providing consent to be contacted by me.

The purpose of this study is to explore the use of small electronic ("accelerometer") sensors to measure gait (how you walk) as a means to evaluate the effectiveness of neurorehabilitation. You will be asked to wear a small sensor on your shoe for 24 hours twice a week for up to 6 weeks. The sensor will be attached securely to your shoe, and will measure how you walk as you go about your daily activities. I will attach the sensor and detach the sensor after 24 hours.

No personal or identifying information will be included in written reports or presentations and your confidentiality and privacy will be respected at all times. If you would like more information, you may contact me at anitako@mie.utoronto.ca or 416 318 6606.

Thanks for your consideration,

Anita Ko, Student Researcher
To be completed by Participants

Please select one of the three options below:

☐ I agree to be contacted by the student researcher.

☐ I need more information regarding the study before being contacted by the student researcher.

☐ I do not agree to be contacted by the student researcher.

I understand that I am free to withdraw from the project at any time. I am not obligated to participate in the study by signing this initial consent form.

If I do not wish to be contacted by the student researcher, I can just keep the form.

____________________________ (Signature)  _________________ (Date)

____________________________ (Printed name)

____________________________ (Phone number)

____________________________ (Email address (if applicable))
Client Information Sheet and Informed Consent Form
Study: Ambulatory Gait Analysis

From Student Researcher: Anita Ko, Master of Applied Science student, Mechanical and Industrial Engineering, University of Toronto

Date: ______________

Dear Volunteer,
Thank you for considering to participate in my thesis project. I am currently a Master of Applied Science student in the Mechanical and Industrial Engineering Program at the University of Toronto. This letter is to provide you with information so that you may decide whether or not you would like to participate in my study. Participation is voluntary and you are free to withdraw or stop at any time without penalty. Withdrawal of consent will not affect your therapeutic relationship with the health care staff at Bridgepoint Health.

I have included information about the study to help you make your decision. Please feel free to ask me any questions you may have. At the end of this letter, there is space to indicate if you wish to participate. If you wish to participate, please date and sign the letter. Please return one copy to me and keep the other for your reference. If you do not wish to participate, just keep the form. You may request a copy of the study.
The name of the study is “Ambulatory Gait Analysis.” The study aims to explore the utility of acceleration as an evaluative measure of neurorehabilitation. It is expected that data from this study will help our understanding of how people recover from strokes and injuries. A small sensor will be attached to your existing footwear. The sensor takes measurements of how your feet move while you are walking. The sensor is approximately 7 cm long, 3 cm tall, and 3 cm wide and weighs approximately 50g. This is about the same weight and size of a package of Tic-Tac mints. It will be attached to your shoes securely with the existing shoelaces for 24 hours at a time. I will both attach and detach the sensor from your shoes twice per week. You do not need to do anything besides go about your normal daily activities.

You will be asked to wear the sensor for two days per week for six consecutive weeks. At the end of the experiment, the data across the six weeks will be compared to determine changes in how you walk throughout your neurorehabilitation.

The data we collect will be kept in a secure office. At no time will the data be made public. No personal or identifying information will be included in written reports or presentations, and your confidentiality and privacy will be respected at all times.

As part of the study, I will need to know the proper medical diagnosis, reason for your stay at Bridgepoint Hospital, history of falls, admission and discharge date, and balance scores from your balance tests at Bridgepoint Hospital. Therefore, I will need to access your hospital chart for that information. No personal or identifying information will be included in written research reports or presentations that include your data and your confidentiality and privacy will be respected at all times.
There are no direct benefits and risks to participating in this study. However, we hope to better understand gait changes during neurorehabilitation. This may help develop more focused and personalized rehabilitation.

Any data and information received will be kept confidential. Any study reports and presentations will have all personal patient identifiers removed. Data and participant information will be kept in my possession or stored in a locked office accessible only by me and the other investigators. Electronic information will be password protected. All data will be securely stored until December 31 2010. All data will be destroyed after December 31 2010.

There is no cost or reimbursement for participating in this study. If you have any questions, you may contact myself at (416) 318 – 6606 or Dr. Tammy Sieminowski, the principal investigator at (416) 461 – 8251 x 1969 or the Research Ethics Board at (416) 461 – 8252 x 2343

Thank you for your consideration,

Anita Ko, Student Researcher
To be completed by participants:

☐ I have read this consent form and I understand the research and what is expected of me.

☐ I agree to participate in this study.

☐ I understand that I am free to withdraw from the project at any time.

If I do not wish to participate in the research, I can just keep the form.

______________________ (Signature)  __________________________ (Date)

______________________ (Name, please print)

______________________ (Witness Signature)  __________________________ (Date)

______________________ (Witness Name, please print)

I agree to allow Anita Ko (student researcher) to access my health records.

______________________ (Signature)  __________________________ (Date)

______________________ (Witness Signature)  __________________________ (Date)

______________________ (Person obtaining consent)  __________________________ (Date)
Bridgepoint Health
Research Study Operational Impact Assessment

Name of Study: Ambulatory Gait Analysis

Name of Principal Investigator(s): Dr Tammy Sieminski

Telephone: (416) 461-8251  Fax: ( )  N/A  Email: tsiemino@bridgepointhealth.ca

Name of Contact Investigator: Anita Ko

Telephone: (416) 318 6606  Fax: ( )  Email: anitako@mie.utoronto.ca

The time of the day the investigators plan to be at Bridgepoint 9:00 am – 5:00 pm

The investigator will identify areas/departments affected by research. The Service/Department Manager's signature is required for each of the service(s) that will be affected.

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<th>CLINICAL UNITS</th>
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<td>X 3 East</td>
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<td>☐ 5 West</td>
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Comments: (Please identify resource implications, concerns re: over use of patient population, etc)

Manager's Signature Required

No operational impact is anticipated. Student researcher will obtain consent, apply and remove accelerometers, and abstract data from patient charts for patients admitted to 3E or 7W who have consented to participate

In this study.

☐ approved

☐ approved with conditions (please list)

__________________________
Manager’s Signature

__________________________
Director’s Signature
Please return to the Research Office within 2 weeks.

Note: Operational impact approval does not constitute study approval. REB process will follow.
POST GRADUATE TRAINING

July 1, 1993 to June 30, 1995

Family Practice Residency Programme
Department of Family Medicine, University of Toronto
Toronto, Ontario

EDUCATION

September 2006 to December 2009

Master of Engineering
University of Toronto
Toronto, Ontario

September 1989 to May 1993

Doctor of Medicine
Faculty of Medicine, University of Toronto
Toronto, Ontario

September 1988 to May 1989

Bachelor of Science-second year
Faculty of Arts and Science, University of Toronto,
Toronto, Ontario

September 1987 to May 1988

Bachelor of Science-first year
Faculty of Arts and Science, McGill University
Montreal, Quebec
## PROFESSIONAL EXPERIENCE

<table>
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<tr>
<th>Date Range</th>
<th>Position</th>
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| June 2002 to Present  | **Attending Physician, Neurorehabilitation Units**<br>
                          *Bridgepoint Hospital (formerly Riverdale Hospital)*<br>
                          Toronto, Ontario                                                        |
| June 15, 2009 to Present | **Intake Physician, Neurology Services**<br>
                          *Toronto Rehabilitation Institute, University Site*<br>
                          Toronto, Ontario                                                        |
| July 2001 to June 2006 | **Family Physician**<br>
                          *Private Office*<br>
                          Toronto, Ontario                                                        |
| July 1995 to June 2003 | **Emergency Physician**<br>
                          *University Health Network*<br>
                          Toronto, Ontario                                                        |
| June 2000 to June 2001 | **Family and Emergency Physician**<br>
                          *Hot Spring County Hospital*<br>
                          Malvern, Arkansas                                                        |
| June 1997 to December 1999 | **Attending Physician, Cognitive Support Unit**<br>
                           *Riverdale Hospital*<br>
                           Toronto, Ontario                                                        |
| December 1999 to April 2000 | **Family Physician**<br>
                           *Australian Locum Medical Services*<br>
                           Perth, Australia                                                       |
| November 1998 to April 1999 | **Family Physician**<br>
                           *Australian Locum Medical Services*<br>
                           Melbourne, Australia                                                   |

## AWARDS

<table>
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<tr>
<th>Date</th>
<th>Award</th>
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<tr>
<td>June 1993</td>
<td>Juanita M. Thompson Rural Medicine Award</td>
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</table>
PROFESSIONAL MEMBERSHIPS AND CERTIFICATION

June 1993 to present  College of Physicians and Surgeons of Ontario (CPSO)
June 1995 to present  College of Family Physicians of Ontario (CCFP)
April 1998 to present  Ontario Medical Association
April 2001 to present  Canadian Medical Association
June 1993 to present  Canadian Medical Protective Agency
June 2000 to present  American Academy of Family Physicians
July 2001 to present  American Board of Family Medicine (Diplomat)

ADMINISTRATIVE ACTIVITIES

July 1, 2008 to present  President - Medical Staff Association, Bridgepoint Hospital

July 2003 to June 2008  Vice President - Medical Staff Association- Bridgepoint Hospital

May 2002 to June 2007  Chair - Infections Diseases Committee- Bridgepoint Hospital

May 2003 to present  Member - Medical Advisory Committee – Bridgepoint Hospital

July 2007 to June 2008  Physician Representative - Pharmacy and Therapeutics Committee – Bridgepoint Hospital

Sept 2007 to May 2008  Physician Representative - Lean Initiative – Bridgepoint Hospital and University Health Network

April 2005 to October 2005  Physician Representative (Rehab), Hospital Accreditation Committee- Bridgepoint Hospital
RESEARCH

October 2009 to Present Principal Investigator – *Neurorehabilitation Registry* - Bridgepoint Hospital, Toronto, Ontario

INVITED TALKS

October 11-14, 2009

**Forecasting Discharge For Patients Undergoing Neurorehabilitation**

Presented at the *Institute for Operations Research and Management Science Annual Meeting*, San Diego, CA.

October 22-24, 2008

**Evidence-Based Analysis of Maintenance Practices in Community Hospital**

Presented at the *International Maintenance Excellence Conference*, Toronto, Ontario

TEACHING

July 2007 to Present

**Physician Supervisor** – Year II University of Toronto medical students. Determinates of Community Health course.

Sept 2009 to Present

**Joint Physician Supervisor** – Year IV University of Toronto medical student (Ambulatory Community Experience)

INTERESTS AND ACTIVITIES

- Running - ultramarathons
- Travel
- Diving-PADI Certified
Curriculum Vitae

Mark Chignell

Academic Appointments

July 2003-Present Professor, Department of Mechanical and Industrial Engineering, University of Toronto
July 1996-June 2003 Associate Professor, Department of Mechanical and Industrial Engineering, University of Toronto
July 1990-June 1996 Associate Professor, Department of Industrial Engineering, University of Toronto
September 1984 - May 1990 Assistant Professor, Department of Industrial and Systems Engineering, University of Southern California
May 1983-August 1984 Research Associate, Department of Industrial and Systems Engineering, Ohio State University
May 1982 – April 1983 Postdoctoral Fellow, Human Performance Laboratory, The Ohio State University
March 1981- April 1982 Senior Tutor, Department of Psychology, Monash University (Melbourne, Australia)
February 1980-February 1981 Tutor, Department of Psychology, Monash University (Melbourne, Australia)
June 1977-December 1980 Teaching Assistant, Department of Psychology, University of Canterbury (Christchurch, New Zealand)

Other Academic Activity

General Chair of ACM Hypertext 2010 Conference to be held in Toronto in June, 2010.
September 2009-Present. Member Academic Promotions Committee, Department of Mechanical and Industrial Engineering, University of Toronto
Member of a number of tenure committees at the University of Toronto in the Faculty of Information, and the Departments of Computer Science, Electrical and Computer Engineering, and Mechanical and Industrial Engineering.
January 2003-Present Visiting Scientist, IBM Centre for Advanced Studies
September 2004-Present Visiting Scientist, Keio University
January 2002-September 2005 Director, Bell University Collaborative Effectiveness Laboratory, Bell University Labs, University of Toronto
July 1998-2007. Member of Executive Committee, Knowledge Media Design Institute, University of Toronto.
2006-Present. Member of the KMDI Collaborative Programme Committee
September 1995-present Associate Professor, Department of Computer Science, University of Toronto (status only, joint appointment).
**Consulting and Business Activity**

Founded two startup companies that both received investment funding (Concept 1 Communications, 1995-1997; Personification, 1999-2001.
President and Founder of Vocalage Inc. (Founded in May 2003).

**Education**

B.Sc. (First class Honours) Psychology University of Canterbury, New Zealand, 1977
M.S. Industrial and Systems Engineering, Ohio State University USA 1984
Ph.D. Psychology, University of Canterbury, New Zealand, 1981

**Recent Journal Publications**


Selected Recent Conference Publications


Books

Recent Research Support (selected)

2010 IBM Faculty Award. $15,000

2009, NSERC Strategic Workshops Program, J. Cordy PI (Queens’ University) SITCON, A Strategic Workshop in Smart Internet Technologies (Nov. 2, 2009), $16,950

2009, IBM Canada CAS Student Fellowship (E.Yu), Towards the Next Generation Interface Container, $20,000

2008-2013 NSERC Team Grant D. Plant; T. Le-Ngoc; F. Labeau; M. Coates (McGill); D. Doran; R. Goubran; S. Straus; M.Carter; A. Khandani Healthcare Support through Information Technology $33,000 per year (estimated annual share to my lab)

2008-2013, NSERC Discovery Grant Emotional Interaction with Robots and Computers $140,000 ($28,000 per year)

2007, IBM, IBM Fellowship, Sacha Chua, $10,000

2006, OKI, Project Grant, Research on design and evaluation of flexible audio spaces for a geographically dispersed work group, $4,600

2006-2009, NSERC CRD, (with Charles Clarke, Ravin Balakrishnan, and Diana Inkpen), Management, access and visualization of archived meeting transcripts, ($330,000 over three years)

2006, OKI, Project Grant, $5,000

2004-2006, CITO, Project Grant, S. Straus, R. Balakrishnan, C. Clarke, Improved Medical Collaboration and Case Management: Capture, Structuring and Dissemination of Spoken Discussion, $280,000

2003-2006, IBM, Arise, R. Balakrishnan, C. Clarke, Memories of Synchronicity: Knowledge Management and Visualization of Interaction Transcripts in Innovative Collaboration Environments, $440,000

2003 – 2004, Bell University Laboratories, Project Grant, Architecting Personalization and Usability Engineering of Voice Services, $48,300

2002 - 2006, NSERC, Discovery Grant, Innovations in Voice Collaboration, ($116,000 total over four years)

2007-2008 Bell University Laboratories, Video Web 2.0: Dynamic metadata indexing of over-the-top (OTT) video content, ($60,000 in 2007, $64,800 in 2008, C. Clarke co-Investigator)

Teaching and Advising

Career total of 18 Ph.D students graduated (as main supervisor).

Career total of 25 MASc. students graduated (with thesis), plus numerous M.Eng projects and undergraduate research theses.

Graduate level courses taught over a number of years include Technologies for Knowledge Media Design, Experimental Design and Analysis in Human Factors Research, and Human Factors in information technology.

Undergraduate courses taught multiple times include: Human Factors in Workplace design, and Ergonomic Design of Information systems.
Anita Ko
23 Townson Road, Unionville ON, L6C 1T4
416 318 6606
anitako@mie.utoronto.ca

EDUCATION AND TRAINING

University of Toronto

- Master of Applied Science Student, Mechanical and Industrial Engineering Department (in progress)
  - Supervisor: Professor Mark Chignell
  - Member of the Interactive Media Lab

- Bachelor of Applied Science, Mechanical and Industrial Engineering (2008)
  - Undergraduate Thesis: The Utility of Continuous Measures of Emotion in an Experimental Task

CURRENT RESEARCH

Thesis Project:
- Ambulatory Gait Analysis
  - Measuring the utility of acceleration data as a means to gauge changes in gait
  - Possible implications: measuring gait continuously to measure efficacy of rehabilitation, predict likelihood of falls in elderly based on changes in gait parameters

Research Assistantship Projects:
- Impact of Presentation of Evidence from Systematic Reviews’ on Clinicians’ Abilities to Understand and Apply it to Individual Patients (PI: Dr. Sharon Straus)
- Interprofessional Diabetes Outreach by AHSCs to Promote Interprofessional Diabetes Care in Family Health Teams (PI: Dr. Rene Wong and Dr. Catherine Yu)
- Validation of Usability Checklist (PI: Dr. Catherine Yu)

WORK EXPERIENCE

Fall 2009 – Summer 2010
Conference Secretary – Association for Computing Machinery (ACM) Hypertext 2010 Conference

Summer 2009
Visiting Scientist – Yasumura Lab - Keio University (Shonan Fujisawa Campus) – Tokyo, Japan

Spring 2009 – Winter 2010
Teaching Assistantships – Department of Mechanical and Industrial Engineering (University of Toronto)
- MIE 191 – Introduction to Mechanical and Industrial Engineering (Winter 2009)
- MIE 343 – Industrial Ergonomics and the Workplace (Fall 2009)

Fall 2007 – present
Research Assistant – Interactive Media Lab (University of Toronto)  Toronto, Ontario

2006 - 2007
User Centered Design Specialist – IBM Canada  Markham, Ontario
- Designed interfaces to be used for the IBM Information Management software
- Worked as the User Experience representative on a multi-national team to ensure new tools were developed and design in a usable and accessible manner
- Conducted usability tests to evaluate the usability of various IBM products

Summer 2005
Database and Website Coordinator – The Hearing Foundation of Canada  Toronto, Ontario
CO-CURRICULAR ACTIVITIES

2007 – present

**Vice President – Human Factors Interest Group (HFIG)**
- Help organize and facilitate human factors interest activities and lectures geared towards University of Toronto students
- Organized Inter-University Workshop – annual graduate student conference with over 70 attendees from five universities
- Secretary (2008 – 2009); Undergraduate Representative (2007 – 2008)

2008 – 2009

**Mechanical and Industrial Engineering Leaders of Tomorrow Working Group**
- Selected to be a member of the Leaders of Tomorrow Working Group
- Help organize leadership events and seminars for undergraduate and graduate students in Mechanical and Industrial Engineering

Fall 2007 – Winter 2008

**IBM Campus Ambassador at U of T – IBM Canada**

2006 – 2008

**Volunteer Consulting Group – University of Toronto Consulting Association**
- Student Director of the Volunteer Consulting Group
- Organized student teams to work on pro-bono consulting cases with local non-profits
- Recruited undergraduate students, MBA students, faculty advisors, industry experts and clients to participate in the program
- Organized and provided regular training and feedback sessions for the volunteer consultants and advisors
- Volunteer Consulting Group has worked with clients with many different goals (e.g. JUMP Math, Mainstay Housing, Safe Kids Canada, Youth Assisting Youth)
- Participated as a Volunteer Consultant in 2005 – 2006 academic year

2003 – 2008

**Co – Chairperson – Industrial Engineering Discipline Club**
- Acted as a liaison between students and the university administration
- Planned and organize events for the Mechanical and Industrial Engineering Faculty
- Improved the communication between the student body and the university administration
- Executive member since 2003 (First Year Representative, Second Year Representative, Vice Chairperson, and PEY Representative)

AWARDS AND ACHIEVEMENTS

<table>
<thead>
<tr>
<th>Year</th>
<th>Award/Recognition</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>IBM Centre for Advanced Studies People’s Choice Award for Best Demonstration (Awarded based on votes by conference attendees)</td>
</tr>
<tr>
<td>2008</td>
<td>University of Toronto Student Fellowship</td>
</tr>
<tr>
<td>2005</td>
<td>Province of Ontario Volunteer Service Award</td>
</tr>
<tr>
<td>2004</td>
<td>Summer Language Bursary Program - Université du Québec</td>
</tr>
<tr>
<td>2003</td>
<td>Queen Elizabeth Aiming for the Top Award</td>
</tr>
<tr>
<td>2003</td>
<td>Ontario Scholar Award</td>
</tr>
<tr>
<td>2003</td>
<td>York Catholic District School Board Excellence in Leadership Award</td>
</tr>
<tr>
<td>2003</td>
<td>Excellence in Computer Studies Award</td>
</tr>
<tr>
<td>2002</td>
<td>Shad Valley International – University of Calgary Alumnus</td>
</tr>
</tbody>
</table>
JBWREB Application Form for Access to Retrospective Data for Research

### SECTION 1a  Principal Investigator Information: *(MUST be a Bridgepoint/West Park Staff Member)*

<table>
<thead>
<tr>
<th>Name:</th>
<th>Tammy Sieminowski</th>
<th>Title:</th>
<th>Dr.</th>
<th>Telephone:</th>
<th>416-461-8251 x 1969</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department:</td>
<td>Neurorehabilitation</td>
<td>Site:</td>
<td>Bridgepoint</td>
<td>Fax:</td>
<td>n/a</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:tsiemino@bridgepointhealth.ca">tsiemino@bridgepointhealth.ca</a></td>
<td></td>
<td></td>
<td>Wing/Floor/Room:</td>
<td></td>
</tr>
</tbody>
</table>

Principal Investigator Signature:  
Date of Signature: __________ / _______ / ________  
(DD/MM/YYYY)

### SECTION 1b  Co-Investigator(s) Information:

| Name(s): | 1. Mark Chignell  
2. Anita Ko  
3. | Title: | 1. Prof.  
2. Ms.  
3. | Telephone: | 1. 416-978-8951  
2. 416-318-6606  
3. |

| Department: | 1. Mechanical and Industrial Engineering, U of T  
2. Mechanical and Industrial Engineering, U of T  
3. | Site: | 1. BP  
WP  
Other: U of T  
2. BP  
WP  
Other: U of T  
3. BP  
WP  
Other: |

| Email: | 1. chignell@mie.utoronto.ca  
2. anitako@mie.utoronto.ca  
3. |

Co-Investigator(s) Signature:  
Date of Signature (DD/MM/YYYY): 

### SECTION 1c  Data Abstractor(s) Information: *(To be completed by the individual who will be abstracting the data requested)*

| Name(s): | 1.  
2. |
| Title: | 1.  
2. |
| Institution: | 1.  
2. |
| Telephone: | 1.  
2. |
| Department/Division: | 1.  
2. |
| Email: | 1.  
2. |

| Role and Reason for Access: | 1.  
2. |

Confidentiality Agreement
I, the undersigned, agree to adhere to the Bridgepoint and/or West Park Policy on Confidentiality *(TBA Policies to be identified)* and understand that a breach of this policy will be just cause for termination of my employment and/or affiliation with this hospital. I agree that all health information, which I may have access to, is to be dealt with in keeping with the policies and procedures of the Bridgepoint Health or West Park Healthcare Centre with respect to confidentiality. If identifying information is collected, the information will be kept secure and identifiers removed at the completion of collection. I also accept full responsibility for protection of information that has been collected by a delegate on my behalf.
### SECTION 2  Administrative Authorization

By signing this authorization, I am attesting that I am aware of this proposal and support its submission for ethics review. I consider it to be feasible and appropriate. I further attest that the principal investigator responsible for this study has the qualifications and expertise to carry out this study in a competent and professional manner.

<table>
<thead>
<tr>
<th>Divisional/Department Head Signature:</th>
<th>Print Name:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>______ / ______ / ______</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(DD/MM/YYYY)</td>
</tr>
</tbody>
</table>

### PRIVACY AND CONFIDENTIALITY

Under the Personal Health Information Protection Act (Bill 31) which came into force in Ontario on Nov. 1, 2004, the following information must be provided to the Research Ethics Board (REB) when requesting approval of research studies involving the collection, use and disclosure of personal health information. Other information in this form is required to assess the proposed project from an ethical and scientific perspective.

### SECTION 3  Scope of the Project

<table>
<thead>
<tr>
<th>Project Title:</th>
<th>Ambulatory Gait Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary objective and hypothesis of the study:</strong></td>
<td>This is a quantitative study aiming to investigate the utility of acceleration as an evaluative measure of neurorehabilitation</td>
</tr>
<tr>
<td><strong>Study Summary including the public or scientific benefit of this study (maximum 250 words):</strong></td>
<td>Many balance assessment tools have been developed to measure a patient’s gait and balance. Clinicians at Bridgepoint Hospital make use of the Berg Balance Score, Community Balance and Mobility Scale, and Six-Minute Walk to evaluate the gait of neurorehabilitation patients. These tools require a dedicated testing area and physiotherapist assessment. This research project will explore the use of accelerometers as a tool to quantitatively evaluate changes in gait during neurorehabilitation. Accelerometers may be attached to patients’ shoes to measure the acceleration in their gait as they go about their day-to-day activities. The purpose of this study is to assess whether or not the acceleration data may be used to gauge changes in the patients’ gait. If acceleration is found to be a good measure of change in gait, it may eventually be used as a tool to measure a patient’s progress through their neurorehabilitation.</td>
</tr>
</tbody>
</table>

#### Data to be extracted from (check all that apply)

- [x] Clinical Records
- [ ] Provincial or Other Registries: Specify:  
- [x] Other Database  
  Specify: RiskPRO

<table>
<thead>
<tr>
<th>Proposed number of research subjects:</th>
</tr>
</thead>
</table>
| Bridgepoint: 11  
West Park:  
Other sites: |

<table>
<thead>
<tr>
<th>Proposed start date of project:</th>
</tr>
</thead>
</table>
| 01/06/2010  
(DD/MM/YYYY) |

<table>
<thead>
<tr>
<th>Proposed termination date:</th>
</tr>
</thead>
</table>
| 01/11/2010  
(DD/MM/YYYY) |
<table>
<thead>
<tr>
<th>Date range of requested data under review (e.g. 15/01/2000 to 30/06/2005)</th>
<th>Start: 01/01/2000 (DD/MM/YYYY)</th>
<th>End Date: 01/11/2010 (DD/MM/YYYY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How will this be funded?</td>
<td>☐ Grant Specify funding source:</td>
<td>☐ Industry Sponsor:</td>
</tr>
<tr>
<td></td>
<td>☐ Internal Specify funding source:</td>
<td>☑ No Funding Required</td>
</tr>
<tr>
<td>Will the data being collected be used, now or in the future, for commercial purposes?</td>
<td>Yes ☐ If Yes, please provide details:</td>
<td>No ☑</td>
</tr>
</tbody>
</table>
**SECTION 4 | Data Elements, Confidentiality and Security**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>List specific data requested and specific personal identifiers that will be collected (such as names, initials, date of birth, OHIP or hospitals numbers, etc):</td>
<td>No personal identifiers will be collected. Consenting patients’ hospital chart will be checked for primary diagnosis, admission date, discharge date, demographic information (age, gender), history of falls, balance scores (Berg Balance Scores, 6 minute walk scores, Community Balance and Mobility Scale scores).</td>
</tr>
<tr>
<td>Will this data be linked to any other data?</td>
<td>Yes ☒ If Yes, please provide details on how the linkage will be made: No ☐ It will be linked to acceleration data from the sensors by a unique identification number</td>
</tr>
<tr>
<td>Will data be anonymised after collection or linkage?</td>
<td>Yes ☒ If No, please justify: No ☐</td>
</tr>
<tr>
<td>How long will personal health information will be retained in an identifiable form and why?</td>
<td>No names or identifiable patient information will be collected</td>
</tr>
<tr>
<td>How and when the personal health information will be disposed of or returned to the health information custodian.</td>
<td>The data will be destroyed following the completion of the analysis in the fall of 2010. Hard copies of data will be shredded, electronic copies will be deleted</td>
</tr>
<tr>
<td>Explain why the research cannot reasonably be accomplished without using personal health information.</td>
<td>The purpose of the study is to measure the utility of acceleration as a means to measure gait. The personal health information will be compared with the data from the sensors to gauge how well acceleration can measure changes in gait.</td>
</tr>
<tr>
<td>If explicit Informed Consent is not sought from the individuals to whom the information relates, please provide justification as to why it would be impractical to obtain explicit consent.</td>
<td>N/A</td>
</tr>
<tr>
<td>Describe the <strong>reasonably foreseeable</strong> harms and benefits that may arise from the use of the personal health information, and how the harms will be addressed.</td>
<td>No foreseeable harms associated with collection of personal health information as no personal identification information will be collected. The foreseeable benefit is an increased understanding of the utility of acceleration as a means to measure gait.</td>
</tr>
<tr>
<td>How will security and confidentiality of the data be protected, maintained and retained? (If data is to be transferred outside the institution, describe any additional security precautions)</td>
<td>Electronic files will be protected by passwords. Hard copies of collected data will be kept in a locked cabinet in an office accessible only by the student researcher, co-investigator and principal investigator. Data (hard copies and electronic copies) will be physically transferred to a locked office at the University of Toronto by the Student Researcher.</td>
</tr>
</tbody>
</table>