Development of a Stick-on Hip Protector for Older Adults in the Acute Care Environment

by

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Ethics Statement

The author, whose name appears on the title page of this work, has obtained, for the research described in this work, either:

a. human research ethics approval from the Simon Fraser University Office of Research Ethics

or

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Abstract

Over 90% of hip fractures in older adults are due to falls. Wearable hip protectors have been shown in clinical trials to reduce the risk for hip fracture by up to 80% when worn, but user compliance with conventional garment-based hip protectors averages less than 50%. Improvements in product design may lead to enhanced compliance. This thesis describes the development and preliminary evaluation of usability in the acute care environment of a “stick-on” hip protector (secured over the hip with a skin-friendly adhesive).

Through biomechanical testing, I developed a prototype that attenuates impact force by over 30% (higher than protectors currently used in Fraser Health). In a feasibility pilot trial, five of six patients wore the device for seven days. Additional input from 43 acute care providers during a Feedback Fair resulted in a 20 mm thick donut-shaped prototype of surface area 19x15.5 cm, that provided 36% force attenuation.

Keywords: Falls; hip protector; hip fracture; aging; injury prevention; acute care

To my loving parents & my wonderful partner

“To the world you may be one person, but to one person, you may be the world.” ~ Dr. Seuss

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Glossary

Acceptance	The percentage of potential users who initially agree to wear hip protectors.
Adherence	The percentage of time that hip protectors are worn by the patient in accordance with the study or nursing staff recommendations.
Coding	An analytical process in which data is categorized to facilitate analysis.
Compliance	The percentage of individuals who both initially agree to wear the hip protectors, and then actually wore them. This can be divided into two sub-categories: initial acceptance and continued adherence. Within Fraser Health Authority, compliance is measured by the proportion of "padded" falls where individuals are noted to be wearing hip protectors.
Durometer	A measures of the hardness of a material, based on the material's resistance to indentation.
Effectiveness	The ability of hip protectors to reduce fall-related hip fractures.
Enarthrodial Joint	A freely moving joint in which a sphere on the head of one bone fits into a rounded cavity in the other bone. Also known as a synovial ball and socket joint.
Feedback Fair	A participatory method of encouraging knowledge transfer and exchange (KTE). The Feedback Fair is a low-cost, low-resource method of engaging small groups of stakeholders in collaborative conversations as they travel through a number of stations.
Force Attenuation	The percent reduction in peak force provided by a hip protector, when compared to the baseline, unpadded condition.
Fraser Health Authority	One of six publicly funded health care regions in British Columbia.
Hip Impact Simulator	A system for measuring the force attenuation provided by hip protectors. The hip impact simulator consists of an impact pendulum and surrogate pelvis, and is compatible with international guidelines.
Hip Protector	Special garments (underwear, shorts, or pants) containing soft or hard pads inserted into pockets covering the greater trochanter area. The pads are intended to reduce the force to the hip to mitigate the risk for hip fracture in the event of a fall.

Osteopenia	A reduction in bone mass of lesser severity than osteoporosis.
Osteoporosis	A medical condition involving loss of bone mass. Diagnosed based on measures of bone density from imaging (dual-energy x-ray absorptiometry).

Chapter 1.

Introduction

Falls are the leading cause of injury among individuals over age 65 in Canada and are responsible for 86% of all injury-related hospitalizations and 60% of all injury-related deaths [Scott, V. & Elliot, S., 2010; Public Health Agency of Canada, 2005]. Hip fractures are the most significant injury related to falls, with approximately 28,000 annual cases in Canada [Scott, V. & Elliot, S., 2010] with medical costs in excess of $1 billion [Nikitovic et al., 2013].

Although the age-adjusted rate of hip fractures in Canada has been declining in recent years with increased knowledge and implementation of effective multiple intervention programs, the absolute number of hip fractures continues to increase due to changes in the age distribution of the population [Tinetti, M. & Speechley, M., 1989; Leslie et al., 2009]. It is estimated by the year 2050, the proportion of the population 60 years or older will double in comparison with the year 2000, and it is well documented that age is positively correlated with falls and fracture risk [World Health Organization, 2008].

1.1. Occurrence of Falls in the Hospital Setting

Hospitals are a particularly high-risk environment for hip fractures. Nearly 1 in every 1,000 elderly patients (age 65 and older) suffers a hip fracture during their admission to a Canadian acute care hospital [Pulcins, I. & Wan, E., 2004]. In Canada alone, this translates to over 2,000 in-hospital hip fractures every year.

Falls account for 38% of all in-hospital patient incidents [Briggs, K. & Steel, K., 2007] and 44-60% of these events result in injury [O'Loughlin et al., 1993; Rubenstein, L., 2006; Tinetti, M. & Speechley, M., 1989]. Throughout the duration of a patients stay in the hospital, their fall and fracture risk after admission can change repeatedly. This may be due to a change in the environment (for example being admitted to the hospital or changing units/rooms), administration of new medications, or the onset of new impairments and diseases [Cameron et al., 2009]. This requires constant care and monitoring by the care team to appropriately assess a patient's fall risk.

Based on personal communications, within the Fraser Health Authority Acute Care, in 2014 there were 5149 falls that occurred across 56 units. Of those falls, there were 65 hip fractures [Fraser Health, 2014]. Several major systematic reviews have shown that targeted multi-factorial intervention programs have been effective in reducing the incidence of falls in community-based studies [Gillespie et al., 2015; Scott & Elliott, 2010; Rubenstein, 2006; Tinetti & Speechley, 1989]. However, there is limited knowledge in regards to multiple intervention programs within the hospital environment with some studies showing a reduction in the relative risk of recorded falls, but no significant reduction in the incidence of falls-related injuries [Dykes et al., 2010]. Not all falls can be avoided, so focusing on injury reduction programs, such as hip protectors, are important topics of discussion for when unavoidable falls occur.

Hospitals are expected to be safe places for patients. As such, hospitals must utilize best practices to reduce the potential for injuries when falls occur. Furthermore, research is required to improve best practices.

1.2. Impact of In-hospital Hip Fractures

In-hospital hip fractures can have an enduring and devastating impact on the faller and their family. Elderly patients can experience decreases in independence and quality of life [Corsinovi et al., 2009; Zidén et al., 2008; Scott, V. & Elliot, S., 2010]. The psychological impact of a fall may result in a post□fall syndrome that includes dependence on others for daily activities, loss of autonomy, confusion and mental deterioration, immobilization and depression [World Health Organization, 2008]. Falls also negatively effect staff morale and decrease family/caregiver trust.

Hip fractures are also associated with increased mortality, with almost half of the patients who experience an in-hospital hip fracture dying within 1 year [Johal et al., 2009; Scott, V. & Elliot, S., 2010]. This may be due to underlying frailty of individuals who experience a hip fracture. Complications from hip fracture may include: pneumonia, muscle atrophy, postoperative infections, poor bone healing, chronic pain, bedsores and a compromised immune system [Vestergaard et al. 2007].

Hip fractures are more common in older people because bones become thinner and weaker with age, leading to osteopenia or osteoporosis. However, fracture risk is governed not only by bone fragility, but also by the mechanics of the fall (defined by the direction of the fall, the location of impact, and the impact velocity of the body) [Robinovitch et al., 1997]. Based on analysis of video footage of 520 falls experienced by 160 older residents in long-term care, hip impact occurred in 40% of falls. Furthermore, hip impact was equally likely in falls initially directed forward as sideways, due to body rotation during decent [Yang et al., 2015].

Hip fractures are also associated with longer lengths of hospitalization [Hill et al., 2007]. Patients that experienced a hip fracture during their hospital stay had an average length of stay of approximately 27 days longer when compared to match controls. There are also increased health care costs, with the average cost of treating a single hip fracture in Canada at approximately $40,000 [Nikitovic et al., 2013; Woolcott et al., 2012]. The initial direct attributable health care cost for the fracture accounts for the largest component to the cost (approximately 40%). It is estimated that the annual direct attributable health care cost for hip fractures in Canada is 1.1 billion dollars [Rubenstein, L. Z., 2006]. Other factors that affect the cost within the first year after the fracture includes: complex continuing care, rehabilitation, and physician services [Nikitovic et al., 2013]. Also, patients may require relocation from their homes to a residential home depending on their recovery.

1.3. Hip Anatomy and Fractures

The hip joint (Figure 1) is an enarthrodial or synovial ball and socket joint formed by the reception of the head of the femur (the ball) and a cup-like structure on the os coax, known as the acetabulum (the socket).

Adequate function of the hip joint is crucial to humans’ ability to walk, jump and run. The hip is among the strongest and most flexible joints of the body, able to circumduct freely over 360 degrees. Movements of the femur about the hip joint include flexion and extension, abduction and adduction, and inward and outward rotation [Özkaya, N. & Nordin, M., 1991].

The stability of the hip joint is provided by its relatively rigid ball and socket configuration, and by the large and strong ligaments and muscles crossing it. The ligaments of the hip joint, such as the transverse and teres femoris ligaments, support and hold the femoral head in the acetabulum as the femoral head moves [Özkaya, N. & Nordin, M., 1991].

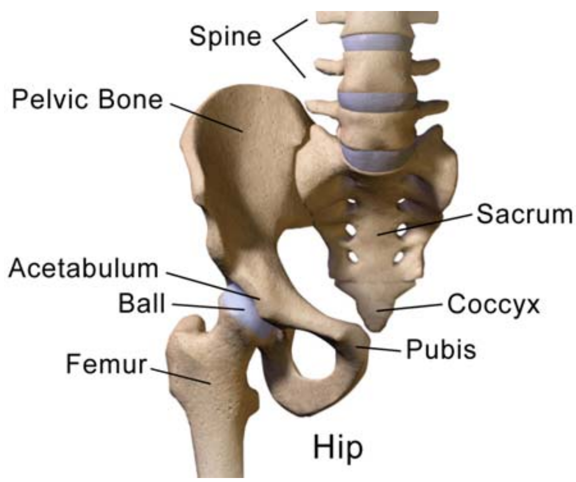

Figure 1. Anatomy of the hip joint
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The incidence of hip fractures increases exponentially with age, with the average fracture patient being 82 years old [WHO, 2008]. For older adults, 90% of hip fractures are caused by falls from standing height or lower, typically while performing activities of daily living (ADL's) [Grisso et al., 1991; Robinovitch et al., 1997]. The two most common types of hip fracture are femoral neck fractures and intertrochanteric hip fractures (Figure 2). Femoral neck fractures occur at the neck of the femur and are the most common for older adults in the event of a fall. Intertrochanteric hip fractures occur between the greater and lesser trochanters of the femur.

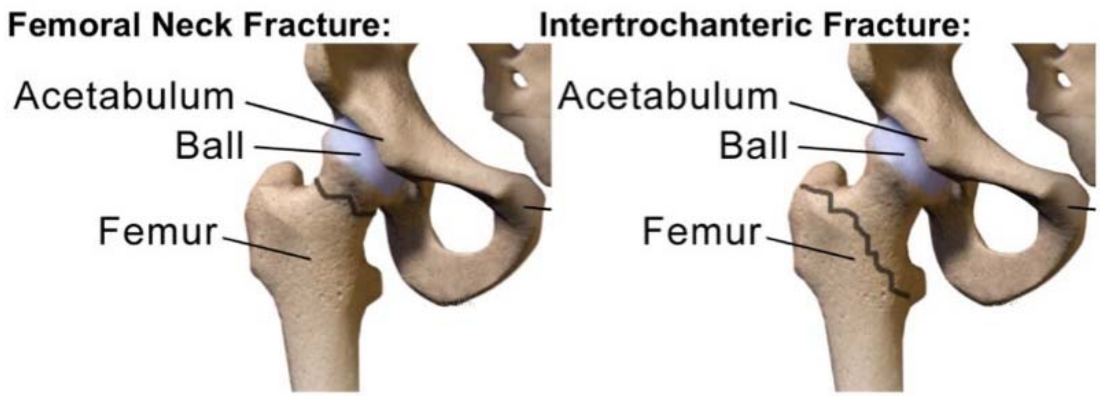

Figure 2. Two most common types of hip fracture; the femoral neck fracture and the intertrochanteric hip fracture

Note: Image reproduced with permission from BruceBlaus under the Creative Commons Attribution 3.0 Unported licensing. Ticket link: https://ticket.wikimedia.org/otrs/index.pl?Action=AgentTicketZoom&TicketNumber=2013061010006654 by Blausen Medical Communitcations, commons.wikimedia.org. (2013). Image was cropped and femoral neck and intertrochanteric fracture lines added.

The treatment that is most common for hip fractures is surgery. Following surgery, various rehabilitation interventions are employed to assist in the recovery process. Despite these efforts, 15-25% of patients experience a decline in physical ability to perform daily activities, [Haentjen et al., 2010; Oliver et al., 2010] and approximately 50% of the patients who experience an in-hospital hip fracture die within 1 year [Johal et al., 2009]. Typical causes of death after experiencing an in-hospital hip fracture are septicemia, pneumonia/influenza, a digestive system disorder, cardiovascular disease, neoplastic disease or cerebrovascular disease [Myers et al., 1991]. Of those who survive, about 50% will suffer a major decline in independence [Wolinsky et al., 1997; Empana et al., 2004; Laing & Robinovitch, 2008]. It is important to note that this high 1-year mortality rate decreases to 13% if the fracture occurs in a community-dwelling setting, and 30% if the fracture occurs in a nursing home or residential care setting [Schnell et al., 2010]. This highlights the importance of hip fracture prevention efforts in the acute care setting.

1.4. Hip Protectors as a Prevention Strategy

Preventing falls and fall related injuries is challenging due to the complex interactions between intrinsic, situational and environmental factors. Patients in acute care often present with multiple risk factors that increase their probability to experience a fall. Mobility and patient independence is encouraged during their hospital stay, further complicating the issue of minimizing risks for falls. As a result of intense efforts over the past three decades, specific interventions have been shown to reduce falls in the hospital setting from 4.18 [95% CI, 3.45-5.06] per 1000 patient-days to 3.15 [95% CI, 2.54-3.90] per 1000 patient-days; however, none have positively influenced fall related injuries [Dykes et al., 2010].

Wearable hip protectors have been promoted as a method for the prevention of hip fractures in high-risk populations [Robinovitch et al. (1995a)]. Conventional, wearable hip protectors are special garments (underwear, shorts, or pants) containing soft or hard pads inserted into pockets covering the greater trochanter area (Figure 3).

Figure 3. Conventional garment-based hip protector

Biomechanical testing has shown that hip protectors can reduce impact force to mitigate risk of injury. This is due to several mechanisms, including shunting of impact force away from the bone and decreasing the stiffness at the contact site [Derler, S., 2005; Mills, N., 1996; Minns et al., 2004; Parkkari et al., 1994; Robinovitch et al., 1995]. However, a recent meta-analysis yielded conflicting results on the clinical effectiveness within the community and residential care facilities of existing hip protectors [Gillespie et al., 2010]. This likely resulted from: (1) poor adherence among users in wearing the device (often less than 50%), [Cameron et al., 2003; Forsen et al., 2004; Kannus et al., 2000] and (2) variability in the biomechanical effectiveness of tested devices. The force reduction provided by commercially available devices has been found to range from 2-40% [Laing et al., 2011]. There are currently no regulations in place to control the level of protection provided by hip protectors. The consequence of this is commercially marketed hip protectors without a minimum force attenuation requirement. Future industry priority should be to improve standards and appropriate guidelines for manufactures.

Clinical trials within the community and residential settings have indicated that specific types of hip protectors reduce risk for fracture by up to 80% if worn at the time of the fall [Cameron et al., 2003; Forsen et al., 2004; Kannus et al., 2000]. However, there is currently insufficient knowledge, due to minimal research preformed, about the effect of hip protectors in a hospital environment. This creates a foundation for assumptions to be made about hip protectors based on randomized control trials from residential or community settings, which may not be transferable to the acute care setting.

1.5. Hip Impact Simulator

The Simon Fraser University (SFU) Hip Impact Simulator (Figure 4) was designed to measure the total force applied to the skin overlying the hip region and the force delivered to the femoral neck during a sideways fall. The system consists of an impact pendulum and a surrogate pelvis, and is compatible with published guidelines from an international team of biomechanics and clinical experts on recommended methods for testing the force attenuation provided by hip protectors. [Robinovitch et al., 2009].

The surrogate pelvis was designed to match the average surface geometry and local variation in soft tissue stiffness measured in elderly patients [Laing & Robinovitch, 2008]. The soft tissues are simulated with closed-cell polyethylene foams (Plastazote HD80 of density 80 kg/m^{3}and LD45 if density 45 kg.m^3) directly over the proximal femur and closed-cell copolymer foam (Evazote EV50) over the regions anterior, posterior and superior to the femur. These materials have been glued together to form a single 21.6 X 24.5 X 8.0 cm^3 block. A 1.2 cm thick layer of open-cell ester foam (SCH180-60E1 of density 29 kg/m^3) is secured over the entire outer surface of the pelvis, along with a 1.6 mm layer of gum rubber on top to simulate skin. Surface geometry and local variation in soft tissue stiffness match average measurements from older women to within one standard deviation [Laing, A. & Robinovitch, S., 2008b].

The artificial version of the proximal femur (Sawbones, Vashon, WA) is mounted onto a 25.0 X 25.0 X 0.7 cm^3 polyvinyl chloride base plate. The proximal femur is 13 cm in length from its distal end to the center of the greater trochanter. The femur is secured to the base plate using a single bolt directly behind the greater trochanter, leaving the distal end free.

The stiffness of the surrogate pelvis was selected to match human measures from two separate experiments: the pelvis research experiments of Robinovitch, Hayes & McMahon (1997) on five male and five female young adults with a mean age of 25 years

(SD 4, range 21-33), and the measures by Laing & Robinovitch (2008) of surface geometry and soft tissue force-deflection behaviour on 15 older women with a mean age of 77.5 years (SD 8.5, range 66-91).

The surrogate pelvis is connected to the pendulum arm via leaf springs that simulate the compliance of the pelvis producing a total effective stiffness of 42.2kN/m. [Laing, A. & Robinovitch, S., 2010; Robinovitch et al., 1997]. This helps to account for the compressive stiffness of the pelvis itself, as well as the total effective stiffness of the articulations between the pelvis, trunk and lower extremities. At the junction of the femoral neck of the surrogate pelvis is a load cell (Kistler model 9712A5000, Amherst, NY), which captures the amount of impact force transmitted to the joint during the fall. The total force applied to the skin surface is measured by a floor-mounted force plate (model 2535-08, Bertec Corp., Columbus, OH).

The impact pendulum and surrogate pelvis are released from an inclined position by an electromagnet to strike the ground in a horizontal position. The impact velocity of the pelvis can be adjusted via the angle from which the pendulum is dropped. This allows sideways fall simulations from different fall heights. During the test sessions hip protectors are positioned with the aid of a laser that indicates the location of the greater trochanter within the surrogate pelvis.

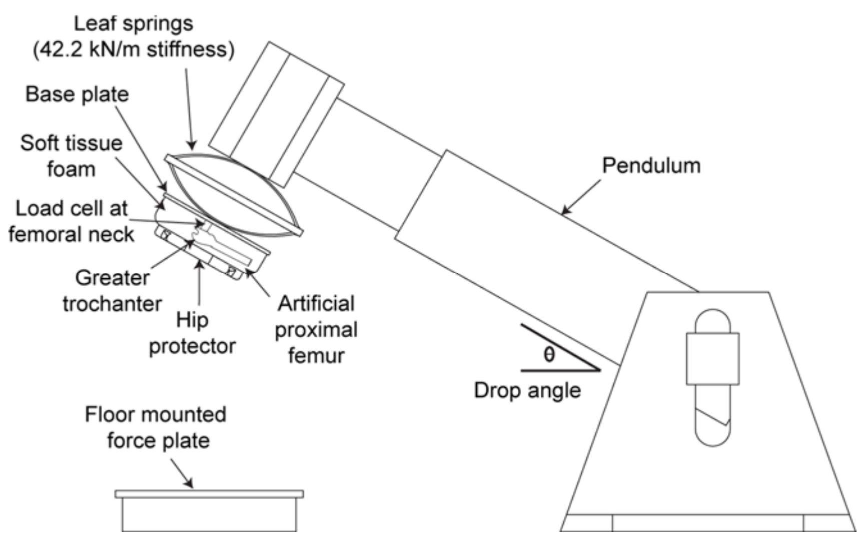

Figure 4. The Simon Fraser University Hip Impact Simulator

1.6. Literature Review of Barriers and Facilitators to Hip Protector Compliance in the Acute Care Setting

Traditional hip protector garments present challenges related to user compliance (initial acceptance and continued adherence) [Foster et al., 2007; Haines et al., 2006; Hayes et al., 2008; Lockwood et al., 2003; Witchard, S., 2004], cost, [Van Schoor et al., 2002] workload [Lockwood et al., 2003; Witchard, S., 2004] and availability [Foster et al., 2007; Haines et al., 2006; Witchard, S., 2004] of hip protectors for patients within the hospital. Currently, within hospitals in the Fraser Health region of British Columbia, patient compliance in wearing hip protectors averages below 20%. This is considerably lower than the approximate 50% patient compliance in wearing hip protectors in nursing homes within Fraser Health [O'Halloran et al., 2007]. Within the Fraser Health Authority, compliance is measured by the portion of "padded" falls where individuals are noted to be wearing hip protectors.

Previous literature reviews [Van Schoor et al., 2002; Santesso et al., 2014; Korall et al., 2015] have yielded conflicting results on the effectiveness of existing hip protectors [Parker et al., 2006; Oliver et al., 2007; Hanley, D. & Adachi, J., 2005; Kiel et al., 2007]. One factor influencing effectiveness is compliance among users in wearing the device, which in clinical trials is often less than 50% [Cameron et al., 2003; O'Halloran et al., 2006; Bentzen et al., 2008; Meyer et al., 2003; Cryer et al., 2002; Burl et al., 2003].

Currently, there are only a few studies of acceptance and adherence within the hospital environment, and no randomized controlled trials of hip protectors being deployed as a single intervention in hospitals [Haines et al. 2006]. This results in limited information on hip protector effectiveness within hospitals. However, given the strong correlation between effectiveness and compliance, there is an urgent need to determine the perceived barriers to initial acceptance and continued adherence with hip protectors in an acute care hospital setting.

To address this need, I conducted a literature review to synthesize available evidence on perceived barriers to initial acceptance and continued adherence with hip protectors within a hospital setting, and to provide evidence-based strategies to improve these outcomes. I performed the search using the following keywords: hip*, hip protector, hospitals, acute care, aged*, protect, pad, fracture, hip fracture*, fall, equipment, pad, patient compliance*, acceptance*, adherence*, and protective devices* (* all variations of the keyword). The keywords search was developed first for the electronic database OVID Medline, and then was adapted for other databases including PubMed, CINAHL, Ageline and Cochrane Database of Systematic Reviews. Published articles were inclusive of qualitative, quantitative and mixed methods research articles. Eligibility criteria for the search results were that articles must be published in English between January 2000 and May 2013. A supplemental search was performed by cross-referencing selected studies, contacting experts in the field for additional references, and reviewing all of the references of each systematic review obtained from the literature search. Studies were included if they focused specifically on hip protectors as an intervention or if hip protectors were part of a multiple intervention program. The sample of interest was comprised of older adults, in most cases 60 years or older, in an acute care hospital setting. The articles must pertain to hip protector compliance, acceptance and/or adherence.

A total of 1426 potential articles were identified via the search strategy. Immediately, 115 studies could be excluded for obvious inclusion/exclusion criteria, leaving us with 1311 studies. After a more detailed evaluation, 1239 videos were excluded. Studies were screened for having compliance as primary or secondary outcomes, reducing the number of articles down to 60. Of those, 12 appeared potentially relevant and a hard copy was obtained for screening. After full text reviews, 6 studies specific to acute hospital settings were found to meet the inclusion criteria and were included in the review (Figure 5).

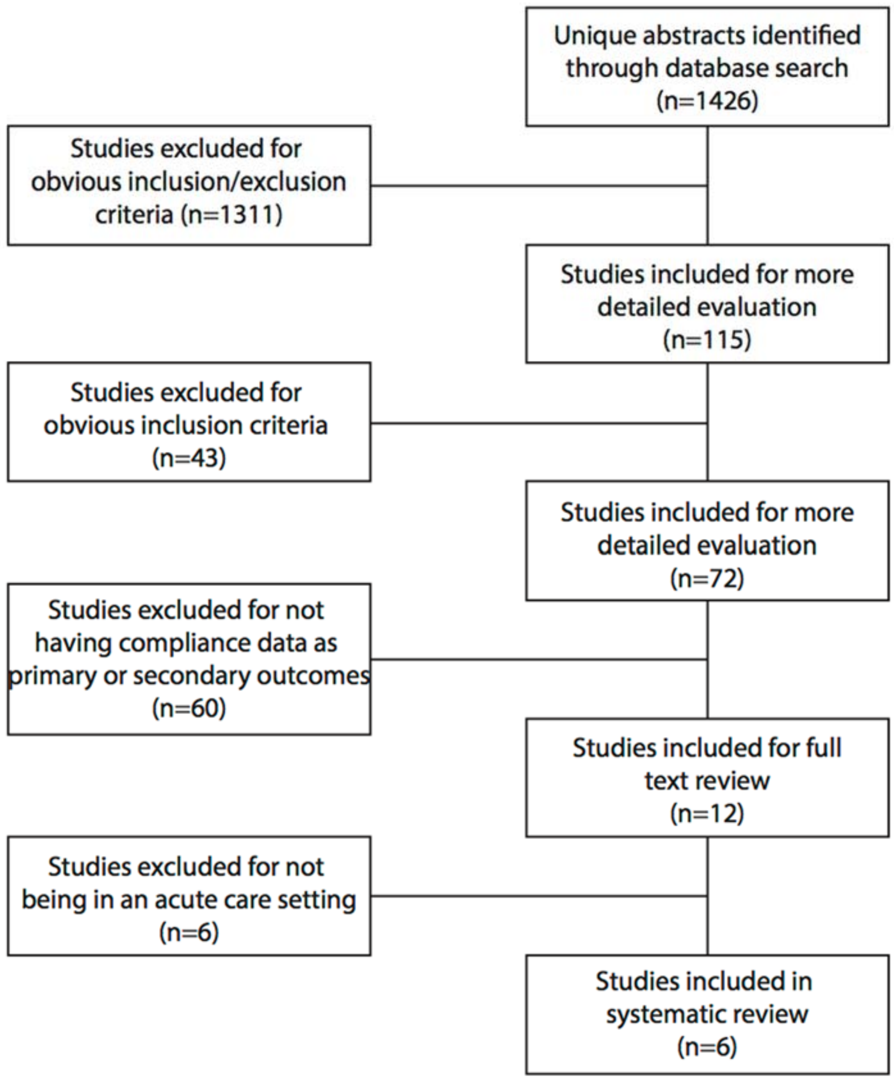

Figure 5. Flowchart summarizing the screening process for the systematic review

1.6.1. Compliance

Hip protector effectiveness has been defined as the ability to successfully reduce the rate of fall related injuries and hip fractures. A hip protector cannot be effective if the patient is not compliant in wearing them. Compliance has been defined as the percentage of individuals who both initially agree to wear the hip protectors, and then actually wore them. Compliance can be divided into two sub-categories: initial acceptance and continued adherence.

From the literature review, 6 papers from Hong Kong, Australia and England were identified that addressed compliance within a hospital environment. Due to the lack of standardization, the six studies show significant inconsistencies between them when defining and measuring compliance. This makes it difficult to accurately compare the studies and produce evidence-based strategies to overcome low levels of patient compliance within hospitals.

The efficacy of hip protectors in a hospital is an area that requires additional study. Often, assumptions are drawn from residential homes and the community due to the lack of knowledge. This information is not always applicable, however many of the problems can be similar.

1.6.1.1 Acceptance

One definition of acceptance is the percentage of potential users who initially agree to wear the hip protectors. However, of the six studies included in the literature review, only three studies reported on acceptance and they all had unique definitions and measurement techniques. Of the three studies reporting on acceptance, the rates were 40%, [Chu, L., 2002] 63% [Lockwood et al., 2003] and 77.5% [Hayes et al., 2008] of study participants initially agreed to wear the pads.

Factors found to affect initial acceptance within a hospital environment included lack of nurse encouragement to accept hip protectors as a method of injury prevention and patient attitude or perception of not being at risk for falls and therefore not requiring a hip protector [Foster et al., 2007; Haines et al., 2006; Witchard, S., 2004].

Organizational commitment to hip protector use, and an enthusiastic leadership style has been shown to facilitate both acceptance and adherence with hip protectors in an acute hospital setting [Hayes et al., 2008]. Staff compliance and support of hip protectors is important to facilitate acceptance and adherence amongst patients. A few studies provided initial staff education and training sessions, as well as using staff for patient recruitment [Foster et al., 2007; Lockwood et al., 2003; Haines et al., 2006]. Without nurse education and patient communication, encouragement and support, patients do not understand the importance of wearing the hip protector garment [Foster et al., 2007; Hayes et al., 2008; Witchard, S, 2004].

In studies conducted in residential care-home settings, it has been suggested that the use of a structured teaching program can help to facilitate compliance [Meyer et al., 2003]. An educational tool that was used in the Foster (2007) study included large informational posters that were put around the facility. These served two purposes: (1) to help educate patients and promote acceptance of hip protectors as a new fracture prevention method; (2) to remind patients to wear the hip protectors that had been assigned to them and adhere to the study and nurse recommendations. The posters were hung in prominent areas around the hospital ward and above each of the 80 in-patient beds [Foster et al., 2007]. Visual cues for both patients and nurses help to keep hip protectors in the forefront. However, despite extensive education on the benefits of hip protectors, staff motivation often started out strong but had the tendency to decline with time [Foster et al., 2007]. And for the patients, long lengths of stay in the hospital were documented to be inversely related to hip protector adherence in the Hayes and colleagues (2008) study.

There is contradicting information amongst the six hospital studies in regards to education. In the Hayes (2008) study, a univariate analysis of determinants of compliance was performed and they found individually tailored education programs on hip protectors to be not significant within the hospital setting [Hayes et al., 2008]. Staff and patients alike were given the information they needed to make decisions on health and safety. Monitoring the affects and success rate of staff/patient education could be difficult because it can rely on other factors, like motivation, personality and, for patients, mental state. All these factors affect how an individual process' and acts on the information provided to them. It is not yet clear why some studies find that education is a successful method to improve acceptance and assist with continued adherence, where other studies do not. Staff and patient education and training is an area requiring more study in both residential and hospital facilities.

Several of the studies also touched on the emotional state of patients, looking at patient attitude, history of falls, their external support system, and motivation. A positive attitude from the patient has been seen to improve willingness to try something new [Witchard, S., 2004]. Previous fracture(s), or recent/frequent falls can improve the patient's initial acceptance of the hip protector within the hospital [Witchard, S., 2004]. If a previous fall had resulted in a fracture, patients were keener to try anything that might get them home faster or protect their hips if they were to fall again [Witchard, S., 2004].

Patient perception of requiring hip protectors can be a major motivational barrier [Foster et al., 2007; Haines et al., 2006]. Often patients do not feel that this method of protection is necessary [Foster et al., 2007; Haines et al., 2006; Witchard, S., 2004]. Ten percent of patients were recorded in the Haines and colleagues (2006) study that did not feel they required the hip protector garment. Patient's perception of their risk of falls and fractures will directly affect their motivation to comply with nurse recommendation [Foster et al., 2007]. In the Foster and colleagues (2007) study, the main reason patients refused to participate in the study was that they did not like the idea of wearing hip protectors. This resulted in refusal of the hip protectors as a fracture prevention method [Lockwood et al., 2003].

Finally, if the hospital provided the hip protectors to the patient, initial acceptance seemed to improve [Haines et al., 2006; Hayes et al., 2008; Lockwood et al., 2003; Witchard, S., 2004]. However, long-term adherence faired better if the patients purchased their own hip protectors. Patient ownership of hip protectors helped increase motivation to actually wear the hip protectors, improving continued adherence [Foster et al., 2007].

1.6.1.2 Adherence

A definition of adherence is the percentage of time that the hip protectors are worn by the patient in accordance with the study or nursing staff recommendations. Of the six studies included in the literature review, five reported on adherence. The methods of data collection and definitions were, again, not standardized affecting comparability. Of the five studies reporting on adherence, the rates ranged from 12.8% [Chu, L., 2002] to 72% of study participants, [Foster et al., 2007] with a median adherence of 53% [Hayes et al., 2008].

Factors affecting adherence within a hospital environment include loss of garment and laundry issues, increased functional dependency on the staff with toileting activities and discomfort while wearing the device [Foster et al., 2007; Haines et al., 2006; Hayes et al., 2008; Witchard, S., 2004].

Many barriers within the hospital are similar to those found in a community or residential setting, but some barriers are unique to the hospital environment, and are difficult to overcome. An example of this is how demanding it is to keep track of hip protectors, due to the size of a hospital. This is unique to an acute hospital environment [Witchard, S., 2004]. In the Hayes and colleagues (2008) study, 24% of all hip protectors that were issued to patients were lost in hospital.

Laundry and lost or damaged hip protectors were frequently discussed as an obstacle within the hospital environment [Foster et al., 2007; Hayes et al., 2008; Lockwood et al., 2003; Witchard, S., 2004]. The amount of time required to wash and dry the hip protectors affects staff workload. Hip protectors are often not returned to the correct hospital ward, [Hayes et al., 2008] which causes high levels of lost garments [Foster et al., 2007; Haines et al., 2006; Witchard, S., 2004] and shortages within the hospital. It increases workload at the staff level because nurses constantly have to track down hip protectors or riffle through piles to find the appropriate size for the patient. There are often delays, turn around time is insufficient and lost garments occur frequently. The result of this was that patients were unprotected for days at a time [Hayes et al., 2008; Witchard, S., 2004]. In the Hayes and colleagues (2008) study, patients cited 25% of the time, that the reason for non-adherence was laundry related. Laundry issues were also documented by 14% of the patients in the Foster and colleagues (2007) study. Often, lost garments within the hospital are not replaced immediately due to the financial burden on the hospital.

Incontinent patients or those who require frequent toileting often have difficulty when it comes to hip protectors [Foster et al., 2007; Haines et al., 2006; Hayes et al., 2008; Lockwood et al., 2003; Witchard, S., 2004]. These patients require a higher level of staff assistance [Haines et al., 2006]. The tight fitting garments cause patients to have troubles pulling pants down quickly, and this problem can be compounded with frequency or urge incontinence [Witchard, S., 2004]. Men, who are often not used to tight fitting garments, seem to be especially susceptible to this problem [Witchard, S., 2004; Hayes et al., 2008; Witchard, S., 2004]. Men also have the tendency to not wear underwear while in the hospital. Instead they wear pyjama trousers, which enable them to use a urinal bottle or commode. Hip protectors slow them down and accidents can occur.

In the Hayes and colleagues (2006) study, two factors were found to be statistically significant in facilitating hip protector adherence, and have been supported by other studies. These two factors were independence in fitting the hip protectors (making the patient less reliant on staff for toileting), and being of the female gender [Hayes et al., 2008; Witchard, S., 2004]. Being independent in fitting the hip protectors without nurse assistance was possibly because patients were likely to be motivated and engaged with rehabilitation, and less reliant on the staff for prompting and for assistance with toilet access. These patients were also more likely to be discharged home, rather then to institutional care, which would account for the statistical effect of discharge destination in the univariate analysis [Hayes et al., 2008]. Being female may, however, not be so much a facilitator to compliance, but that males are less compliant overall. This can be comparatively explained by the design of the male garments, as discussed above.

Better adherence has also been seen with shorter duration of time in acute care [Hayes et al., 2008]. This could be related to the motivation of the patient, which could decline with time, or the increased risk of loosing garments over a longer duration. On average, patients who are in the hospital for longer, also tend to be discharged to residential or institutional care. Patients, who are discharged home, tend to take a more active role in rehabilitation. This portrays a key difference from the more passive compliance of a dependent care-home population [Hayes et al., 2008].

Discomfort is the number one patient complaint about hip protectors both at night and during the day. It is the foundation of most non-compliance amongst the studies. In the Haines and colleagues (2006) study, 82% of patients did not wear the hip protectors at night and in the Hayes and colleagues (2008) study, nighttime compliance decreased from 58% during the day, to 23% at night. Discomfort can lead to problems sleeping, as well as reduce mobility of the patient when lying down [Haines et al., 2006, Hayes et al., 2008; Witchard, S., 2004]. Skin irritation, abrasions, and allergies are also common complaints. This barrier is something that manufactures need to address and repair. Patient aversion to hip protectors is understandable when the garment makes them uncomfortable throughout the day. Appearance and design immediately put off patients when they are presented with the garment. Patients have an aversion to the appearance of the hip protectors under any clothing, and have indicated that they are bulky and unfashionable [Foster et al., 2007; Haines et al., 2006, Hayes et al., 2008; Witchard, S., 2004]. Manufacturers need to improve the design of hip protectors [Witchard, S., 2004]. With an improved design that addresses patient complaints of discomfort, hip protector compliance should be positively effected.

Being unwell is expected in the hospital. Patients are there for a reason. It can also make it difficult to adjust to new intervention methods. Patients can have psychological issues, depression, confusion, be worried over discharge, worries about arrangements and paying bills, or their medical condition or mental state could be deteriorating [Foster et al., 2007; Hayes et al., 2008; Lockwood et al., 2003; Witchard, S., 2004]. There are a number of factors that can cause a patient not to be able to cope with the introduction of hip protectors at the present time. This was recorded as a barrier in four of the six articles found. The hospital experience can be overwhelming and patients feel like they do not want to have to make extra decisions or take in any new information [Witchard, S., 2004]. Deterioration in medical condition or mental state can cease patient compliance.

Staff must support the use of hip protectors in order for patient compliance to be high within a hospital. Hip protectors can unintentionally increase staff workload with respect to laundry, lost garments, patient toileting, and patient encouragement. This can be a barrier when it comes to getting nursing staff to promote them. More research and clinical trails need to occur to make hip protectors more efficient and not be a burden on staff workload.

In four of the six studies, hip protectors were found to increase patient confidence, self-efficacy, motivation and engagement in the rehabilitation process [Foster et al., 2007; Haines et al., 2006; Hayes et al., 2008; Witchard, S., 2004]. All these positive effects can help to increase patient quality of life both during their stay in the hospital and post discharge if they continue to wear them. This is encouraging and is one of the reasons why many researchers, health care staff and administration are so optimistic about hip protectors becoming a recognized public health intervention and fracture prevention method.

1.7. Stick-on Hip Protector

A potential solution to many of the barriers associated with garment-based hip protectors is to attach the pads directly over the skin of the patients at high risk for falls and fractures. Adhesive ("stick-on") hip protector pads may offer many advantages over conventional garment-based models within a hospital environment including:

a) Increased force attenuation – tested using the Simon Fraser University hip impact simulator and compared against the current pads in use within Fraser Health hospitals to guarantee equal or superior protection;

b) No shifting – shifting has been shown to substantially decrease the biomechanical effectiveness of hip protectors [Minns et al., 2007]; once placed in the correct position, adhesive pads will move comparatively less than pads inserted into pockets of garments;

c) Offers continuous protection – including during toileting, which was identified as a high-risk activity for falls and fractures within hospital settings [Malkin, S. & Frankenburg, F., 1978];

d) Decrease staff workload – care providers only need to check the pads once or more daily; patient dependency on staff while toileting should decrease and time spent searching for the appropriate hip protectors will decrease;

e) No laundry or disinfecting requirements – reducing the risk of lost garments and garment availability; each patient can be given a set of one-patient use stick-on hip protectors for the duration of their stay, if they pads become soiled, they can be properly disposed of by staff;

f) No need for different sizes or male/female models; a one-size-fits-all approach;

g) Decreased supply cost – the average cost of providing a typical ward with hip protectors within the Fraser Health region is CAD $5000 annually, at $40-150 per device, and by three months the supply of hip protectors has been shown to decrease by 80% due to hip protectors going missing/damaged [Foster et al., 2007; Hayes et al., 2008; Witchard, S., 2004].

Despite these benefits, our literature search revealed no evidence of clinical evaluations of hip protectors that incorporate an adhesive to secure the device directly to the skin. A patent search revealed two stick-on hip protector designs, one assigned in 1995 [Olsen, H., 1999] and the other in 2005 [Minns, J., 2005]. Both designs included hard shell devices and different methods of adhesion. An Internet search revealed no evidence of commercialization of these products.

1.8. Goals and Objectives

The goals of this research are to initiate and complement the development of a low-cost single-patient use adhesive hip protector pad that provides greater force attenuation than hip protectors currently being used in hospitals. This research will provide a foundation for further clinical exploration of stick-on hip protectors in a hospital environment.

Aim 1: Biomechanical Development: To develop and optimize pad prototypes using the Simon Fraser University Hip Impact Simulator. Currently, Fraser Health hospitals provide patients with two commercial hip protectors; Safehip® Soft (Air-X) and Hip Saver®. These hip protectors reduce femoral impact forces by 24% and 25% respectively [Laing et al., 2011]. Through systematic testing and qualitative feedback from the feasibility pilot trial, I intend to produce a pad that has a force attenuation of at least 30%.

Aim 2: Feasibility Pilot Trial: To conduct a 7-day qualitative pilot trial at Burnaby Hospital, Medicine Unit, using a preliminary pad prototype comparable to the current standard of care to test feasibility and tape adhesion.

Aim 3: Feedback Fair: To conduct a Feedback Fair at two Surrey Memorial Hospital units; Acute Care for Elders (ACE) Unit and Medicine Unit. The Feedback Fair will probe staff perspectives on the current garment hip protectors within a hospital environment and elicit feedback on the stick-on hip protector prototype design. Participants will complete a series of six stations that include information displays, interactive posters and a questionnaire.

Chapter 2.

Biomedical Testing and Development of a Stick-on Hip Protector

2.1. Introduction

This chapter describes my efforts to develop and optimize the biomechanical performance of a stick-on hip pad prototype. Currently, Fraser Health hospitals provide patients with two commercially available garment-based hip protectors: Safehip® Soft (Air-X) and Hip Saver®. Previous studies have shown that, when tested with the Simon Fraser University Hip Impact Simulator (Figure 4), these hip protectors reduce the peak force applied to the proximal femur by 24% and 25%, respectively [Laing et al., 2011]. By systematically varying the pad surface area and thickness, I hoped to produce a stick-on hip protector prototype that provides at least 30% force attenuation.

My efforts built upon recent results from our laboratory [Deshmukh, 2013], which examined the effect of foam stiffness, as well as pad thickness and surface area, on the force attenuation provided by hip protectors. These previous studies found that a shore hardness of approximately 60 durometer provided optimal protection, in the sense that force attenuation decreased for durometers that were below or above this value. Accordingly, I used foam stock having approximately 60 durometer hardness for all prototypes, and focused on examining how force attenuation was affected by variations in surface geometry and thickness, that extend well beyond the variations in these parameters examined by Deshmukh [Deshmukh, 2013].

2.2. Methods

All testing was conducted with the Simon Fraser University Hip Impact Simulator (Figure 4), which simulates the effective mass and stiffness of the body during a fall on the hip, and is compatible with recommended guidelines for biomechanical testing of hip protectors [Robinovitch et al., 2009]. The system consists of an impact pendulum, which can be raised and released from various heights (producing different impact velocities). A surrogate pelvis at the end of the pendulum contacts the ground, and a load cell (Model 9712B5000, Kistler, Amherst NY) records the force applied to the proximal femur during a sideways fall at a rate of 1000 Hz. Most fractures seem to be caused by a sideways impact with direct impact on the greater trochanter of the proximal femur [Cummings, S. & Nevitt, M., 1989; Hayes et al., 1993, Yang et al., 2015]. The primary outcome measure from testing of a specific hip protector is the percent reduction in peak force applied to the proximal femur (force attenuation), when compared to the peak force measured in baseline, unpadded trials.

Testing was conducted at four different velocities (2, 3, 3.4, and 4 m/s), simulating falls of different severity, and presented in random order. An impact velocity of 3.4 m/s is the value recommended by international guidelines [Robinovitch et al., 2009]. The impact velocity of 2 m/s was achieved with a 10.9 deg release angle, 3 m/s with a 25.7-deg release angle, 3.4 m/s with a 33.7 deg release angle and 4 m/s with a 49.6 deg release angle.

For each impact velocity, each hip protector pad was tested three repeated times. Each hip protector was centered over the greater trochanter and secured to the surrogate pelvis with double-sided adhesive tape. Three unpadded trials were conducted at the beginning and end of the test session. In all tests, force data were sampled for 2 s at 1000 Hz, and filtered with a dual-pass fourth-order Butterworth low pass filter with a 35 Hz cut-off frequency, using Labview software (version 6.1, National Instruments, Austin, TX, USA).

For each hip protector, force attenuation (at a given impact velocity) was calculated as the percentage decrease in peak femoral neck force (average value over the three repeated trials), compared to the peak femoral force in the unpadded condition (average of the six repeated trials).

2.2.1. Hip Protector Surface Geometry Testing

In the first round of testing, eight different surface geometries were evaluated (Figure 6): (1) 17x13.5cm and (2) 19x15.5cm “no hole” pads (having a continuous surface); (3) 17x13.5cm and (4) 19x15.5cm “small donut hole” pads (donut-shaped with an inner hole of 4 cm width); (5) 17x13.5cm and (6) 19x15.5cm “large donut hole” pads (donut-shaped with an inner hole of 6 cm width); (7) 19x15.5cm “horseshoe” pad (shaped like a horseshoe, with the top portion of the pad resting above the greater trochanter); and (8) 19x15.5cm vented holes pad. The products were evaluated in random order. All pads had a constant thickness of 16 mm.

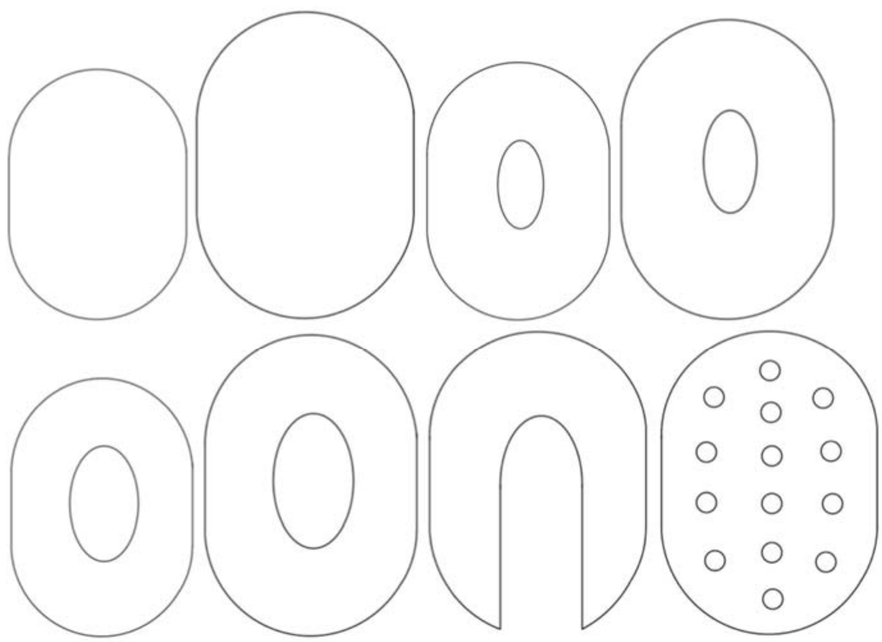

Figure 6. Variations in pad surface geometry. Pad prototypes had surface areas of 19x15.5cm or 17x13.5cm, and were either continuous (no hole), horseshoe shaped, donut shaped (with small or large holes), or containing vent holes.

A two-factor analysis of variance (ANOVA) was used to examine whether force attenuation was associated with impact velocity and pad type. Significant associations (based on an alpha = 0.05 significance level) were followed up with Tukey HSD post-hoc comparisons. All analyses were conducted with JMP (Version 10.0.0) statistical analysis software.

2.2.2. Hip Protector Pad Thickness Testing

A second round of testing focused on examining the effect of pad thickness on the force attenuation provided by the "large donut hole" pads (of surface areas 17x13.5cm or 19x15.5cm), which provided the greatest mean force attenuation in the first round of testing. The "large donut hole" pad was ultimately chosen over the horseshoe pad to use for further testing due to its structural integrity and easier positioning for staff.

Three pad thicknesses were tested: 16 mm, 20 mm and 24 mm. These values were selected based on previous observations that the thickness of commercial hip protectors ranges from 7 to 31 mm, with the most commonly used devices having thicknesses of 16-19 mm [Laing et al., 2011]. All tests were conducted at an impact velocity of 3.4 m/s.

Singe factor ANOVA was used to test the hypothesis (consistent with previous observations [Laing et al., 2011]) that increases in the thickness of the pad would lead to improved force attenuation.

2.3. Results

2.3.1. Hip Protector Surface Geometry Testing

From the first round of testing, force attenuation associated with surface geometry (F-ratio 6.73, p-value 0.0001; Figure 7), and with impact velocity (F-ratio 53.5, p-value 0.0001; Figure 8). Furthermore, there was a significant interaction between surface geometry and impact velocity on force attenuation (F-ratio 42.5, p-value 0.0001). The best performance was provided by the 19x15.5cm large donut hole pad and the 19x15.5cm horseshoe pad (as shown in the connected letters report for the mean effect of surface geometry on force attenuation; Figure 9). For all products, force attenuation decreased with increasing impact velocity. However, the effect was less pronounced for the “no hole” pad than for pads with holes. Pads with holes performed especially well at low impact velocities. Table 1 provides means, standard deviation and confidence intervals for the force attenuation (shown as a percent) for the various surface geometries. Appendix A presents raw data (in the order of testing) for all eight surface geometries.

Table 1. Force attenuation (shown as a percent) for the various surface geometries.

Level	Mean (%)	Std Dev (%)	Std Err (%)	95% Confidence Interval
19x15.5cm Large Donut Hole Pad	23	8	4	10-35
19x15.5cm Horseshoe Pad	22	7	4	11-34
19x15.5cm Small Donut Hole Pad	22	7	4	10-24
17x13.5cm Large Donut Hole Pad	20	7	3	9-30
17x13.5cm Small Donut Hole Pad	18	6	3	8-27
19x15.5cm No Hole Pad	18	4	2	12-24
19x15.5cm Vented Holes Pad	18	3	2	13-24
17x13.5cm No Hole Pad	15	2	1	11-19

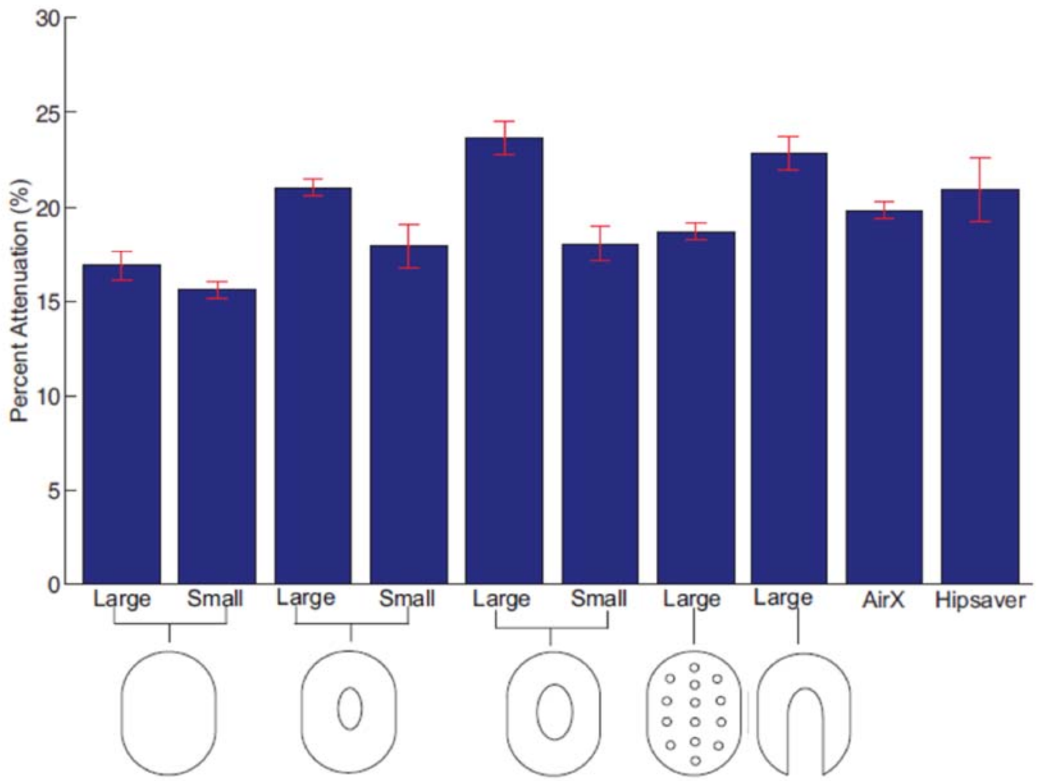

Figure 7. **Mean values of force attenuation (with error bars showing +/- one standard deviation) provided by the eight pad geometries at an impact velocity of 3.4 m/s. In all cases, pad thickness was 16 mm.**

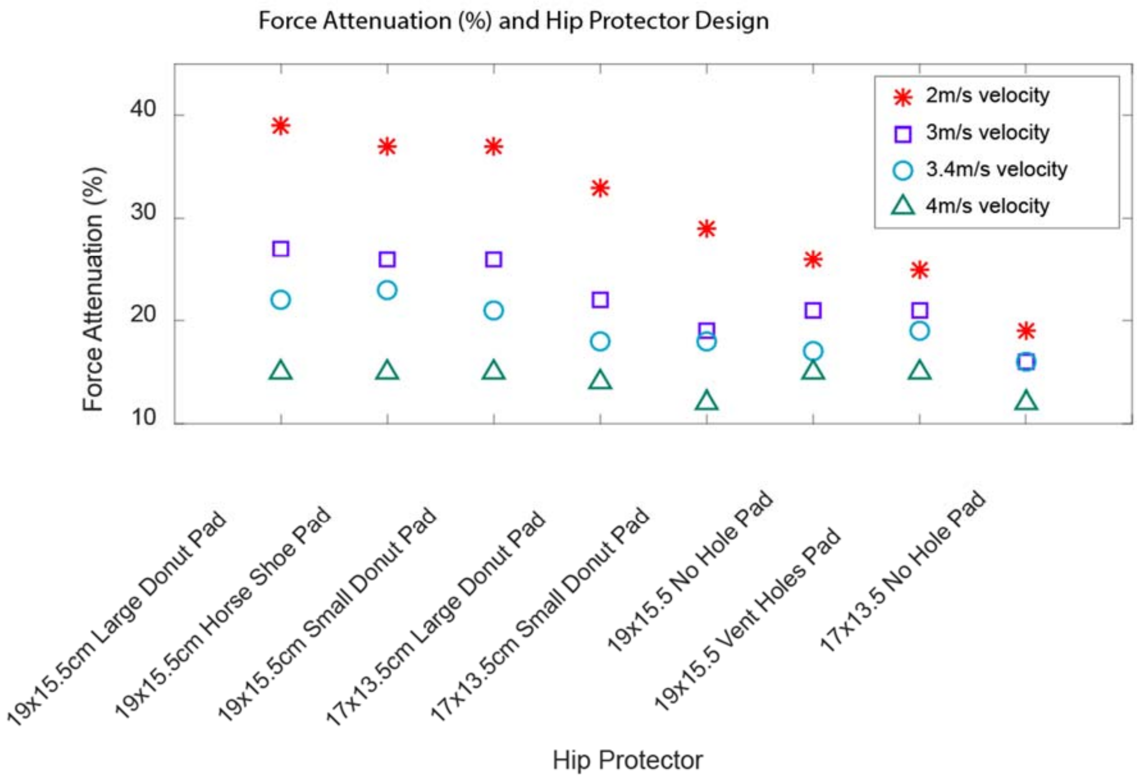

Figure 8. **Scatter plot showing mean values of force attenuation provided by each of the eight pad geometries, at four different impact velocities.**

Level						**Least Square Mean**
19x15.5cm Large Donut Pad	A					0.23
19x15.5cm Horse Shoe Pad	A	B				0.22
19x15.5cm Small Donut Pad		B				0.22
17x13.5cm Large Donut Pad			C			0.20
19x15.5cm 13 Vent Holes Pad				D		0.18
19x15.5cm No Hole Pad				D		0.18
17x13.5cm Small Donut Pad				D		0.18
17x13.5cm No Hole Pad					E	0.15

Figure 9. **Connected letters report of effect of hip protector surface geometry on force attenuation. Levels not connected by same letter are statistically different.**

2.3.2. Hip Protector Pad Thickness Testing

From the second round of testing, there was a significant association between force attenuation and pad thickness (F-ratio 91.9, p-value 0.01; Figure 10). As expected, force attenuation increased with pad thickness, in a roughly linear manner. For the 19x15.5cm large donut hole pad, force attenuation increased from 28% at 16 mm thickness, to 36% at 20 mm thickness and 43% at 24 mm thickness. For the 17x13.5cm large donut hole pad, force attenuation increased from 20% at 16 mm thickness, to 30% at 20 mm thickness, and 34% at 24 mm thickness. Accordingly, both prototypes provided at least 30% force attenuation with a thickness of 20 mm. Table 2 provides means, standard error and confidence intervals for the force attenuation (shown as a percent) for the various thicknesses. Appendix B presents raw data (in the order of testing) for all three thicknesses.

Table 2. Force attenuation (shown as a percent) for the various pad thicknesses

Level	Mean (%)	Std Err	95% Confidence Interval
16mm Thickness	24	0.76	21-27
20mm Thickness	33	0.76	30-36
24mm Thickness	38.5	0.76	35-42

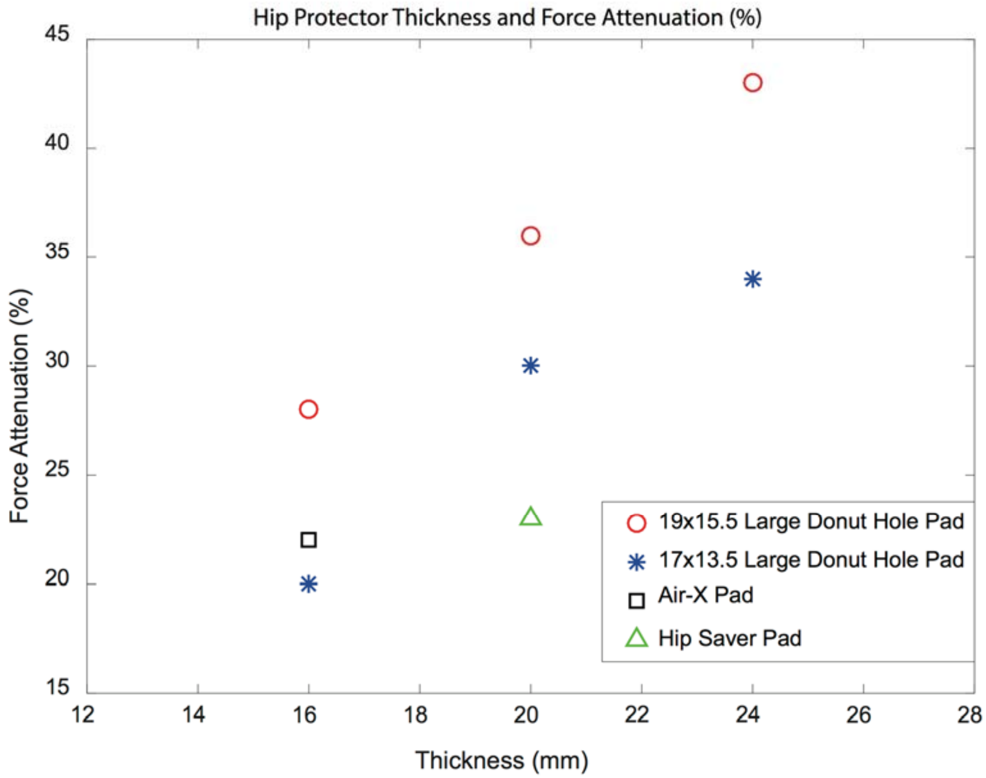

Figure 10. Mean values of force attenuation for three thicknesses (16 mm, 20 mm and 24 mm) of the 19x15.5cm and 17x13.5cm large donut hole pads. Also shown are the two hip protectors currently used within Fraser Health hospitals. Impact velocity was 3.4 m/s.

2.4. Discussion

From our tests of pad geometry, we found that the 19x15.5cm large donut hole pad, and the 19x15.5cm horseshoe pad, provided the greatest force attenuation. Each of these two products exceeded the force attenuation provided by garment-based hip protectors currently used within Fraser Health hospitals. Accordingly, assuming equivalent or better patient compliance, these designs should meet or exceed the standard of care in hip protectors currently being received by patients.

The donut hole and horseshoe designs provide a combination of energy absorption and energy shunting to the surrounding soft tissue by forming a bridge over the bone. The large donut hole provided more force attenuation than the small donut hole pad, apparently due to greater force shunting. Increasing the surface area of the large donut hole pad from 17x13.5cm to 19x15.5cm caused an increase in force attenuation. Apparently, the smaller surface area restricted distribution of the force to a region closer to the bone. The “no hole” (continuous) and vented holes pads exhibited inferior performance, apparently due to their reliance on energy absorption, and less effective force shunting.

Impact velocity had a significant effect on force attenuation, and this effect depended on pad geometry. At the 2 m/s impact velocity, the donut hole and horseshoe shaped pads provided approximately 50% greater force attenuation than the “no hole” (continuous) or vented hold pads. Substantial differences were also present at the recommended 3.4 m/s impact velocity. However, at an impact velocity of 4 m/s, there was little difference in performance between the various pad geometries. A possible reason for these trends is greater compression of the pad under high impact velocities, reducing the ability of the donut and horseshoe pads to form an effective bridge over the bone.

Increasing the thickness of the large donut hole pads caused a substantial improvement in force attenuation. When compared to 16 mm thick products, a 24 mm thick version provided 54% more force attenuation for a 19x15.5cm surface area, and 70% more force attenuation for a 17x13.5cm surface area. These trends probably reflect that increasing pad thickness results in increased energy absorption, less “bottoming out” of the pad, and more effective force shunting.

Previous literature has documented that the average force required to fracture an elderly woman’s proximal femur under simulated fall-loading conditions is 3100 N (however this number will vary between individuals depending on the structural and material properties) [Cheng et al., 1997; Kannus et al., 1999]. If hip protector pads are worn at the time of the fall, the impact force will be absorbed and shunted to the surrounding soft tissues, reducing the force directly experienced by the proximal femur and subsequently reducing the risk for hip fracture.

Patient acceptance and adherence with hip protectors depends on surface geometry, thickness and stiffness. It may be necessary to increase pad thickness to provide adequate biomechanical protection, however the elderly may be unwilling to wear something that makes their hips look wider or makes them uncomfortable [Neil, A., 2007]. Honkanen and colleagues found that soft and flexible pads were selected over their stiffer counterparts due to perceived comfort when worn [Honkanen et al., 2006]. However, users consider both comfort and perceived protective value in selecting products. This was demonstrated by Deshmukh, who reported that participant perceived hip protectors with the smallest thickness as most comfortable and attractive when worn. However, hip protectors with intermediate values of thickness were perceived to provide the greatest protective value [Deshmukh, 2013]. Since hip protectors must be worn at the time of the fall to be effective, the success of the technology depends on selecting a pad thickness that represents the ideal balance between biomechanical performance and user acceptability. Both the 20 mm thick 19x15.5cm and 17x13.5cm large donut hole pad achieved acceptable biomechanical performance. Chapter 3 addresses issues of user acceptance of this product.

2.5. Conclusions

Biomechanical testing of foam hip protectors having eight different surface geometries was conducted using the Simon Fraser University Hip Impact Simulator. The 19x15.5cm large donut hole pad and the 19x15.5cm horseshoe pad provided the greatest force attenuation, presumably due to their combined energy absorption and energy shunting. Differences between surface geometries were most striking at low impact velocities. The force attenuation provided by the 19x15.5cm and 17x13.5cm versions of the large donut hole pad increased with pad thickness. At an impact velocity of 3.4 m/s, 20 mm thick versions of these products provided 36% and 30% force attenuation, meeting our target design criteria.

Chapter 3.

Product Evaluation

3.1. Introduction

A commonly identified barrier to current garment-based hip protectors is discomfort, both at night and during the day [Witchard, S., 2004; Haines et al., 2006, Hayes et al., 2008]. Improvements in the design of hip protectors must be based on enhanced understanding of the clinical challenges experienced by end-users. Market research and product evaluation are commonly used strategies to develop a competitive and functional product. This chapter describes the opinions of end users in the acute care setting on hip protectors from a Feedback Fair and a pilot trial of patient compliance with novel stick-on protectors.

Two stages of product evaluation were completed to assess the appropriateness of stick-on prototypes for the hospital setting. First, during the preliminary stages of development of the stick-on protector, I conducted a pilot trial to gather observations and feedback from patients and families/caregivers as patients wore the protector for 7 days. The pilot trial was conducted to determine if patients and staff would be willing to wear and accept the stick-on pad and to warrant further biomechanical testing to refine the design. The feedback provided during the pilot trial facilitated product improvements and proof-of-concept regarding the protector, as well as clinical feasibility.

Following product improvements, I conducted a second stage of product evaluation, involving planning, execution and analysis of data emerging from a Feedback Fair. The Feedback Fair targeted staff from an Acute Care for Elders (ACE) unit and a Medicine unit within a Fraser Health (FH) hospital, and focused on the challenges experienced with conventional garment hip protectors and opinions regarding the strengths and barriers to the stick-on hip protector prototype.

3.2. Pilot Trial of Patient Compliance in Acute Care

3.2.1. Methodology

A feasibility pilot trial was conducted over a two-week period using a preliminary (Version 1) stick-on hip protector prototype with patients in a Medical unit at Burnaby hospital. The prototype was a 16 mm thick, 19x15.5 cm no hole" pad (having a continuous surface) (Figure 11). Registered nursing staff approached six patients to wear the stick-on protector. Five patients wore the stick-on protector for 7 consecutive days and one patient refused to participate. The patient who refused to participate had previously refused the conventional garment hip protectors and had been admitted to the hospital for reasons of confusion.

The pad was fixed to the skin using a skin friendly adhesive tape (3MTM Gentle Silicone Two- in-One Polyester, Double Coated Tape 2477P). This adhesive tape was specifically design for medical device attachment and used for patients with sensitive, compromised or at-risk skin (e.g., elderly patients). The tape offers reliable, strong adhesion, with minimal epidermal cell stripping. It incorporates two adhesive systems: a acrylate adhesive on one side for device attachment and a proprietary hypoallergenic, latex free silicone adhesive on the other side for gentle, repositionable attachment to skin. Manufacture specifications outline that the tape can remain adhered to the skin for up to 21 days, during which time it can be removed and reapplied without compromising adhesion.

During the pilot trial, posters were displayed around the unit informing staff of proper application and awareness of the new product. Nursing staff was educated by the unit's Clinical Nurse Educators on how to properly attach the adhesive (Figure 11). Nursing staff was asked to remove the pads on a daily basis to inspect the skin for any side effects and monitor the adhesive stickiness. They also reported on a daily basis on issues related to use. Reports were based on direct observation and feedback from patients and families/caregivers. All information regarding the stick-on hip protector prototypes were recorded in nurse Medical Administration Record (MAR) binders during morning, evening and night shifts.

The Office of Research Ethics for Simon Fraser University and the Fraser Health Research Ethics Board approved the study.

Figure 11. Patient wearing the preliminary stick-on hip protector prototype. Note that this particular patient is also wearing an incontinence garment over the hip protector.

3.2.2. Results

Feedback from patients and staff in the pilot trial was encouraging. Of the 6 patients approached, three patients had no complaints about discomfort, one complained about discomfort at night only and resorted to wearing them only during the day, one found them uncomfortable but wore them anyway, and one refused to try them. No side effects were reported related to the adhesive tape and there were no complaints of pain when removing the pads (Table 3). Only one patient had problems with loss of adhesive stickiness after bathing. Cleaning and fully drying the skin before reapplying the pad solved this problem.

Some barriers to the stick-on protector were also noted during the pilot trial. There were some complaints of underwear and incontinence products “catching” on the edges of the pad when pulling them down. While sleeping, patients found that the pads came off if they were turning or moving around in bed. Difficulties with pad adhesion were also seen with larger patients.

The pilot trial helped to transform the preliminary Version 1 protector. The Version 2 protector included gently tapered edges to enhance adhesion and eliminate the “catching” problem. A ventilation hole was added to improve force attenuation of the pad and pad breathability for the patient. To further improve force attenuation, the pad thickness was increased from 16 mm to 20 mm and four grooves were added to allow the pad to form to the shape of the hip when adhered to the skin (Figure 12). Originally the Version 1 prototype had a force attenuation of 17% at 3.4 m/s impact velocity (testing using the SFU Hip Impact Pendulum; Figure 4). By making these adjustments, the Version 2 pad had a force attenuation of 36% at 3.4 m/s impact velocity.

Table 3. Pilot trial patient demographics and qualitative results

Patient	Age	Accepted Wearing Hip Protectors	Number of Days Wearing Hip Protectors	Nurse Comments
A	90	Yes	7	No side effects Patient stated they were uncomfortable once
B	91	Yes	7	No side effects No complaints of any discomfort
C	87	Yes	7	No side effects No complaints of any discomfort
D	82	Yes	7	No side effects Patient complained of stiffness in the right hip (admitted to the hospital for a hip fracture) Patient had previously worn garment hip protectors
E	79	Yes	7	Patient was larger in size, hip protectors fell off easily
F	76	No	0	Previously refused garment hip protector Admitted to hospital for confusion

Figure 12. Version 2 stick-on hip protector; 19x15.5cm large donut hole pad, 20 mm thick with tapered edges and grooves to allow foam to form to the skin

3.3. Feedback Fair with Care Providers in Acute Care

Feedback fairs are a form of market research. They are a flexible, health care appropriate, model of a popular participatory method of encouraging knowledge transfer and exchange (KTE), called the World Café [Fouché & Light, 2011]. Feedback Fairs are a low-cost, low-resource method of engaging small groups of health care professionals [Sims-Gould et al., 2014].

In collaborative conversations participants travelled through a number of “stations”. The small group format facilitates participants to ‘drop-in’ during their coffee breaks, at any point in the day. This flexibility is imperative due to the context and demands of health care professionals working in an acute care environment.

ACE and general Medicine units have been identified as an ideal location to conduct a Feedback Fair focused on hip protectors because they typically have patients who are 75 years or older who have suddenly fallen seriously ill, have a number of medical problems at one time and/or are at risk of losing the ability to function independently. Due to the multiple co-morbidities and age of the typical patient, ACE and Medicine units are identified as high-risk fall zones. The staff are specially trained to address these issues and within the last five years, hip protectors have become an important addition to their fall and injury prevention protocols. Health care professionals who work on these units are very familiar with the challenges experienced by the garment-based hip protectors. Their opinions and advice regarding hip protectors, and the final stages of development of the stick-on hip protectors, were considered to be indispensable.

3.3.1. Methodology

The Feedback Fair was conducted during a single workday following the development of Version 2 of the stick-on hip protector. This version incorporated tapering of the pad edges and additional modifications described above. The Feedback Fair was set up in an all-purpose room on the Acute Care for Elders (ACE) unit at Surrey Memorial Hospital. Six stations were set up in a horseshoe formation (Figure 13). At the first station, a researcher explained the study in plain language and provided background information on conventional garment-based hip protectors. This first station discussed the consequences of hip fractures and how the incidence of hip fractures can be reduced. The next two stations were interactive stations for participants to share their opinions on barriers, and strategies for overcoming these, with conventional hip protectors. These stations also probed improvement initiatives for conventional hip protectors. Participants were given sticky notes and asked to write down at least two ideas for each of the columns. Station 4 introduced stick-on hip protector prototype (Version 2), explaining the biomechanical and pilot clinical trial results. A researcher was present to discuss and explain the poster in plain language. Another interactive (sticky note) poster asked participants to provide responses regarding their initial likes and dislikes of the stick-on hip protector prototypes. Two stick-on prototypes were available for participants to manipulate and inspect. At the sixth and final station, a quick questionnaire was available for participants to fill out (See Appendix C). The questionnaire probed: opinions on design features of the stick-on hip protector prototype (including colour, shape, size, thickness and stiffness), and an evaluation of the Feedback Fair experience.

Throughout the Feedback Fair, a researcher was present to answer questions, encourage dialogue and record observational field notes. Healthy complimentary snacks and beverages were available to participants as they worked their way through the six stations and interacted with the researchers. The stations typically required less than 15 minutes to complete in total. After participants filled out the questionnaire, a researcher provided them with a $5.00 Starbucks gift card thanking them for their participation.

Data was collected in three formats from the feedback fair including conversation between researchers and participants, which were recorded as field notes during participant lulls, through the interactive posters with the sticky notes and with the questionnaire. Data analysis focused on systematic gathering and interpretation of participant feedback by coding and clustering codes into common trends. Member checking between the three forms of data collection (field notes, interactive posters and questionnaire) was used to confirm consistency within the findings. Member checking is a method to ensure internal validity by validating intentionality of the findings.

The Office of Research Ethics for Simon Fraser University and the Fraser Health Research Ethics Board approved the study.

Figure 13 **Format of the feedback fair six stations: 1) Study explanation and background information on conventional hip protectors; 2) Interactive station looking at barriers and strategies with conventional hip protectors; 3) Interactive station probing improvement initiatives for conventional hip protectors; 4) Lab and feasibility pilot test results of stick-on hip protector prototypes; 5) Interactive station looking at initial likes and dislikes of the stick-on hip protector prototypes; 6) Stick-on hip protector questionnaire. Along the back windows, complimentary healthy food and drinks were available.**

3.3.2. Results

Overall, 43 participants attended the feedback fair and completed the questionnaire; 18 from the Medicine unit, 22 from the ACE unit and 3 participants who floated between both units.

3.3.2.1 Conventional Hip Protectors

Three trends emerged from the interactive posters and field notes on the reasons patients refused to wear conventional garment-based hip protectors during their hospital stay. These included: 1) poor fit; 2) lack of availability; and 3) patient discomfort when wearing the garments.

Within Fraser Health Authority hospitals, hip protectors are provided to high-risk fall patients during their stay. Unfortunately, the correct size garments are not always available for a given patient. One registered nurse commented, “sometimes patients are between small and medium so it doesn't fit right!" Another said, "that is one of the biggest problems we face with hip protectors, improper sizing." Research has shown that when hip protectors shift and are worn improperly, they become less effective in the event of a fall [Minns et al., 2007; Choi et al., 2010]. Poor fit also affects patient independence when toileting. "Patients trying to go to the washroom independently can not get the garment off." Another concern with garments was the risk for patients tripping while trying to remove the garment. "Patients are weak and when they try and take them off, sometimes they fall. We don't want to be increasing falls with a fracture prevention method," stated one registered nurse. Another registered nurse confirmed this concern when they said, "Models that are too big end up around patient's knees and act as a tripping hazard. Whereas, models that are too small are too difficult to remove for weaker patents, which result in loosing their balance and/or soiling themselves when going to the washroom."

Availability was another common barrier experienced by staff when dealing with garment-based hip protectors. One registered nurse stated, "you need them and they are not there… they never come back from the laundry." Another registered nurse said, "hip protectors go missing in the laundry or to other units… this happens all the time… we've had hip protectors from Peace Arch and pillows from Chilliwack General show up on our unit!" Participants described that, even after labeling hip protectors with laundry-markers and color-coding, they often did not return from the laundry room. Furthermore, lack of availability perpetuates the previously discussed trend of poor fitting garments. "Different styles of hip protectors for each patient would address the problem of improper fit, however the lack of availability does not allow this to be possible," declared a registered nurse.

The third emerging trend was patient discomfort. On the interactive posters, "too tight" was posted nine times, "uncomfortable" was posted eight times, "too hot" was posted five times, and "too bulky" was posted twice. One registered nurse commented, "patients don't want to wear [garment] hip protectors because they don't fit properly… they are uncomfortable." Another registered nurse pretended to mimic a patients saying, "Agh, its too hot, why do we need to wear so many layers?" She said this as she shook her hands in the air, she continued to explain, "it's too many layers, the hip protectors and the incontinence pads, they can't get them down in time [to go to the washroom]."

3.3.2.1.1 Strategies to Improve Patient Compliance

The interactive poster posed the following question to staff: “In your experience, what are the best strategies to encourage patients to wear hip protectors during their stay at your facility?” The response focused on sizing, availability, design to improve comfort, and education of the patient, family and staff on the value of hip protectors.

Staff noted that it was important that patients were aware that they were at risk for falling and the repercussions of a fracture in a later stage of life. Registered nurses commented that, “[you need to] explain that this is a preventative measure” and “make the patient aware of the consequences of hip fracture and the benefits of wearing [hip protectors].” Due to the hospital setting, often, patient cognitive impairments make this process difficult. “If [patients are] disoriented, sharing this information and involving the care givers and/or family to help encourage the patient to wear them really helps.” One registered nurse admitted that she took a more of a proactive approach. “I just put them on, I take the ‘mom approach!’… This is what we are wearing today!”, while clarifying that the patients can always say no.

3.3.2.2 Stick-on Hip Protector Prototype

3.3.2.2.1 Stick-on Hip Protector Prototype Likes

Three trends emerged from the interactive posters and field notes in regards to what staff initially liked about the stick-on hip protector prototypes including: 1) ease of use; 2) their potential to improve patient comfort; and 3) their potential to reduce hospital hip protector costs. One registered nurse said, “can’t wait to test them out!” Another nodded approvingly and said, “very impressive,” and a few agreed that they “would love to trial [the stick-on hip protectors] on our unit!”

Ease of use was the most reoccurring affirmative trend acknowledged by staff. A typical initial impression of the stick-on pad was that “it is easy to put on and I think will save us time.” On the interactive posters, “easy to use,” “easy application,” and “easy removal” was documented. Staff also commented repeatedly on how they felt that the stick-on hip protectors would improve patient toileting and patient independence. One registered nurse was impressed that the prototypes “avoids specialized underwear that is hard to pull down and consequently facilitates incontinence." Others credited that they felt that the stick-on hip protector prototypes will "promote easier toileting". Additionally, its was recognized that the "best thing will be we don't need to take them off for the washroom."

Staff was excited that the pilot trial results suggested less discomfort among patients. Conversations around the fact that there were "decreased layers" and "not baggy" or "bulky" were very common. However, staff also expressed the need for more information and a more carefully designed clinical trial. Staff also noted that a range of sizes might also be beneficial to fit a variety of body shapes.

Many staff agreed that the stick-on hip protectors have the potential to reduce costs, however a few people include a clinical nurse educator, a patient care coordinator, a physiotherapist, and an occupational therapist expressed their desire to see a cost effectiveness evaluation within the context of a larger clinical trial.

3.3.2.2.2 Stick-on Hip Protector Prototype Dislikes

Three trends emerged as concerns regarding the stick-on hip protectors, including: 1) environmental impact, 2) apprehensions with the adhesive and long-term skin integrity, and 3) colour preference.

Originally, the prototypes were not recyclable. Staff wanted to know "why is it disposable rather then recyclable?" and "how can we reduce the waste?" One registered nurse commented, "You need to fix that they are not recyclable!" The environmental impact was a major concern for a variety of staff members. Some staff suggested a plan of sending the stick-on pads home with patients; however there were also concerns about patients not knowing how to properly place the pads for maximum protection. Another suggestion was to provide an inexpensive garment with pockets for patients to purchase at discharge, that they could put their pads into. This could increase the number of hip protectors in the community and reduce the waste in the hospital.

Regarding the adhesive, staff were concerned that the pads might fall off easily and that patients could remove the pads. This was particularly a concern with dementia and/or confused patients. Despite the lack of evidence of skin irritation from the pilot trial, staff were concerned that the “skin [was] not being able to breath” over longer durations. Again, a longer clinical trial could address these concerns. The issue of infection control was raised, stemming from feces or urine sticking to the adhesive.

The final suggestion from the staff was to make the pads a lighter colour, (skin colour or white/beige) to reduce the visual signs that patients are wearing the pads – an issue many tend to be sensitive about.

3.3.2.3 Feedback Fair Evaluation

When asked how they would rate their overall experience in the Feedback Fair, staff responded with a mean score of 4.2 on a 5-point scale, circling ‘satisfied’ most frequently with one participant responding ‘neutral’. On whether they would be willing to participate in a similar event in the future, staff responded with a mean score of 4.5 on a 5-point scale, circling ‘very interested’ most frequently. On whether they learned anything new about hip protectors, staff responded with a mean score of 4.2 on a 5-point scale, circling ‘somewhat’ most frequently (Figure 14).

How would you rate your overall experience at the feedback fair?

5	4	3	2	1
Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied

Would you be willing to participate in a similar event in the future?

5	4	3	2	1
Very Interested	Somewhat Interested	Neutral	Not Very Interested	Not At All Interested

Did you learn something new about hip protectors that you did not previously know?

5	4	3	2	1
Very Much	Somewhat	Undecided	Not Really	Not At All

Figure 14. Feedback fair questionnaire staff evaluation results

3.4. Discussion

The results of the pilot trial of patient compliance with Version 1 of the stick-on hip protector support the feasibility of this product in the hospital setting and provided important information to guide the design of future pad prototypes. Despite the low sample size, five of the six patients agreed to wear the stick-on pads, which is much higher then the current acceptance rate with garment-based hip protectors. Changes brought on by the pilot trial included tapering of the edges of the pad in order to allow a smoother transition from pad to skin, enhancing pad adhesion, and reducing underwear and incontinence products from catching on the edges of the pad during donning and doffing. A central hole was added for improved force attenuation (as described in Chapter 2), breathability and ease of use for staff when applying the hip protectors to patients.

The results of the Feedback Fair provided valuable feedback from care providers on Version 2 of the stick-on protector to support a future large-scale clinical trial. The interactive posters and field notes produced three trends in regards to what staff initially liked about the stick-on hip protector prototypes which included overall ease of use, their potential to improve patient comfort, and their potential to reduce hospital hip protector costs. Three trends that emerged as concerns regarding the stick-on hip protectors, where the environmental impact, apprehensions with the adhesive and long-term skin integrity, and colour preference. The Feedback Fair also highlighted hospital specific barriers with conventional garment hip protectors.

The Feedback Fair emphasized the need for a clinical trial to further test the concerns regarding skin irritation, comfort, and the adhesive. An education program would be recommended for staff, patients and patient's family/caregivers. A white or skin colour pad should be considered as advised by the staff. It will be important to conduct a cost comparison during the clinical trial between the different models. It's essential to track the amount of money spent on conventional garment-based hip protectors, and how many become lost or damaged during the trial, as well as the number of stick-on hip protectors required.

It would also be beneficial to look into increased size options to meet all body types. Efforts should be made to ensure the pad is recyclable, and/or to provide patients at discharge with a garment to insert their adhesive pads. Proper disposal methods could help to reduce the waste produced by disposable pads and increase the number of hip protectors used in the community. Lab testing should also test hospital grade antibacterial wipes to determine if they can be effectively used to clean the disposable pads.

Staff expressed excitement for the new product, and frustration with the old garment-base hip protectors. It may be important to conduct a sizable run-in period during future clinical trials to adjust for this effect.

3.5. Conclusion

End-user feedback and product evaluation are important steps to developing and implementing useful products within healthcare. The pilot trial successfully demonstrated the feasibility of a stick-on hip protector within a hospital environment as well as informed prototype optimization. The Feedback Fair provided a number of recommendations for conducting the clinical trial, including the need for a cost comparison, an education program targeting all levels, pad colour, and the need for flexibility within this setting. It also indicated more areas for additional lab testing on issues such as increased size options, softer materials, environmentally friendly options and hygiene.

Chapter 4.

Conclusion

Falls are the leading cause of injury among individuals over age 65 in Canada [Scott, V. & Elliot, S., 2010; Public Health Agency of Canada, 2005], and hip fractures have been noted as a major public health problem. More than 90% of hip fractures are due to falls and wearable hip protectors represent a promising strategy to decrease hip fractures in high-risk elderly individuals.

Clinical trails have indicated that specific types of hip protectors reduce risk for fracture by up to 80% if worn at the time of the fall [Cameron et al., 2003; Forsen et al., 2004; Kannus et al., 2000]. Biomechanical testing has shown that hip protectors can reduce impact force to mitigate risk of injury. However, a recent meta-analysis yielded conflicting results on the clinical effectiveness of existing hip protectors [Gillespie et al., 2010], due largely to poor adherence among users in wearing the device (often less than 50%).

Unfortunately, hip protectors cannot be effective unless they are worn, and worn properly, at the time of the fall. The literature review I conducted identified barriers and facilitators to patient compliance with current garment hip protectors specific to the hospital environment. Factors found to affect initial acceptance included nurse encouragement and patient perception of not being at risk for falls and therefore not requiring a hip protector [Foster et al., 2007; Haines et al., 2006; Witchard, 2004]. Factors affecting adherence include discomfort while wearing the device, functional dependency and loss of garments [Foster et al., 2007; Haines et al., 2006; Hayes et al., 2008; Witchard, 2004].

A potential solution for addressing these barriers is to attach the pad directly over the skin of the patients requiring hip protectors. An adhesive (“stick-on”) hip protector pad may offer advantages over conventional models within a hospital environment including:

a) increased force attenuation; b) no shifting; c) continuous protection; d) decreased staff workload; e) no laundry or disinfecting requirements; and f) decreased supply costs.

The goals of this research were to initiate and complement the development of a low-cost adhesive hip protector pad that provides a force attenuation of at least 30%.

Product development required many collaborators, including researchers, health care professionals and industry partners. Through a series of prototype development, product evaluation, and product optimization, a final prototype pad was produced.

Biomechanical testing was conducted using the Simon Fraser University Hip Impact Simulator. Lab testing (described in Chapter 2) considered variations in surface geometry, size and pad thickness. A 20 mm thick, 19x15.5cm large donut hole pad was found to surpass the initial objective of 30% force attenuation, with a final force attenuation of 36%. Multi phase clinical evaluations of the preliminary prototypes (Version 1 and Version 2) enhanced the design by tapering the edges and recommending a neutral colour (described in Chapters 3).

End-user feedback and product evaluation was important when developing an acute care specific product. Several recommendations emerged through the different forms of product evaluation. The Feedback Fair emphasized the need for a clinical trial to further test the concerns regarding skin irritation, comfort, and the adhesive. An education program would be recommended targeting all levels. It will be important to conduct a cost comparison during the clinical trial between the two models and it would also be beneficial to look into increased size options to meet all body types. Staff expressed excitement for the new product, so it may be essential to conduct a sizable run-in period during future clinical trials to adjust for this effect.

The end result of this research was to develop a product that is now ready to be evaluated in the acute care environment, with regard to patient compliance, cost and protective value when compared to conventional garment-based hip protectors. The final product is a white 19x15.5cm large donut hole pad that is 20 mm thick, with tapered edges. The pad is made out of a polyethylene closed cell foam with approximately 60 durometer hardness for optimal protection. The material used should be easily recyclable. The final pad has a force attenuation of 36%, exceeding the force attenuation provided by garment-based hip protectors currently used within Fraser Health hospitals, and has four grooves that allow the pad to conform to the shape of the hip (Figure 15).

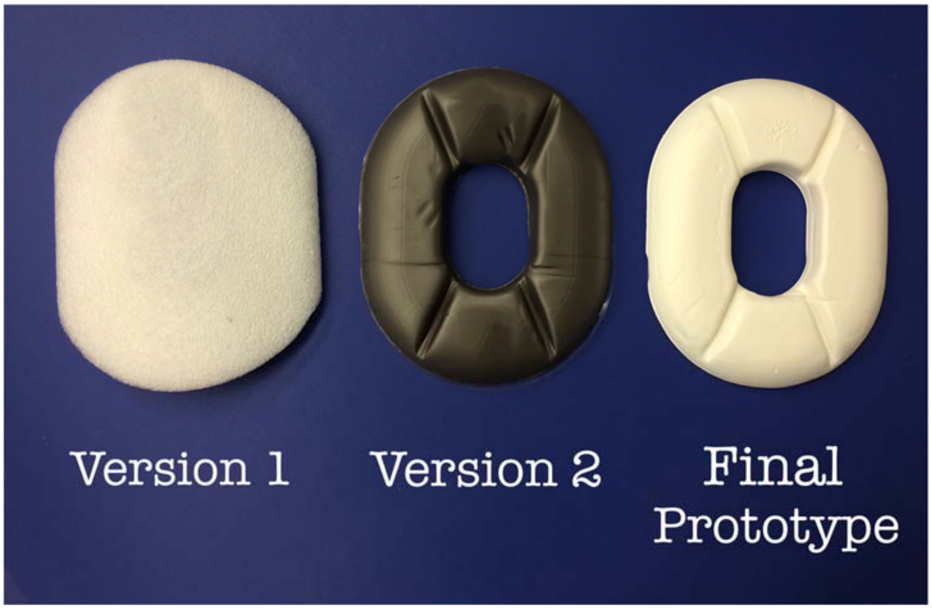

Figure 15. Pad transformation from the preliminary Version 1 pad to the Version 2 pad, and the final product ready for future clinical trials

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Appendix A.

Effect of Pad Surface Geometry on Force Attenuation – Raw Data

Raw values of peak force applied to the proximal femur from the first round of testing, which focused on surface geometry. Values are presented in the (randomized) order of testing.

Hip Protector	Size (cm)	Impact Velocity (m/s)	Peak Force (Load Cell) Trial 1 (N)	Peak Force (Load Cell) Trial 2 (N)	Peak Force (Load Cell) Trial 3 (N)	Load Cell Average (N)	Force Attenuation (%)
Unpadded	Control	3.4	2663	2684	2663	2670	
No Hole	19x15.5	3.4	2202	2243	2222	2222.3	17
Small Donut Hole	17x13.5	3.4	2160	2202	2222	2194.7	18
No Hole	17x13.5	3.4	2243	2264	2264	2257	16
Ventilation Holes	19x15.5	3.4	2160	2181	2181	2174	19
Horse Shoe	19x15.5	3.4	2034	2076	2076	2062	23
Large Donut Hole	19x15.5	3.4	2055	2097	2097	2083	22
Small Donut Hole	19x15.5	3.4	2097	2118	2118	2111	21
Large Donut Hole	17x13.5	3.4	2160	2202	2202	2188	18
Unpadded	Control	3.4	2663	2705	2663	2677	
Unpadded	Control	2	1761	1782	1782	1775	
Large Donut Hole	19x15.5	2	1069	1111	1111	1097	39
No Hole	19x15.5	2	1321	1342	1342	1335	26
Large Donut Hole	17x13.5	2	1195	1216	1237	1216	33
Small Donut Hole	19x15.5	2	1111	1132	1132	1125	37
Horse Shoe	19x15.5	2	1111	1132	1132	1125	37
Ventilation Holes	19x15.5	2	1342	1342	1342	1342	25
No Hole	17x13.5	2	1468	1447	1447	1454	19
Small Donut Hole	17x13.5	2	1258	1279	1279	1272	29

Unpadded	Control	2	1824	1824	1824	1824	
Unpadded	Control	4	2851	2893	2872	2872	
Small Donut Hole	17x13.5	4	2537	2537	2537	2537	12
No Hole	19x15.5	4	2432	2453	2474	2453	15
Ventilation Holes	19x15.5	4	2453	2474	2474	2467	15
Large Donut Hole	17x13.5	4	2495	2495	2495	2495	14
Small Donut Hole	19x15.5	4	2453	2474	2495	2474	15
No Hole	17x13.5	4	2537	2537	2537	2537	12
Horse Shoe	19x15.5	4	2453	2453	2474	2460	15
Large Donut Hole	19x15.5	4	2432	2453	2474	2453	15
Unpadded	Control	4	2935	2935	2935	2935	
Unpadded	Control	3	2453	2453	2474	2460	
Large Donut Hole	17x13.5	3	1908	1929	1929	1922	22
No Hole	17x13.5	3	2055	2076	2076	2069	16
Small Donut Hole	17x13.5	3	1971	1992	2013	1992	19
Large Donut Hole	19x15.5	3	1782	1803	1824	1803	27
No Hole	19x15.5	3	1929	1971	1971	1957	21
Small Donut Hole	19x15.5	3	1803	1824	1824	1817	26
Ventilation Holes	19x15.5	3	1929	1950	1950	1943	21
Horse Shoe	19x15.5	3	1803	1824	1824	1817	26
Unpadded	Control	3	2474	2474	2495	2481	

Appendix B.

Effect of Pad Thickness on Force Attenuation – Raw Data

Raw values of peak force applied to the proximal femur from the second round of testing, which focused on pad thickness. Values are presented in the (randomized) order of testing.

Hip Protector	Size (cm)	Thickness (mm)	Impact Velocity (m/s)	Peak Force (Load Cell) Trial 1 (N)	Peak Force (Load Cell) Trial 2 (N)	Peak Force (Load Cell) Trial 3 (N)	Load Cell Average (N)	Force Attenuation (%)
Unpadded	Control		3.4	2663	2663	2663	2663	
Large Donut Hole	19x15.5	16	3.4	1908	1950	1950	1936	28
Large Donut Hole	17x13.5	24	3.4	1761	1782	1803	1782	34
Large Donut Hole	17x13.5	16	3.4	2139	2160	2181	2160	20
Large Donut Hole	19x15.5	20	3.4	1677	1740	1740	1719	36
Large Donut Hole	17x13.5	20	3.4	1866	1908	1908	1894	30
Large Donut Hole	19x15.5	24	3.4	1510	1552	1552	1538	43
Unpadded	Control		3.4	2726	2705	2705	2712	

Appendix C.

Stick-on Hip Protector Feedback Fair Questionnaire

Stick-on hip protector questionnaire administered to the health care professionals at the sixth station of the feedback fair. The questionnaire probed: opinions on design features of the stick-on hip protector prototype (including colour, shape, size, thickness and stiffness), and an evaluation of the Feedback Fair experience.

Stick-on Hip Protector Questionnaire

1. Which unit do you work at most of the time?

   ☐ACE 5E

   ☐MED 5W

2. What is your current job title? ___________________________

3. Do you like the surface area of the **stick-on** hip protector prototype?

   ☐Yes

   ☐No If no, how would you change it? ___________________

4. Do you like the thickness of the **stick-on** hip protector prototype?

   ☐Yes

   ☐No If no, how would you change it? ___________________

5. Do you like the stiffness of the **stick-on** hip protector prototype?

☐Yes

☐No If no, how would you change it? ____________________

6. Do you like the colour of the **stick-on** hip protector prototype?

☐Yes

☐No If no, what colour would you prefer? ________________

7. Do you have any further comments about the **stick-on** hip protector prototype?

8. Please circle a number from 1 to 5 that most represents how you feel.

How would you rate your overall experience at the feedback fair?

5 Very Satisfied	**4** Satisfied	**3** Neutral	**2** Dissatisfied	**1** Very Dissatisfied

Would you be willing to participate in a similar event in the future?

5 Very Interested	**4** Somewhat Interested	**3** Neutral	**2** Not Very Interested	**1** Not At All Interested

Did you learn something new about hip protectors that you did not previously know?

5 Very Much	**4** Somewhat	**3** Undecided	**2** Not Really	**1** Not At All

Thank you for completing our survey

Enjoy the complimentary treats & beverages