DESIGN AND DEVELOPMENT OF A HYBRID SUPPORT SURFACE AND ITS EVALUATION FOR STRESS AND COMFORT EXPERIENCE AMONG OLDER ADULTS

A Thesis

Presented to the Faculty of the Graduate School

of Cornell University

In Partial Fulfillment of the Requirements for the Degree of

Master of Science in Human & Environment Relations with concentration in Human Factors & Ergonomics

by

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ABSTRACT

Background: Pressure ulcers are injuries to the skin and underlying tissue over prominent bony areas, mainly due to constant pressure. Even though pressure ulcers are preventable, millions of people suffer from these wounds every year. Support surfaces are devices specifically designed to help with the prevention and care of pressure ulcers. Hybrid support surfaces combine different components and features to meet specific needs and conditions of users.

Objective: This study concerns the design and development of a hybrid support surface prototype, intended for the prevention and care of pressure ulcers, and its evaluation for stress and comfort experience among older adults.

Method: The prototype was developed after conducting interviews with clinicians, patients, and other stakeholders to establish design criteria. Forty-six healthy older adults (35 females and 11 males) aged 51-93 years were recruited to evaluate the prototype in a laboratory setting and a continuing care retirement community. The hybrid support surface provided automated pressure changes and an automated tilting mechanism. Participants were required to lie down on the hybrid support surface in a supine position for 15-minutes. Participants' stress levels (heart rate variability) were measured on and off the support surface. Participants also completed the General Discomfort Assessment (GDA), the Discomfort Intensity Score (DIS) assessment, and a structured interview session to measure comfort.

Results: Results indicated a significant difference in stress level ($p<.0001$) when participants were on the support surface compared to when they were off the support surface. Comfort scores for both GDA and DIS were very low, indicating participants were comfortable when lying on the hybrid support surface.

Conclusion: Although further studies are required to evaluate the efficacy of the hybrid support surface for the care and prevention of pressure ulcers, results indicate this new hybrid support surface reduces stress without sacrificing comfort in older adults.

BIOGRAPHICAL SKETCH

Paulina Villacreces was born and raised in Quito, Ecuador. She earned her Bachelors of Science degree at San Francisco State University in Industrial Design with a concentration in Product Design and Development, and did a minor in International Business. Prior to Cornell University, Paulina was working at Pro-Movilidad, designing and developing different mobility devices and adaptive equipment for children with cerebral palsy and other disabilities.

During her time at Cornell University, she pursued a Master of Science degree in Human and Environment Relations with a concentration in Human Factors and Ergonomics. Through Cornell University, she participated in various competitions and won multiple awards. She won the award of *selected innovation* of SmartRest, an innovation for the prevention and care of pressure ulcers, at the Whole Human Healthcare Innovation Challenge, sponsored by the Cornell Institute for Healthy Futures. Paulina also received a *finalist award* at the Aging Innovation Challenge organized by New York State Department of Health, for her innovative stair-climbing walker design. She was also awarded a Tech Grant, to support her research, by the College of Human Ecology.

Additionally, Paulina participated in two entrepreneurship programs. Paulina along with her team UPOD received a *finalist award* at the Biomimicry Global Design Challenge, for their solar-powered and sustainable innovation to help vulnerable populations with the prevention of mosquito-borne illnesses. As part of this award, team UPOD participated in the Biomimicry Launchpad, an accelerator program for one year. Paulina received second place at the startup pitch competition organized by the Student Agencies Entrepreneurship at Cornell – eLab. Her startup SmartRest was one of the selected startups to participate in the eLab accelerator program.

To my grandmother, Antuquita, who inspired this research.

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I would like to give special thanks to José Holguín, who walked beside me at every step; this research would not have been possible without you.

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TABLE OF CONTENTS

CHAPTER 1

INTRODUCTION

Pressure ulcers (also known as bedsores, pressure sores or decubitus ulcers) are injuries to the skin and/or underlying tissue usually over a bony prominence as a result of prolonged pressure, shear and/or friction (European Pressure Ulcer Advisory Panel, National Pressure Ulcer Advisory Panel, & Pan Pacific Pressure Injury Alliance, 2014). There are several conditions highly associated with pressure ulcer risk, such as diabetes, cardiovascular disease, sensory deficits, neuromuscular system disorders (like spasticity, spinal cord injury, multiple sclerosis, Parkinson's disease or similar neurological conditions), surgical procedures, falls, traumatic injuries, malnutrition, incontinence and others (Association for the Advancement of Wound Care, 2010; Bansal, Scott, Stewart, & Cockerell, 2005; Davis & Kotowski, 2015). Individuals with mobility impairment are at highest risk for pressure ulcers, not only due to advanced age, but also due to other conditions such as spinal cord injuries. Older adults are also substantially at risk of developing pressure ulcers. About 70% of all pressure ulcers occur in older adults who are 65 years of age or older (Thomas, 2006).

Patients with incontinence also have a higher risk of pressure ulcer development as well as risk of infection. Incontinence produces a five-fold risk of pressure ulcer development (Thomas, 2006). A survey by the International Pressure Ulcer Prevalence analyzed 176,689 patients based on data collected between 2013-2014 to determine the risk of facility acquired pressure ulcers and the incontinent patient (Lachenbruch, Ribble, Emmons, & VanGilder, 2016). Continent patients accounted for 47% of the sample, while incontinent patients accounted for 53%. Continent patients had a 4.1%

of pressure ulcer prevalence, while incontinent patients had 16.3% of pressure ulcer prevalence; the prevalence of facility acquired pressure ulcers was 1.6% and 6.0% respectively (Lachenbruch et al., 2016). The study concluded that incontinence was associated with an increased risk for all pressure ulcers.

The National Pressure Ulcer Advisory Panel (NPUAP), the European Pressure Ulcer Advisory Panel (EPUAP), and the Pan Pacific Pressure Injury Alliance (PPPIA) have classified pressure ulcers using an international classification system (2014). The international classification system describes the different stages of pressure ulcers, and includes two additional categories for unstageable pressure ulcers and suspected deep tissue injury (European Pressure Ulcer Advisory Panel et al., 2014). There are four identified stages of pressure ulcers: Stage I or nonblancheable erythema, Stage II or partial thickness skin loss, Stage III or full thickness skin loss, and Stage IV or full thickness tissue loss (European Pressure Ulcer Advisory Panel et al., 2014). Although pressure ulcers are classified by stages, pressure ulcers do not follow an orderly progression between these stages (Bansal et al., 2005). A person can have a Stage I pressure ulcer, which can quickly become a Stage IV pressure ulcer. A detailed description and visual representation of each stage is provided in Appendix A.

Pressure ulcers do not behave like a typical wound; they are extremely difficult to heal and no one treatment works on its own (Bansal et al., 2005). In terms of pressure ulcer healing times, 13% of pressure ulcers heal within 2-weeks in acute hospital settings, while in long-term care settings, the rate of healing depends on the stage of the pressure ulcer (Thomas, 2006). About 59% of Stage III pressure ulcers can heal within 6-months, but in some cases it can take up to 1-year or more. One third of Stage

IV pressure ulcers heal after 6-months (Thomas, 2006). Moreover, if a patient manages to recover from a pressure ulcer, it is highly likely that the pressure ulcer will develop again, as recurrence rates for pressure ulcers can be as high as 90% (Bansal et al., 2005).

About 95% of pressure ulcers occur in the lower part of the body; the sacrum is the most common area with (36% of occurrence), the heel is the second most common area with (30% of occurrence), and other body areas account for (6% of occurrence) (Cooper, 2013; Thomas, 2006).

Pressure ulcers can lead to other complications, such as mortality, osteomyelitis and sepsis (Thomas, 2006). During acute hospitalization, 67% of patients that develop a pressure ulcer die. In long-term care settings, developing a pressure ulcer within 3-months of admission was associated with a 92% mortality rate (Thomas, 2006). Additionally, in skilled nursing facilities 77.3% of residents who had a pressure ulcer had a 6-month mortality rate (Thomas, 2006).

Healthcare Burden

Pressure ulcers are a significant economic and healthcare burden worldwide. Each year about 2.5 million patients are affected by pressure ulcers and about 60,000 patients die as a direct result of a pressure ulcer (Agency for Healthcare Research and Quality, 2011). The estimated cost of treating pressure ulcer in the United States is between $9.1 to $11.6 billion dollars per year, and the cost of individual patient care ranges from $20,900 to $151,700 per pressure ulcer (Agency for Healthcare Research and Quality, 2011). Additionally, in 2007, Medicare estimated that pressure ulcers added $43,180 in costs to a hospital stay (Agency for Healthcare Research and

Quality, 2011). Due to the high costs of pressure ulcers, Medicare and Medicaid Centers no longer provide reimbursement for pressure ulcers acquired at the healthcare facility. Therefore, if pressure ulcers develop at the healthcare facility, it becomes the responsibility of the facility to cover the cost of care (VanGilder, MacFarlane, Harrison, Lachenbruch, & Meyer, 2010). Medicare provides detailed comparisons and ratings of hospitals, nursing homes, and other healthcare facilities, and one of the categories associated with care quality has to do with "providing appropriate pressure ulcer care and preventing new ulcers from developing" ("Find & compare doctors, hospitals & other providers - Medicare," n.d.). Therefore, a decrease in pressure ulcer development has become one of the priorities of healthcare facilities.

Patient migration toward the foot of the bed and the constant turning and repositioning needed for patients with pressure ulcers can be problematic both for the patient and for the caregiver (Davis & Kotowski, 2015). Lifting a patient in bed is a repetitive task that can result in injuries. Estimates indicate that nurses reposition patients as much as 10-times per shift or more than 20-times per week (Davis & Kotowski, 2015; Lynch & Freund, 2000; Vasihadou, Karvountzis, Soumilas, Roumehotis, & Theodosopoulou, 1995). Likewise, among healthcare workers, lifting and transferring patients out of bed is associated with 73% of back injuries (Lynch & Freund, 2000). While positioning patients in bed and transferring patients is usually a two-person or three-person job in most cases (Lynch & Freund, 2000), the reality of the healthcare system is that repositioning is mostly done by a single person. In 2010, according to the Occupational Health and Safety Administration (OSHA), nursing aides, orderlies, and attendants had the highest rates of musculoskeletal disorders

(MSDs). There were 27,020 cases, which is equal to an incidence rate of 249 per 10,000 workers -- more than seven times the average for all industries (Occupational Safety and Health Administration, 2010). According to OSHA, about 20% of nurses who decide to leave their positions do so due to the risks associated with the work they do. Within the healthcare industry, it is estimated that about $20 billion are spent annually on costs associated with back injuries (Occupational Safety and Health Administration, 2010). Wound care nurses and nurses who are part of turning programs suffer from these injuries first hand, as patients with pressure ulcers need to be turned and repositioned on a daily basis, usually every 2-hours.

Prevention

There is an inverse relationship between the amount and duration of pressure (Agrawal & Chauhan, 2012). Constant pressure is one of the main causes of pressure ulcers, such that higher constant pressure reduces the time for a pressure ulcer to develop (Agrawal & Chauhan, 2012). Different postures cause different average pressures. When a person is sitting, the average pressure over the ischial tuberosity (sit bones) and surrounding area can exceed 100mmHg; when a person is lying on a supine position the average pressure of the sacral area is about 40-60mmHg; and, when a person is lying down on the side the average pressure over the trochanteric area (hip region) is 70-80mmHg (Agrawal & Chauhan, 2012).

The sigmoid curve (Figure 1) provides a description of how much internal pressure or muscle tissue deformation is allowed and for how long to avoid tissue damage (Gefen, 2009). Pressures higher than 70mmHg should be avoided for prolonged periods of time.

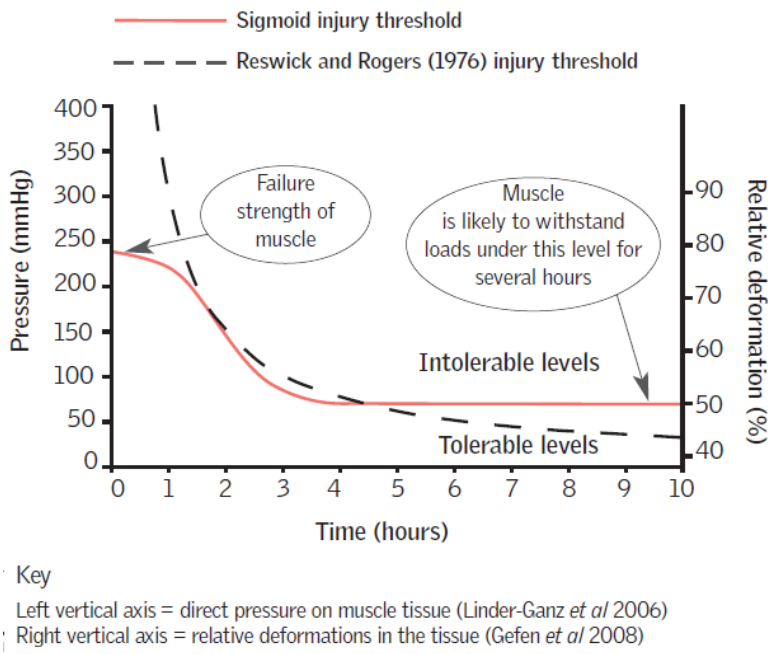


Figure 1. Sigmoid Injury Threshhold

In a study that looked at how pressure signatures influence tissue response for individuals using an alternating mattress, the findings indicated that small pressure amplitude variations, from 10-20mmHg, can provide enough pressure relief to maintain tissue viability (Chai, Sadou, Worsley, & Bader, 2017). When pressure amplitudes are larger (100/0mmHg), tissue viability can be compromised (Chai et al., 2017).

An effective method to prevent pressure ulcers is through frequent turning and positioning. Frequent position changes help relieve constant pressure and reduce the length of time that pressure is applied to certain areas of the body, particularly those where bony prominences exist (Defloor, De Bacquer, & Grypdonck, 2005; Z. Moore, Cowman, & Conroy, 2011; Vanderwee, Grypdonck, De Bacquer, & Defloor, 2007). While studies done have not revealed the exact interval for optimal turning, most

recommend an interval of 2-hours, which will depend on the condition of the patient (Association for the Advancement of Wound Care, 2010; Bansal et al., 2005; Cooper, 2013; Thomas, 2006). Vulnerable individuals should be repositioned according to their specific condition (Association for the Advancement of Wound Care, 2010; European Pressure Ulcer Advisory Panel et al., 2014; MacGregor, 2010).

Certain position changes are more optimal than others when it comes to pressure ulcer prevention (Defloor, 2000; European Pressure Ulcer Advisory Panel et al., 2014). To reposition patients in bed, the EPUAP, NPUAP and PPPIA provide some suggestions: use a 30° tilted side-lying position, alternating between right side, back and left side, or prone position depending on the condition of the patient; avoid positions that increase pressure over bony prominences, such as the 90° side-lying position; and limit the head-of-bed elevation to 30° on bedrest depending on the condition of the patient (European Pressure Ulcer Advisory Panel et al., 2014; MacGregor, 2010). Similarly another study suggests that a 30° laterally inclined position helps reduce pressure, while a 90° side lying position increases pressure and reduces blood flow, therefore should be avoided (Defloor, 2000). These studies were conducted on healthy volunteers, which does not provide direct evidence for patients at risk of developing pressure ulcers; however, positions that increase the pressure on certain areas of the body are better to be avoided. Additionally, patients who must have a head of bed elevation due to a particular medical condition should be repositioned more frequently (MacGregor, 2010).

Successful Interventions

Several studies have been conducted regarding the degree of tilt and interval time to reposition patients with pressure ulcers. One study compared four preventive treatments to assess the effects of turning (30° semi-fowler position) with different intervals on the development of pressure ulcers (Defloor et al., 2005). The following four treatments were used during a 4-week period: turning every 2-hours on a standard institutional mattress (n = 65); turning every 3-hours on a standard institutional mattress (n = 65); turning every 4-hours on a viscoelastic polyurethane foam mattress (n = 67); turning every 6-hours on a viscoelastic polyurethane foam mattress (n = 65); and a control group that received standard care (n = 576). The study concluded that turning every 4-hours on viscoelastic polyurethane foam mattress using a 30° tilt contributed to a significant reduction of pressure ulcers (p = .003), which is also feasible in terms of effort and cost (Defloor et al., 2005). This study used a mattress with pressure relieving properties, which is a confounding variable, as the use of the mattress could have contributed to the reduction of pressure ulcers along with the repositioning.

A randomized control trial on repositioning compared an experimental group (*n* = 99) that were repositioned every 3-hours at night using a 30° tilt with a control group (*n* = 114) that were repositioned every 6-hours using a 90° tilt (Moore et al., 2011). In the experimental group 3% of the patients developed pressure ulcers, while in the control group 11% of the patients developed pressure ulcers (*p* = 0.035). The study concluded that repositioning older adults every 3-hours at a 30° tilt reduced the risk of pressure ulcer development (Z. Moore et al., 2011). In this study, 86% of participants

in the control group and 96% of participants in the experimental group were utilizing a pressure redistribution device, so it is unclear if having or not having a pressure redistribution device contributed to the development of pressure ulcers. Another randomized control trial looked at the effectiveness of turning with unequal time intervals on the incidence of pressure ulcers (Vanderwee et al., 2007). In the experimental group (n = 122) patients with Stage I pressure ulcers were repositioned every 2-hours in a lateral positon and 4-hours on a supine position; while in the control group (n = 113) patients with Stage I pressure ulcers were repositioned with the same turning scheme as the experimental group but every 4-hours. Both groups used the same mattress. In the experimental group, 16.4% patients developed a pressure ulcer, while 21.2% patients developed a pressure ulcer in the control group, which resulted in no statistically significant difference between the groups (p = 0.40) (Vanderwee et al., 2007). This could have been attributed to the fact that there was very little difference in the reposition times.

Additionally, a study on the economic analysis of repositioning for the prevention pressure ulcers concluded that repositioning individuals every 3-hours, using a 30° tilt, was more effective in terms of the cost and time spent by nurses, compared to standard care (repositioning every 6-hours using a 90° tilt) (Z. Moore, Cowman, & Posnett, 2013). A 90° tilt is more likely to increase the pressure in certain areas and reduce blood flow as previously mentioned, and can be more demanding, effort wise, than a 30° tilt.

Support Surfaces

Support surfaces are devices that can help with the prevention and care of pressure ulcers. By definition, a support surface is (The National Pressure Ulcer Advisory Panel, 2007, p.1):

> *"A specialized device for pressure redistribution designed for management of tissue loads, micro-climate, and/or other therapeutic functions, such as mattresses, integrated bed systems, mattress replacement, overlay, seat cushion or seat cushion overlay".*

The risk factors associated with pressure ulcers are different for each individual. In order to select a support surface, some of these factors need to be taken into consideration: the condition of the patient, pressure ulcer risk, existing pressure ulcers, the level of mobility, the level of comfort, tissue loads, therapeutic functions, microclimate management (to manage heat and moisture) as well as the care setting where the support will be used (European Pressure Ulcer Advisory Panel et al., 2014; MacGregor, 2010).

According to the Pressure Ulcer Guidelines, patients at risk of pressure ulcer development require the use of an appropriate support surface (high specification mattress, static air mattress, overlay, low air loss or alternating pressure mattress, alternating pressure overlay) as well as constant repositioning (Association for the Advancement of Wound Care, 2010). Moreover, additional support surfaces or devices should be used to relieve pressure under the heels (Association for the Advancement of Wound Care, 2010; European Pressure Ulcer Advisory Panel et al., 2014). These devices should offload the heel completely, without adding pressure on

the achilles tendon (Cooper, 2013; European Pressure Ulcer Advisory Panel et al., 2014).

Although support surfaces help to redistribute pressure, these support surfaces have to be used in combination with proper nutritional support, moisture management, turning and repositioning, risk identification and patient and caregiver education (MacGregor, 2010; McNichol, Watts, Mackey, Beitz, & Gray, 2015). Support surfaces, both reactive and active, help with pressure redistribution. While some active support surfaces help with the duration of tissue load, these do not eliminate the need for turning and repositioning. Turning and repositioning is needed to reduce the time of tissue load (McNichol et al., 2015). However, turning and repositioning will greatly depend on the condition of the patient. The use of an active support surface (overlay or mattress) is recommended for patients with a higher risk of developing a pressure ulcer, especially when manual repositioning is not possible (European Pressure Ulcer Advisory Panel et al., 2014).

Reactive support surfaces. A reactive support surface is "a powered or non-powered support surface with the capability to change its load distribution properties only in response to applied load" (The National Pressure Ulcer Advisory Panel, 2007, p.5). Reactive support surfaces have two modes of pressure redistribution: immersion and envelopment (MacGregor, 2010), which can be more clearly appreciated in Figure 2. Some of the most common components of reactive support surfaces are higher specification foams, air or gel filled cells, and air fluidized (MacGregor, 2010; The National Pressure Ulcer Advisory Panel, 2007).

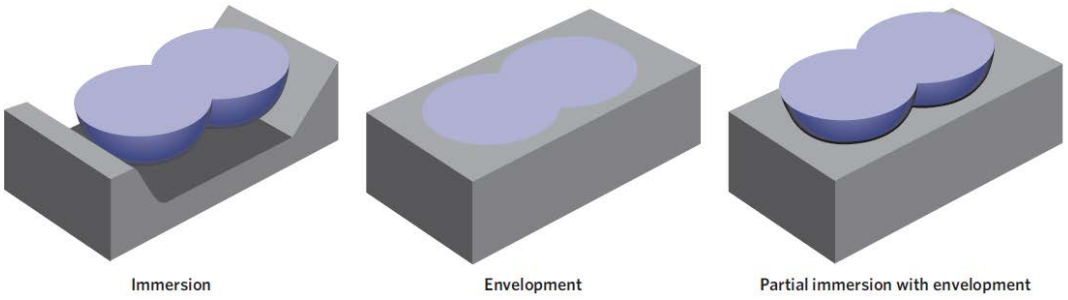


Figure 2. Reactive support surfaces - immersion and envelopment

Many studies have investigated reactive support surfaces and pressure ulcer incidence. There were five randomized controlled trials (RCTs) comparing a viscoelastic foam to another support surface (D. G. Gray & Smith, 2000; Park & Park, 2017; Russell, 2003; Van Leen, Hovius, Neyens, & Schols, 2013; Vanderwee, Grypdonck, & Defloor, 2005). When the viscoelastic foam was compared to a standard hospital mattresses, viscoelastic foam was more effective for the prevention of pressure ulcers (D. G. Gray & Smith, 2000; Park & Park, 2017). When viscoelastic foam was compared to other types support surfaces the results were inconclusive (Russell, 2003; Van Leen et al., 2013; Vanderwee et al., 2005). Other studies have investigated continuous low pressure mattresses, which are another type of reactive support surfaces. These support surfaces have high degrees of immersion and envelopment. Most of the studies found that compared these support surfaces were not statistically significant concerning pressure ulcer incidence (Branom & Rappl, 2001; Malbrain et al., 2010; Russell, 2003; Van Leen, Hovius, Neyens, Halfens, & Schols, 2011). Other studies comparing low-air-loss mattresses to other support surfaces were also not statistically significant concerning pressure ulcer incidence (Branom & Rappl,

2001; Rosenthal et al., 2003; Theaker, Kuper, & Soni, 2005). All the studies were biased by confounding factors, as they used different pressure ulcer care protocols, such as frequent repositioning. As mentioned previously, regardless of the support surface used, frequent repositioning can prevent the development of pressure ulcers (European Pressure Ulcer Advisory Panel et al., 2014).

Active support surfaces. An active support surface is "a powered support surface, with the capability to change its load distribution properties, with or without applied load" (The National Pressure Ulcer Advisory Panel, 2007, p.5). These active support surfaces use alternating pressure by cyclically inflating and deflating to redistribute pressure (MacGregor, 2010), which can be more clearly appreciated in Figure 3. Some of the most common active support surfaces are alternating pressure mattresses and overlays (MacGregor, 2010).

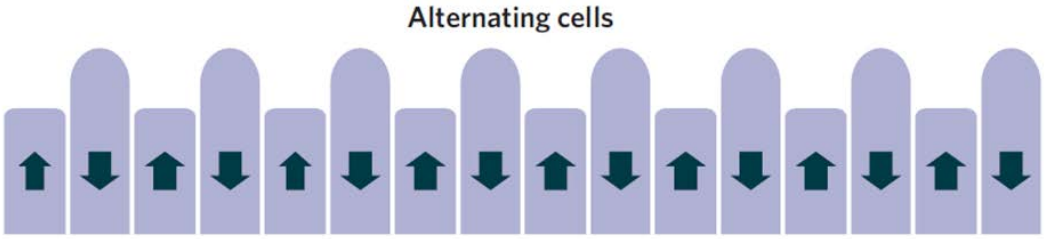


Figure 3. Active support surfaces - alternating pressure

These support surfaces have alternating cells that can vary in regard to inflation time and cycles. Pressure and time are important considerations for the performance of these support surfaces. Sufficient cell amplitude should be achieved between cell cycles. An amplitude that allows low pressure should be able to lift the body on the inflated cells while allowing the body to be off the deflated cells (Phillips, 2007). Air

cells that are less than 4” in diameter cannot be sufficiently inflated to ensure pressure redistribution over deflated air cells (Winnipeg Regional Health Authority, 2012).

RCTs found reported no significant differences, when comparing these active support surfaces to other active and reactive support surfaces (Demarré et al., 2013; Land, Evans, Geary, & Taylor, 2000; Malbrain et al., 2010; Nixon et al., 2006; Theaker et al., 2005). For one of the studies (Vanderwee et al., 2005), the use of an alternating pressure mattress resulted in significantly fewer heel pressure ulcers.

Similar to the studies conducted on reactive support surfaces, these studies were also used different pressure ulcer care protocols, such as the frequency of repositioning.

Hybrid support surfaces. Hybrid support surfaces are a combination of active and reactive support surfaces, and can be used as either a reactive, active, or a combination of both (Fletcher, Gefen, Jones, Sanada, & Irvine, 2015). An example of the mechanism of these support surfaces can be observed in Figure 4. To the left is an example of a non-powered hybrid support surface and to the right an example of a powered one.

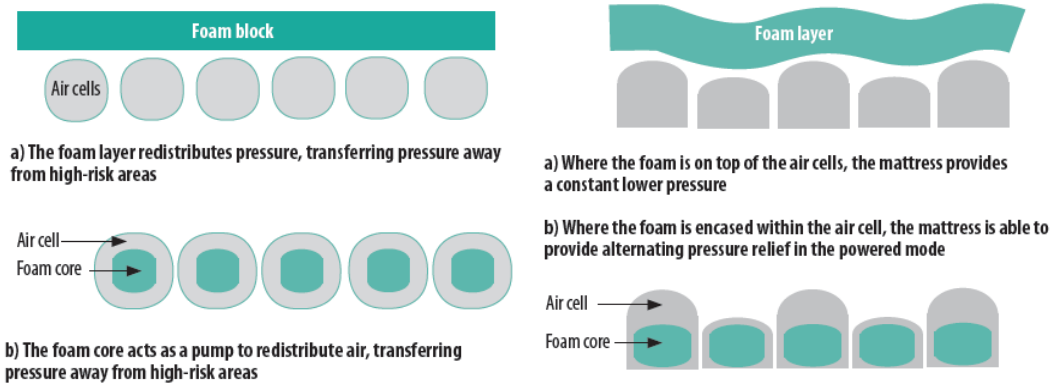


Figure 4. Hybrid support surfaces (Fletcher et al., 2015)

Hybrid support surfaces combine different components and features present in some active and reactive support surfaces to maximize the benefits of both of these support surfaces. Some of the components of reactive support surfaces are air, cell/bladder, viscoelastic foam, elastic foam, closed cell foam, open cell foam, gel, pad, viscous fluid, elastomer, solid, and water (The National Pressure Ulcer Advisory Panel, 2007). Some of the different features of active support surfaces are air fluidized, alternate pressure, lateral rotation, low air loss, single zone pressure redistribution, and multi-zoned surface (The National Pressure Ulcer Advisory Panel, 2007). By combining different components and features, these hybrid support surfaces can provide a wide range of options for different patient needs. Moreover, some of these hybrid support surfaces can adapt as the condition of the patient changes, from static to alternating and vice-versa.

Very few studies have been conducted concerning hybrid support surfaces. Several RCTs evaluated hybrid support surfaces in comparison to other reactive or active support surfaces, but reported no significant differences in pressure ulcer incidence (Bharucha et al., 2018; Demarré et al., 2012; D. Gray, Cooper, Bertam, Duguid, & Pirie, 2008; Malbrain et al., 2010; Theaker et al., 2005; Vanderwee et al., 2005).

Similar to the studies previously mentioned, these studies were also biased by confounding factors, as they used different pressure ulcer care protocols, such as the frequency of repositioning, pressure ulcer care, nutrition and others. Only two out of the six studies evaluated used the standard turning and repositioning protocol of turning patients every 2-hours (Bharucha et al., 2018; Malbrain et al., 2010). The rest

of the studies used different turning and positioning frequencies according to hospital protocols and staff availability (Demarré et al., 2012; D. Gray et al., 2008; Theaker et al., 2005; Vanderwee et al., 2005).

Gaps in Research

Support surfaces are important for the prevention and care of pressure ulcers. In the realm of support surfaces and pressure ulcer incidence, most studies compared different reactive and active support surfaces. Given the relative newness of hybrid support surfaces and the ample range of possibilities they could provide for the care and prevention of pressure ulcers, few studies have been done in regard to the benefits of these support surfaces and their different features in regard to pressure ulcer incidence. However, because these support surfaces combine features of reactive and active support surfaces that have been successful to help with pressure ulcer prevention and care, these support surfaces can offer promising results.

Likewise, most hybrid support surfaces were in the form of mattresses, as opposed to overlays. The current research aims to consider the efficacy of a hybrid support surface overlay on pressure ulcers.

Most hybrid support surfaces compared in existing studies had one main function that was being compared with an active/reactive support surface. Likewise, most of the support surfaces used provided only partial solutions for the prevention of pressure ulcers, as most support surfaces needed to be used in combination with turning programs and additional positioning devices. Since hybrid support surfaces often combine different features and mechanisms, this study seeks to consider the testing of hybrid support surfaces with multiple automated functions.

Current Research

Based on the research gap identified, this study aimed to develop and evaluate a prototype of a hybrid support surface that could accommodate their different needs and conditions.

Research question. How does the use of a smart bed overlay device affect the level of stress and comfort among older adults in a laboratory setting and at a continuing care retirement community?

Hypothesis 1.

The use of a new prototype of a smart bed overlay device will have a positive effect on the level of stress of participants, measured as heart rate variability.

Hypothesis 2.

The use of a new prototype of a smart bed overlay device will have a positive effect on comfort levels reported through a questionnaire and a structured interview exercise.

CHAPTER 2

RESEARCH AND DESIGN DEVELOPMENT

Customer Discovery

In addition to the literature reviewed, extensive research and customer discovery was conducted with key experts and practitioners in the field to learn more about pressure ulcers and the different support surfaces. Interviews and communication was held with nurse directors (24), wound care nurses (18), doctors (5), rehabilitation experts (8), occupational therapists (11), physical therapists (9), facility administrators and directors (21), geriatrics professors (2), patients with pressure ulcers (17), medical device manufacturers (5), Medicare officer (1), FDA agents (2) and others, from nursing homes, rehabilitation facilities, acute and long-term care facilities, continuing care retirement facilities, cancer treatment centers, and others. Additionally, the researcher attended two conferences (LeadingAge Annual Meeting and EXPO and the Pressure Ulcer Summit hosted by the Association for the Advancement of Wound Care [AAWC]) to gain more knowledge of pressure ulcers and to meet and talk with experts in the field.

One of the main concerns and problems commonly repeated among the interviewees was the need of a solution that would work for the prevention and healing of pressure ulcers both at the healthcare facility and at home. The majority of patients who heal from a pressure ulcer and go home are likely to be re-admitted within one or two weeks of discharge, because patients and caregivers (if any) could not keep up with the necessary home care. As Vicky Hines, Chief Operating Officer at the University of Rochester Medical Faculty Group mentioned (Hines, 2018), “one of

the challenges of home care is the fact that there are usually fewer caregivers available and most of these caregivers tend to be family members". In addition to this, the support surfaces used at the healthcare facility are sometimes not available or too costly for home care. At the Pressure Ulcer Summit, Paul Callahan, CEO of Sail to Prevail, gave a testimonial of his own experience after being bedbound for three years. He said that what doctors recommend, in terms of the proper equipment to help with pressure ulcers, is not always feasible because the equipment is not available or unaffordable. He also expressed that what doctors recommend does not necessarily align with human resources, like being turned every 2-hours (Callahan, 2019).

Support surfaces can be expensive depending on the different features and components, which sometimes makes it impossible for individuals to purchase their own support surfaces. On an interview held with Mark Levine, Long Term Care Administrator, Levine expressed that there is currently the need for a more cost effective option, as most options available in the market are in the form of costly beds that patients cannot afford (Levine, 2018).

According to the research presented by Sarah Brown, RN Executive Director of Empira Inc., (LeadingAge Annual Meeting and Expo), restorative sleep affects both the mind and body. Some of the outcomes mentioned of poor sleep on the mind are memory impairment, depression, anxiety, delusions, paranoia, hallucinations, and disorganized speech. Some of the outcomes mentioned of poor sleep on the body are impaired immunity (which makes patients prone to infections), no cell/tissue repair and regeneration, heart disease,

hormonal changes, poor balance and strength, increase cancer risk, and others (Brown, 2018). When patients are woken up every two-hours to be turned and repositioned during nighttime, their sleep cycle is interrupted (Brown, 2018). Sleep interrupted for prolonged periods of time, usually until the pressure ulcer heals, can have serious repercussions on the patients' health and quality of life, and even delay the pressure ulcer healing process. Sleep deprivation is both a challenge and an opportunity for a solution that helps patients heal from pressure ulcers while not disrupting their sleep cycle.

On an interview held with Jill Vitale-Aussem, President and CEO of The Eden Alternative, Vitale-Aussem mentioned that "at nursing homes residents with pressure ulcers are sleep deprived. Sleep deprivation prevents the skin to maintain its integrity and renewal process. It would be great to have something that helps increase the quality of life of residents" (Vitale-Aussem, 2018). This statement coincides with Sara Brown's research on the effects of restorative sleep on the mind and body. Additionally, Vitale-Aussem mentioned her concern with the huge staffing prices and the fact that many nursing homes are operating with not enough staff (Vitale-Aussem, 2018). Patients with pressure ulcers require a lot of care, and the wounds can take a long time to heal. Not having enough staff makes it even harder to help patients with pressure ulcers.

At the Pressure Ulcer Summit, Stephanie Woelfel gave a talk on "Offloading and Repositioning/Safe Patient Handling". She talked about the advantages and disadvantages of different support surfaces. Woelfel mentioned that, while air fluidized beds provide pressure redistribution, moving a patient or getting them out of

these beds is very hard and can cause shear forces that can worsen pressure ulcers (Woelfel, 2019). Low air-loss support surfaces are used mainly to remove heat and moisture, not pressure; moving patients on these support surfaces can also be difficult (Woelfel, 2019). Alternating pressure support surfaces provide pressure redistribution, but not pressure reduction. Finally, Woelfel explained that lateral beds that provide rotation about the longitudinal axis can be helpful for patients with prolonged bedrest or who are unable to turn on their own.

Among the effective components of best practices for pressure ulcer prevention presented at the Pressure Ulcer Summit, pressure reduction, repositioning, and incontinence were three of the main best practices of performance and improvement (Creehan, 2019).

People who are most affected by pressure ulcers are mainly people who are bedridden or who have mobility impairments, as well as older adults. In an interview held with Fran Paschall, Chief Nurse Executive from Cancer Treatment Centers of America Global Inc., Paschall mentioned that people with cancer are also vulnerable to pressure ulcers. Many people with cancer suffer from weight loss, increased bony prominences, loss of appetite, risk of skin breakdown, and overall become weaker with treatment, are not able to turn on their own, and many become bedridden (Paschall, 2018). According to Paschall, there is a huge need for support surfaces that can help with post-cancer treatment.

The general consensus of the interviews and information gathered from the research and literature review pointed towards the need of a support surface for the prevention and care of pressure ulcers with the following characteristics:

1. The solution will help reduce pressure points.
2. The solution will allow postural changes (turning and repositioning) while still ensuring quality sleep at night.
3. The solution will help caregivers take care of patients with pressure ulcers in the best possible way, relieving them from hard tasks that can cause injuries and interfere with their health, like turning and repositioning.
4. The solution will address incontinence incidents more effectively.
5. The solution will accommodate different patient needs and conditions.
6. The solution can be used both at the healthcare facility and at home.
7. The solution will be accessible and affordable.

Design Criteria

Prior to the design and development of the support surface prototype, each of the characteristics described above were thoroughly analyzed, in order to incorporate them into the design of the prototype. To design and develop the support surface prototype, the following key features of pressure ulcer prevention and care were taken into consideration: pressure reduction, frequent postural changes, and effective incontinence management. These key features combined into a bed overlay device can accommodate different needs and conditions of users and allow for the device to be used both at the healthcare facility and for home care.

Pressure reduction. Pressure ulcers are the result of constant pressure being applied to parts of the body where bony prominences are located. The more pressure these areas receive the more likely the bone will slowly damage body tissue and skin surrounding it. The reason why these wounds are so hard to heal is that they are hard

to detect, and usually when detected the damage can already lead to Stage I up to Stage IV pressure ulcer or worse. Therefore, one of the key factors of pressure ulcer prevention is pressure reduction, specifically in areas where bones are more prominent. As mentioned in the introduction, pressure reduction in the form of small pressure variations in cell amplitude, can provide enough pressure relief to maintain tissue viability (Chai et al., 2017). Additionally, cell amplitude should not be less than 4” to allow for pressure redistribution (Winnipeg Regional Health Authority, 2012).

Frequent postural changes. One of the most common ways of reducing pressure to avoid the development of pressure ulcers is to turn and reposition patients as often as possible (European Pressure Ulcer Advisory Panel et al., 2014; McNichol et al., 2015). Turning and repositioning allows pressure to be frequently redistributed among different body areas, to avoid constant pressures that could cause the development of pressure ulcers. Even though an optimal turning time has not been yet established, as this might vary from person to person, a two-hour turning interval is the most commonly suggested and used (Association for the Advancement of Wound Care, 2010; Bansal et al., 2005; Thomas, 2006). A 30° tilted side-lying position is the most recommended when turning a patient (Defloor, 2000; European Pressure Ulcer Advisory Panel et al., 2014; MacGregor, 2010)

Effective incontinence management. Another factor that is important to consider are incontinence incidents. Patients who have a pressure ulcer and are incontinent are more at risk of acquiring an infection, aggravating the condition of the pressure ulcer and endangering their health. Therefore, it is extremely important that

incontinence incidents are taken care of as soon as they happen, to avoid the risk of infection.

Hybrid support surface. The design of a hybrid support surface was preferred over active and reactive support surfaces. Hybrid support surfaces, by combining components and features of both active and reactive support surfaces, can provide a wide range of options and capabilities that can be tailored to the specific needs and condition of the patient—to either help prevent the development of pressure ulcers or help with the healing process.

Overlay design. A bed overlay was preferred over a mattress. The advantage of a bed overlay versus a mattress is that the bed overlay can be easily transported and used in different settings; both at the healthcare facility and at home.

Design Responses and Prototype

Given the time and resources available, the hybrid support surface prototype could not be built according to the design features and specifications originally envisioned. Therefore, for the purposes of designing, developing and testing a prototype of the support surface, some compromises were made pertaining to the top layer of the support surface. This section will provide a description of how the *original* design of the support surface was envisioned and how the *prototype* of the support surface was adapted, given the limited resources. The description will also include some of the design iterations and different materials explored.

Both the original and prototype hybrid support surfaces comprised three layers—a top layer, a mid-layer and a bottom layer—as described in detail below.

Top layer *original* concept

The top layer as originally envisioned was designed and rendered using SolidWorks (Figure 4). This hybrid support surface would be made out of a pallet or sections of individual air cells, preferably molded from any plastic, vinyl or neoprene material that is durable and flexible. The size and dimensions of the individual air cells will vary according to the need of the user, the minimal number of air cells would be 78 (6”x6”x4”), and the maximum number of air cells would be 312 (3”x3”x4”). Each individual air cell would have a pressure sensor and would be connected to a solenoid valve. The solenoid valves would be activated by the microcontroller board that would act according to the information received by the pressure sensors. Depending on the pressure information the individual air cells receive, the cells would react accordingly by inflating or deflating; to increase or decrease the amount of pressure in certain body areas. The system would allow different body areas to have the same pressure at all times, while not allowing certain body areas to have more pressure than others. The automated system would be constantly sensing and updating the pressure data information and adjusting the pressure on the air cells accordingly.

The air cells could adopt different shapes and forms according to the need of the patient and provide subtle pressure changes to offer pressure relief and maintain tissue viability. The air cells would be assembled in a cellular pattern that would be optimized for human anatomy and allows targeting of specific areas in the body that have more pressure. Even though the air cell system would be completely automated, it would allow for individual cell adjustments that might be needed according to the condition of the patient. For instance, if a patient had a pressure ulcer on the heel prior

to using the support surface, the cells could be manually adjusted to completely offload the pressure from the heel area until the pressure ulcer completely heals. The system would allow localized pressure reduction; that targets specific body areas individually as well as a central system that targets the whole body collectively. The system would also allow for the use of machine learning algorithms to process data. With this data, the device could learn when and where to change the pressure and could adapt to patient movements and sleeping patterns.

Additionally, the air cells located in the lower back and buttocks area would have embedded humidity/temperature sensors that could detect temperature changes and send alerts. This would be specifically useful for incontinence incidents. This feature could alert caregivers, to take care of these incidents as soon as they happen, in order to avoid the risk of infection (Lachenbruch et al., 2016 and Thomas 2006). With the use of machine learning algorithms, the device could potentially predict incontinence incidents in advance and even help detecting urinary tract infections (UTI's). The top layer of the *original* support surface concept can be observed in the following figure.

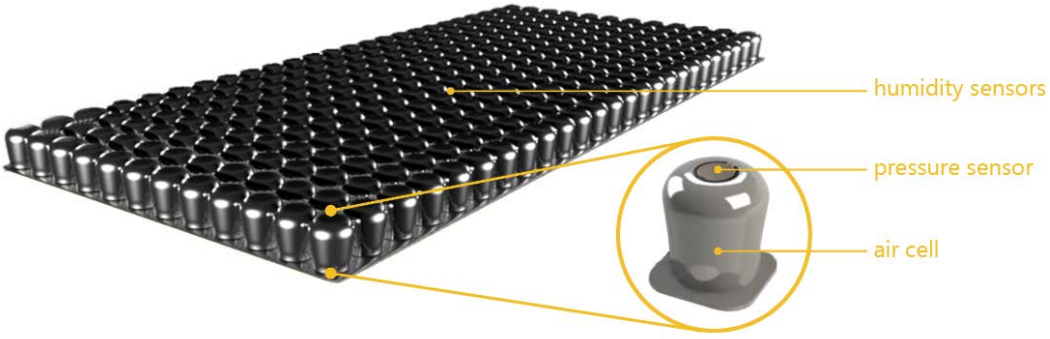


Figure 5. Top layer of the original concept of the hybrid support surface

Top layer *prototype* iterations

Prior to the construction of the final top layer, multiple prototype iterations and materials were tested. The first prototype was made out of foam (FlexFoam-iT! III – Smooth-On, Inc.), following the procedure of a research study that introduced the use of a buckled foam for soft pneumatic actuators (Mac Murray et al., 2018). To cast the foam a cube (3”x3”x3”) with a middle slot (to insert the pressure sensor) was modeled in SolidWorks and 3D printed (Figure 6). Following the manufacturer’s instructions, the foam precursos were mixed by hand and casted using the 3D printed box. Before casting, a release agent was applied (Ease Release 2831) to the 3D printed box, for ease of removal of the foam. Once the foam was casted, a piece of nylon mesh was cut and placed on the bottom and strings of nylon mesh were placed around the foam by using a PU elastomer (VytaFlex 20 – Smooth-On, Inc.). A plastic valve with a silicon tube was inserted inside the foam. A coat of a PU elastomer was manually applied to seal the porous foam and was set aside to cure. Once cured, a second coat of the PU elastomer was applied. The foam was actuated with compressed air (Figure 7). While an increase in stiffness was noticed, there was really low linear actuation (<1”). The same process was followed adopting an octagonal shape for the foam, to observe if the foam had better linear actuation, but the results were similar (Figure 8). The process was again repeated for smaller shapes: square, cylinder, and hexagon, while linear actuation was greater for the smaller shapes, it was not enough for the purposes of the actuation of the individual air cells needed (>4”). The air cells needed at least 40% strain for a 4” cross section cell. Unfortunately, as mentioned by Mac Murray “getting 40% strain would not have been easy because the foam often tears internally before

getting to that strain" (B. C. Mac Murray, personal communication, October 24, 2018). Additionally, homogeneity between the casted air cells was really hard to achieve, and the casting and sealing process for each unit was between 2-3 days.

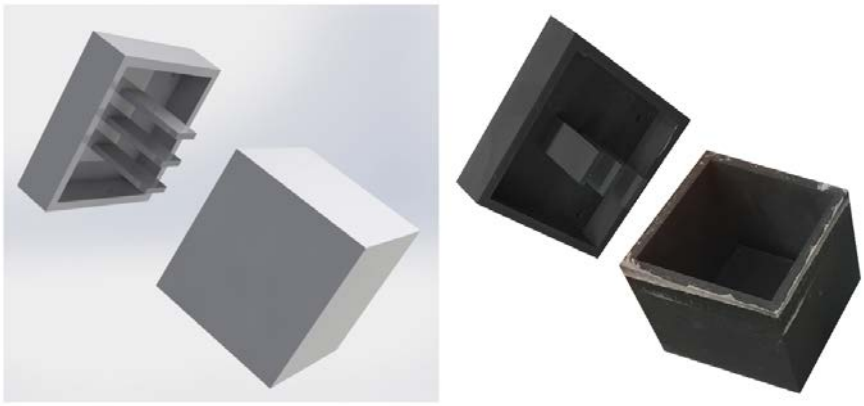


Figure 6. 3D printed cube with inserts

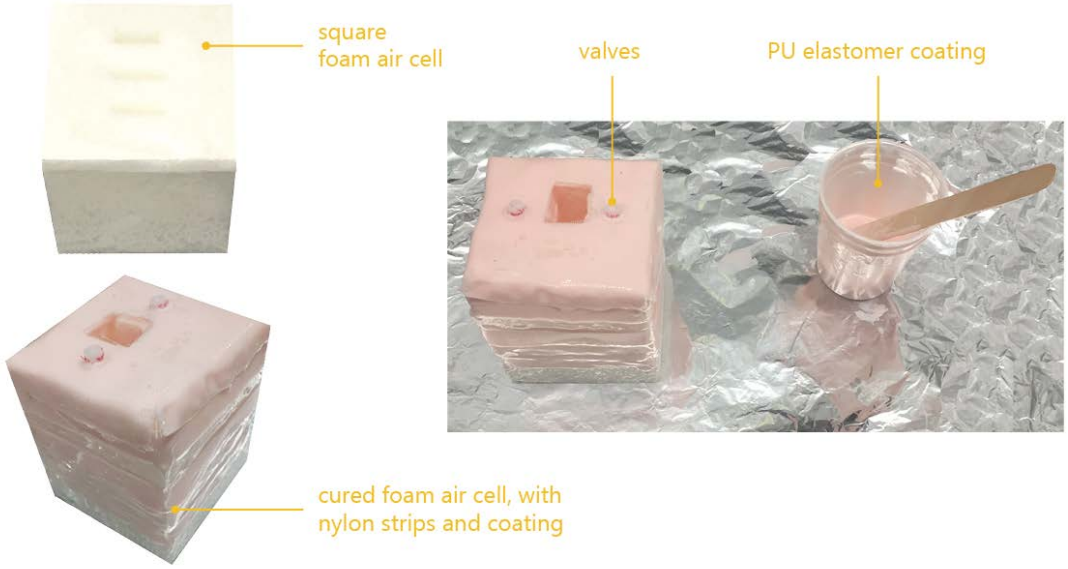


Figure 7. Square shaped foam – 3 stages (foam, foam with nylon strips, and foam with PU elastomer coat)

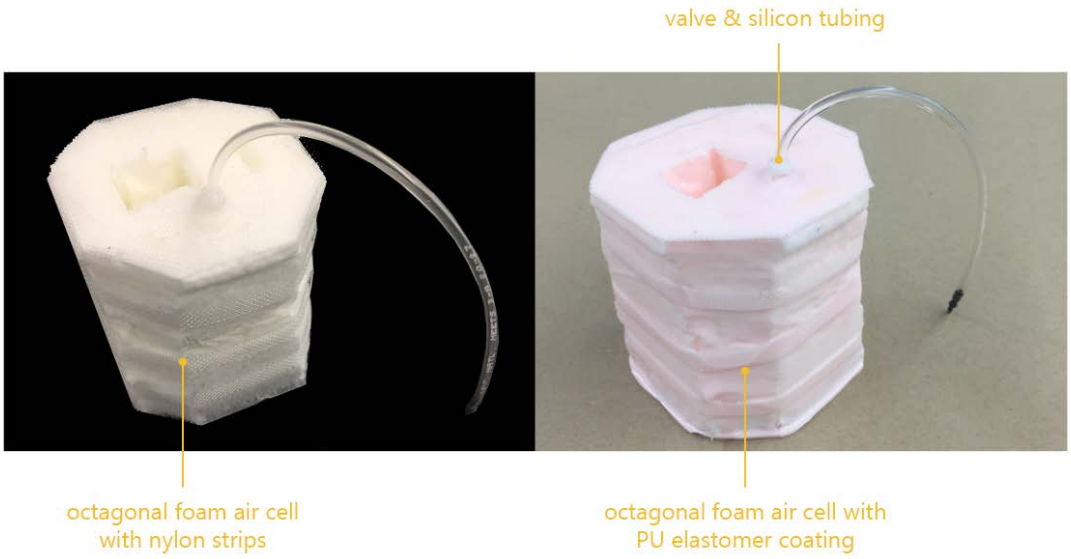


Figure 8. Octagonal shaped foam – 3 stages (foam, foam with nylon strips, and foam with PU elastomer coat)

The second prototype was done re-using the material (PVC) of an inflatable floating device. The material was cut forming a square shape to make a single air cell and a plastic valve (obtained from other inflatable devices) was heat-sealed onto the top side of the air cell. The air cell was then heat-sealed at the seams. An air pump was used to actuate the air cell manually and the air cell showed to have the actuation desired (>4") (Figure 9). Five more air cells were fabricated, to simulate a group of individual air cells. The air cells were then connected to a system to be automatically actuated. The system comprised of 3-way solenoid valves (stackable composite solenoid valves series 3923, Spartan Scientific) mounted on a manifold and connected to the air cells. The manifold was connected to an air compressor. Each solenoid valve was connected to a main controller (LOGO! 8, 6ED10573BA110AA8 device series, Siemens AG). The air cells were actuated by the controller to inflate/deflate (Figure

10). The system worked well but there were a few shortcomings. While the PVC material used for the air cells was flexible and showed the actuation capabilities needed, the material was too thin and could easily be pinched and deflated. The controller used allowed for the connection of 4-outputs at a time, therefore various extension modules of 8-outputs were necessary to obtain a system of 50 individual air cells (which was the original number of air cells envisioned). Due to the cost of the modules, the number of cells was reduced to 9 individual air cells, two alternating air cell mechanism (top layer), and two bigger air cells (bottom layer) with the use of three extension modules (26-outputs). However, after testing the mechanisms needed for the individual air cells, the alternating mechanism and the bottom actuators, the 3-way valves posed not to be the best alternative to open and close the inlets for different cells to inflate/deflate at different times. For the system to work, 4-way solenoid valves had to be used. 4-way solenoid valves required 4-output connections per valve, therefore 52-outputs were needed in total, which implied using 7 extension modules. Given the limited resources to develop the prototype acquiring 7 additional modules was not possible. Either less air cells had to be used for the system or a different controller/system to operate that many valves. Given that the number of air cells was already reduced to the minimum amount of air cells to allow the testing of the two main areas where pressure ulcers are most likely to occur, the investigator opted for a different controller/system.

Figure 9. PVC air cell with plastic valve

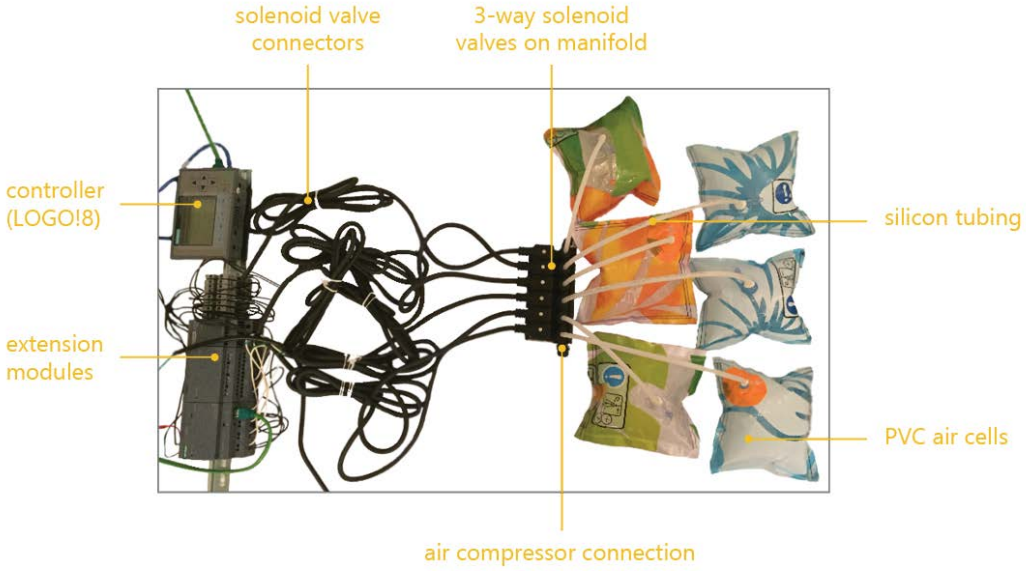


Figure 10. 3-way solenoid valve and LOGO! 8 system with six PVC valve actuated

Before moving to a different controller, a new type of material (TPU coated nylon fabric) was tested. Different shapes and forms were cut out and heat-sealed to

test the resistance of the material and the actuation capabilities (>4”). This material proved to be flexible, while still being able to resist weight and not pinch easily. One of the biggest problems was finding the proper TPU coated valves that could be heat sealed onto the material to create the air cells. The valves used, were the “boston-valves”, provided by a Chinese manufacturer (Kunshan Pinhong Rubber & Plastic CO., LTD). These valves were heat-sealed to the individual cells (Figure 11). This material was used for the final prototype.

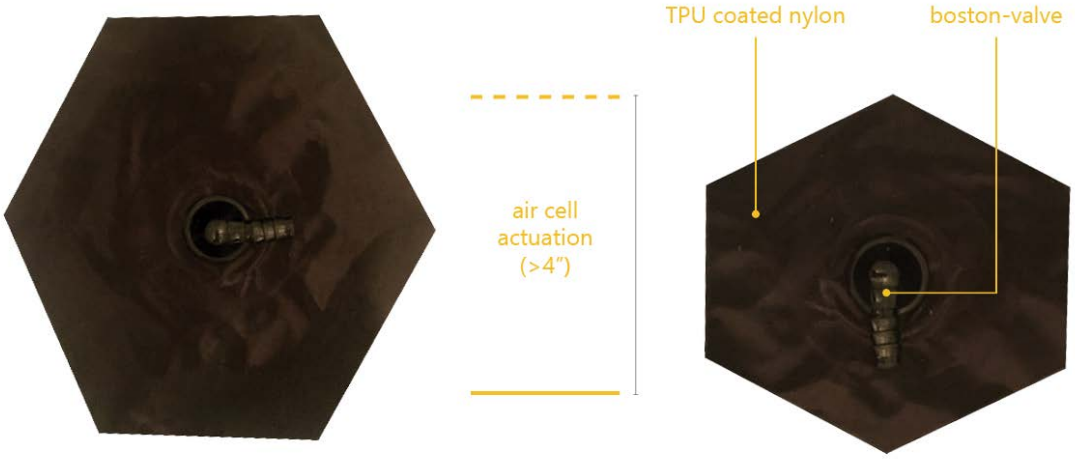


Figure 11. Heat-sealed air cells with boston-valves

Another concern was the fact that the individual cells had to be joined together or kept in place in the specific areas where they were supposed be on the overlay. This was a big concern moving forward, as ideally, the original design concept was a single array/pallet of air cells preferably injection molded into one surface or 3-4 different sections. After multiple tests with the new material found, it was possible to prototype

a single unit of mixed mechanisms of air cells. The following section will describe how the final prototype was constructed by explaining how each layer (top, mid, and bottom) of the prototype was designed and built, and finally a description of how the whole system to actuate the air cells of the top and bottom layers was developed.

Top layer *prototype* final design and construction

The top layer of the hybrid support surface *prototype* was a small-scale version of the *original* support surface. Given the limited resources, the prototype was constructed with fewer individual air cells (11 total) with pressure sensing capabilities, prioritizing areas where pressure ulcers are more likely to develop. These two areas were the lower back and buttocks, and the heels (Thomas, 2006). The top layer was fabricated according to anthropometric considerations of the 50^{th} percentile man and woman (Tilley, 2002), with specific emphasis on the two areas of focus previously mentioned (Figure 12).

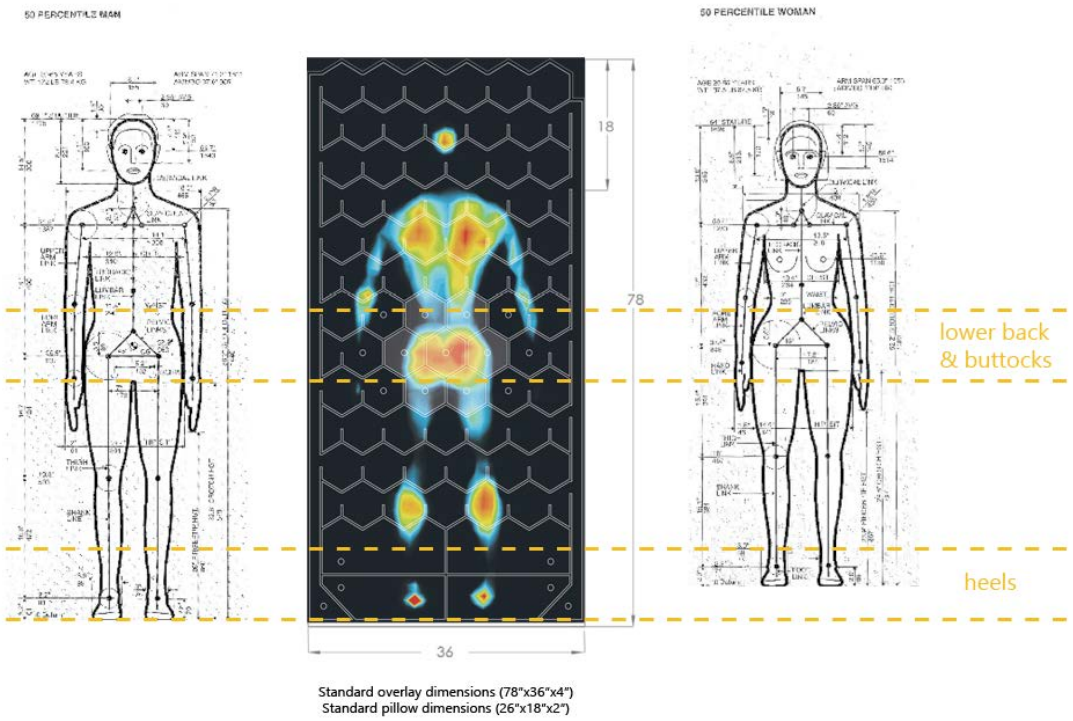


Figure 12. Anthropometric considerations for the top layer

Following the anthropometric considerations, a pattern of the top layer was designed in SolidWorks and laser cut. The design of the top layer contained both the individual air cell system for the lower back, buttocks and heels, combined with an alternating pressure system that simulated the smart behavior of the individual air cells for testing purposes (Figure 13).

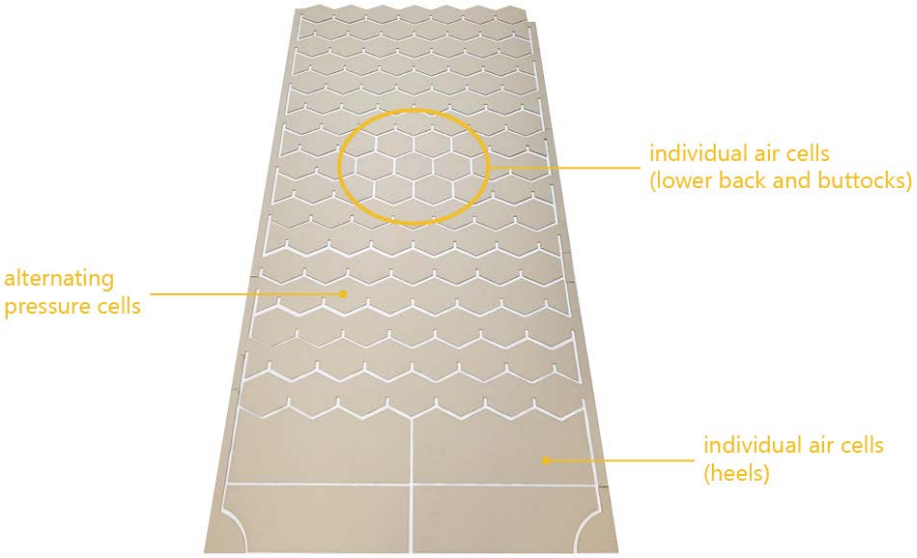


Figure 13. Top layer pattern design

The top layer of the prototype was manually heat-sealed out of a TPU coated nylon fabric, following the laser cut pattern. The pattern was traced onto the fabric and the boston-valves were heat sealed on the individual air cells and on the alternating air cell system (Figure 14). Once the valves were heat-sealed onto the fabric, the fabric was heat-sealed on the seams. The boston-valves were then connected to a flexible PVC tubing (Figure 15). Pressure sensors were positioned on top of all the individual air cells (Figure 16). This type of layer can be found on active support surfaces.

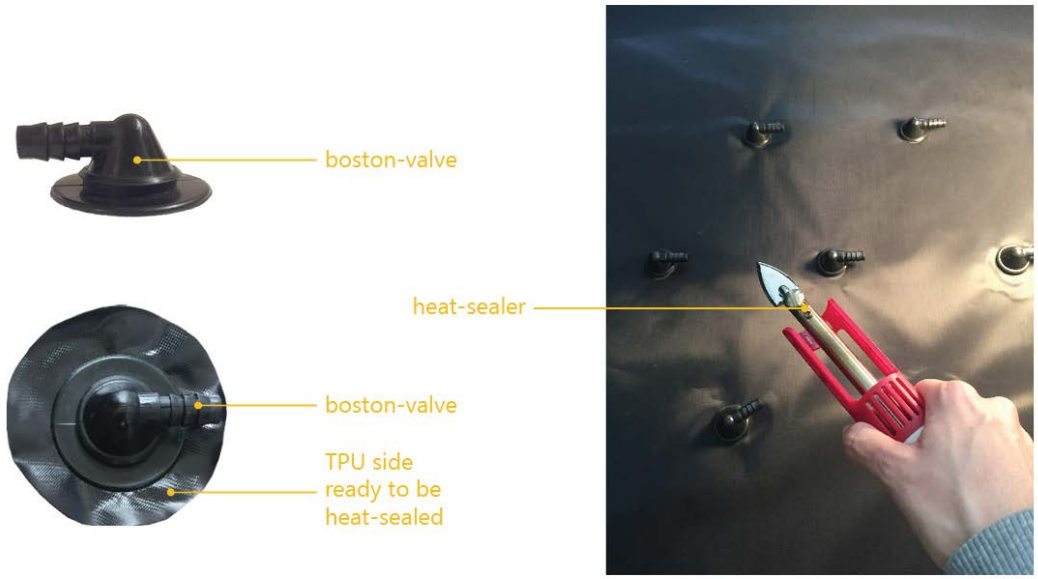


Figure 14. Boston-valves and heat sealing process

Figure 15. Back side of overlay with boston-valves and PVC tubing connectors

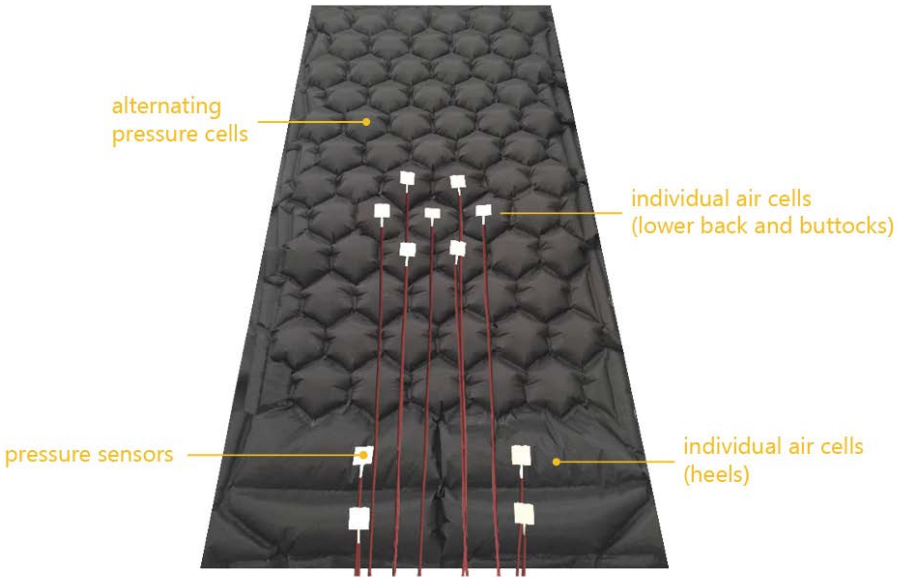


Figure 16. Top layer of the hybrid support surface prototype with pressure sensors

Mid-layer

The mid-layer was the same for the original concept and for the prototype of the hybrid support surface. The mid-layer was made of special memory foam type that was 3” in thickness and allowed for ventilation. The memory foam had an open cell design (Figure 17) that allowed for breathability between the top and bottom layers by increasing air flow and reducing trapped body heat, as well as providing pressure relief. The memory foam also helped reduce air gaps and non-contact regions from the top layer. This type of layer can be found on reactive support surfaces.

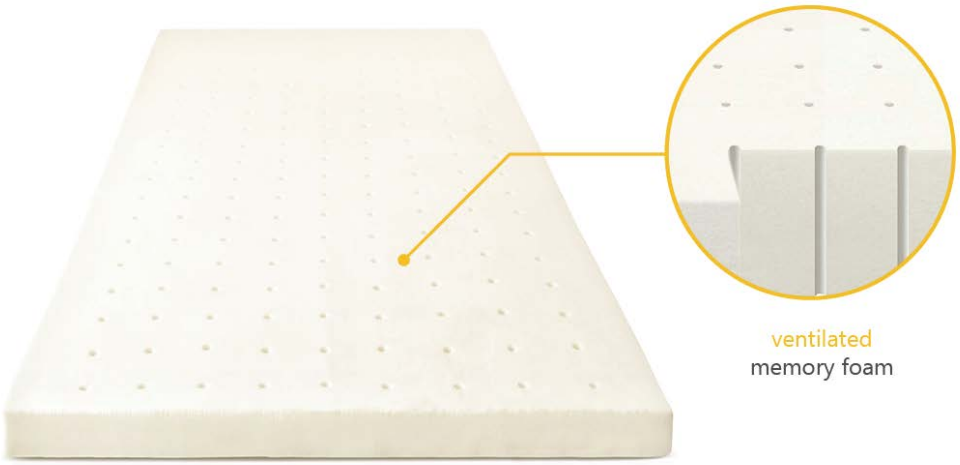


Figure 17. Mid-layer hybrid support surface

Bottom layer. The bottom layer for both the original concept and the prototype of the hybrid support surface were two individual actuators that extended over the length of the support surface. The actuators were manually constructed out of a heat-sealable blue TPU coated nylon fabric, forming a triangular shape of angles (30°-60°-90°) and approximate dimensions (21.78”x18.00”x10.39”). To hold the triangular shape and prevent it from inflating with an irregular shape, internal flaps were heat sealed in place. Each actuator had a boston-valve that was heat sealed, and then connected to a solenoid valve through a flexible PVC tubing. These actuators were capable of inflating and deflating according to specific degree angles and time intervals, to provide lateral postural changes. Both the degree of tilt as well as the time to turn can be adjusted according to patient’s needs and condition. The degree of tilt had a possible range between 0° to 30°. This range was used as a lateral inclination of 30° can help reduce pressure and prevent the development of pressure ulcers (Defloor, 2000; European Pressure Ulcer Advisory Panel (EPUAP) et al., 2014; Moore et al.,

2011), and simulates standard manual repositioning. The actuators were connected to a system that allowed automated postural changes (Figures 18 and 19).

Figure 18. Bottom layer of the hybrid support surface – side view

Figure 19. Bottom layer of the hybrid support surface – top view

System operation. These three layers were then compacted together inside an overlay cover (Figures 20 and 21). The overlay cover used for this prototype was the ROHO reusable mattress cover that is specifically designed for people who have pressure ulcers. The overlay cover used was waterproof, had anti-microbial properties and offered moisture vapor permeability.

Figure 20. Hybrid support surface layers

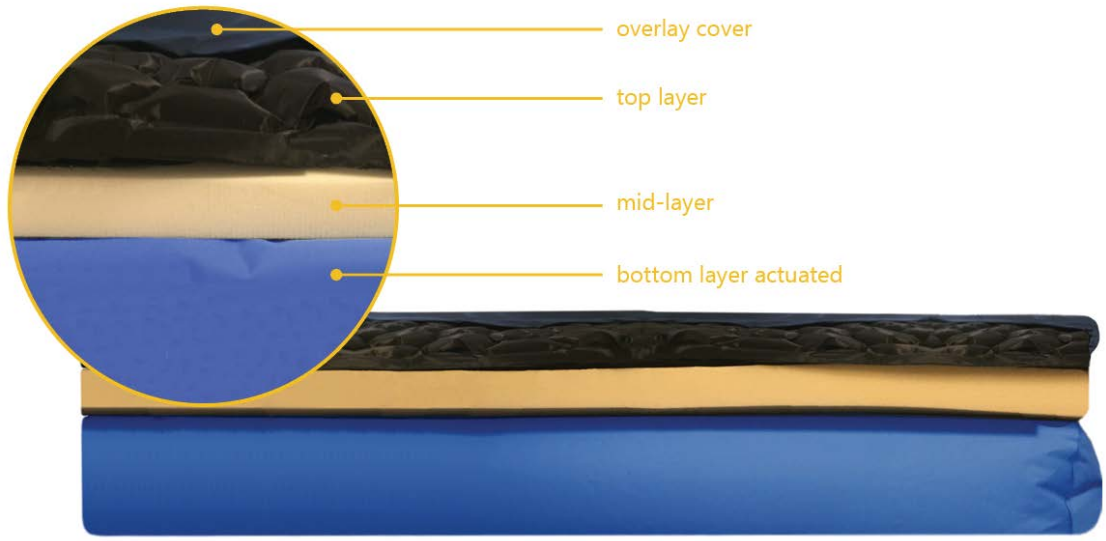


Figure 21. Hybrid support surface layers (actuated)

All the individual air cells had individual boston-valves and pressure sensors. The air cells' valves were connected to pneumatic 4-way solenoid valves (internally piloted acting type, 4V230C-08, AirTAC) with flexible PVC tubing. The solenoid valves were stacked on a manifold for ease of operation and connected to a system of relays. The relays were connected to the main microcontroller board (Mega Arduino). The pressure sensors were also connected to the main microcontroller board. Depending on the pressure information the individual air cells received, the cells reacted accordingly by inflating or deflating, to increase or decrease the amount of pressure and to maintain uniform pressure on all the air cells. The automated system was constantly sensing and updating the pressure data information and adjusting the

pressure on the air cells accordingly. As mentioned before, the individual air cells were combined with an alternating pressure mechanism.

A compressor (Hitachi EC28M) and vacuum pump (California Air Tools MP100LF) were connected to another relay system at one end; and the relay system was then connected to the main microcontroller board. The compressor and vacuum pump were also connected to the manifold. Acoustic enclosures were built for both the air compressor and vacuum pump to reduce the decibel level (Figure 22).

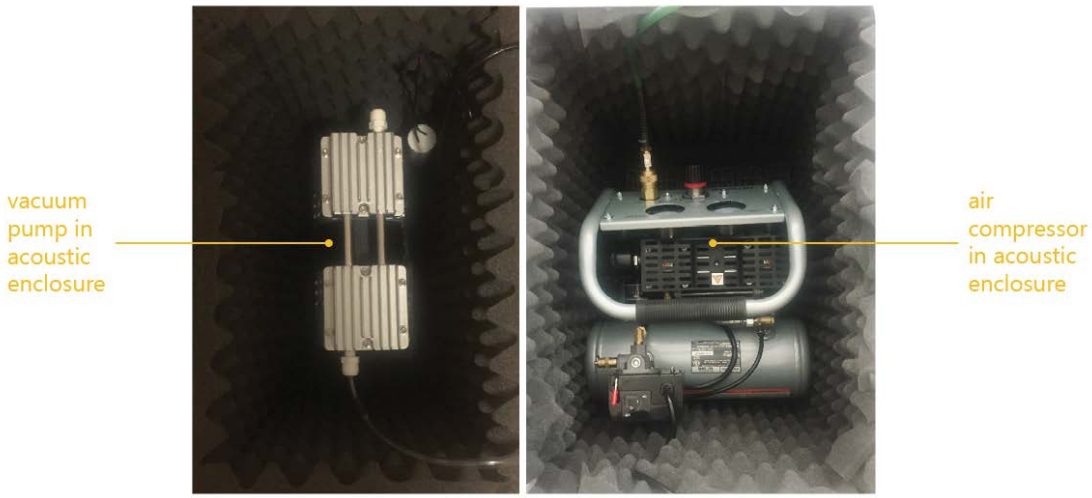


Figure 22. Acoustic enclosures for the air compressor and vacuum pump

The main microcontroller board was programed to provide the pressure sensing of individual cells and to act upon the pressure information received. The main microcontroller board was also programed to actuate the bottom layer, using a 30° angle at specific time intervals. A diagram and photo of the system is shown in Figures 23 and 24.

As a hybrid support surface, this design is advantageous as it can allow for individual customization depending on the needs and the condition of the patient. If a patient cannot be turned or repositioned in bed due to health conditions, the support surface can be programmed so that only the pressure sensing feature provides pressure reduction. For patients that can only be tilted 10°, the support surface can be programed to tilt at a 10° angle at any given time. For patients who are at risk of developing a pressure ulcer, tilting degrees and times could be set in order to prevent the development of pressure ulcers.

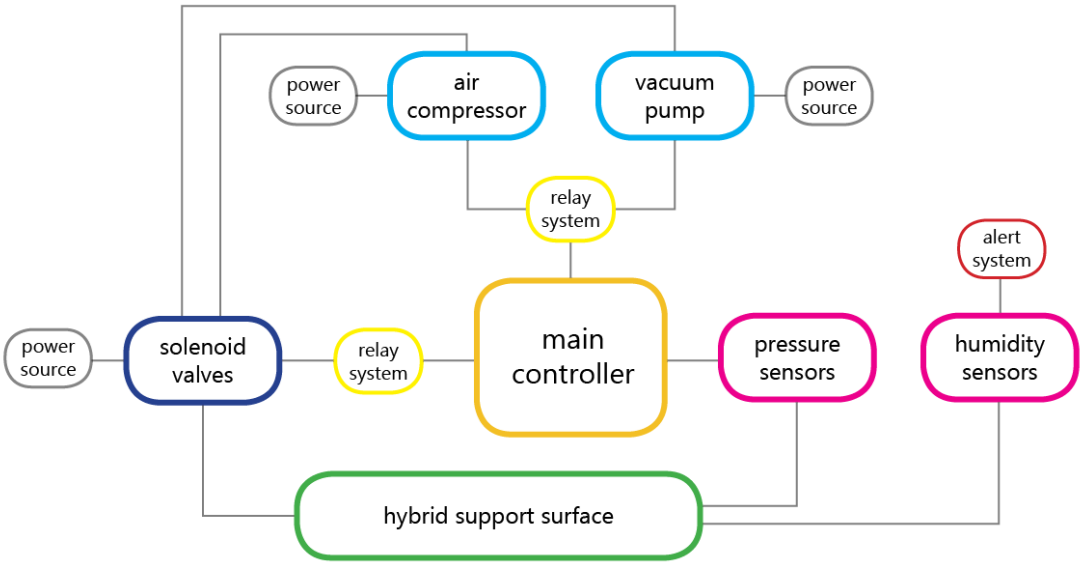


Figure 23. Diagram of the hybrid support prototype system

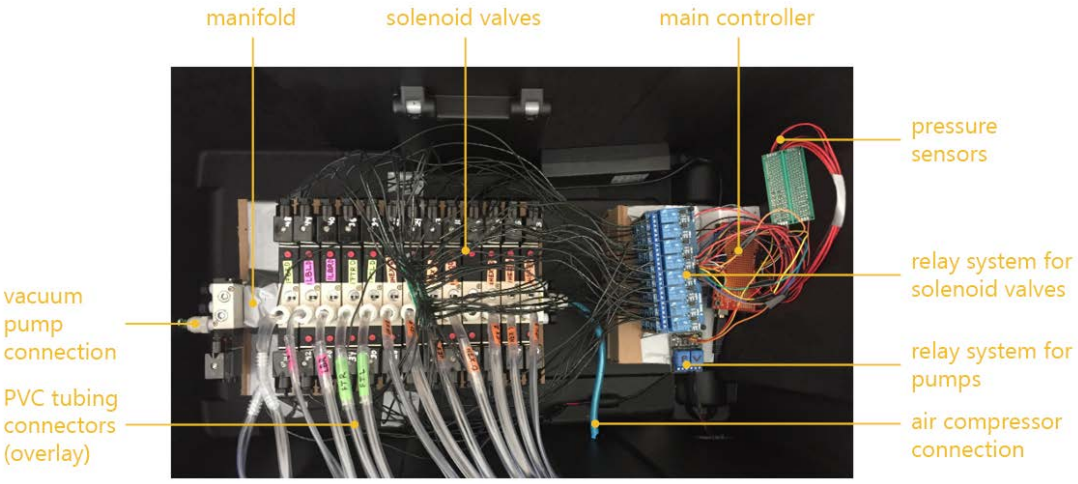


Figure 24. Hybrid support prototype system

CHAPTER 3

METHOD

The purpose of this study was to develop and evaluate a hybrid support surface prototype, intended for the prevention and care of pressure ulcers, in terms of the level of stress and comfort experienced among older adults. The hybrid support surface prototype will be referred to as smart bed overlay device (SBOD).

Participants

Forty-six individuals participated in the evaluation of the SBOD. Twenty-three participants were recruited from the Cornell University community through the Elder email listerve and the Health and Wellness email listserve. An additional 23 participants were recruited from Kendal at Ithaca, a continuous care retirement community. The Director of Marketing and Admissions and the nursing staff at Kendal assisted in recruiting participants from the independent and assisted living areas.

All participants were 50 years of age or older (M = 74.67, SD = 11.06). Of the total sample, 76% (n = 35) identified as female and 24% (n = 11) identified as male. The majority of the sample identified as White/Caucasian, with only one participant of Asian descent (Table 1). The majority of the participants were healthy older adults, except for one participant who had Parkinson's disease. The mean body mass index (BMI) for the sample was 25.07, indicating the sample is somewhat above the overweight range. Of the total sample, three were underweight, 23 had a normal or healthy weight, 11 were overweight, and nine were obese ("About Adult BMI," 2017).

Table 1. Sample Characteristics

	Cornell University	Kendal at Ithaca	Total
Total number of subjects	23 (50%)	23 (50%)	46 (100%)
Female subjects	16 (70%)	19 (83%)	35 (76%)
Male subjects	7 (30%)	4 (17%)	11 (24%)
Age range	51 - 93	65 - 91	51 - 93
Mean age	68.65 (11.30)	80.70 (6.83)	74.67 (11.06)
Mean BMI	25.59 (3.81)	24.55 (5.54)	25.07 (4.73)

Research Design

The hybrid support surface prototype being evaluated in this study was a SBOD, described in the previous chapter. The SBOD had two main functions: (1) to provide localized pressure sensing technology to detect and reduce areas in the body that have high pressure, and (2) to provide automated turning and repositioning.

Qualitative and quantitative methods were combined for a mixed-methods approach to evaluating the SBOD. To assess the influence of the SBOD on stress, heart rate variability (HRV) was measured before, during, and after use. To assess the influence of the SBOD on comfort, a validated scale (TWAC) and a structured interview method were used.

Stress. Heart rate variability (HRV) was used to operationalize stress. HRV measures the variation in time between successive heartbeats (Campos, 2017). This variation is controlled by the autonomic nervous system (ANS). The ANS is

composed by the sympathetic (fight-or-flight mechanism) and the parasympathetic (relaxation response) nervous system (Campos, 2017).

A low HRV (less variability between heartbeats) indicates that the body is under stress, either from exercise, psychological events, or other internal/external stressors (J. Moore, 2016). A higher HRV (greater variability within heartbeats) means the body is more resilient to stress (J. Moore, 2016). Evidence suggests HRV is affected by stress and several studies support the use of HRV as an objective assessment of stress (Kim, Cheon, Bai, Lee, & Koo, 2018; Shmerling, 2017).

In particular, a previous study used the parasympathetic nervous activity of the heart – a component of HRV – to evaluate the degree of comfort of a support surface among bedridden older adults (Futamura, Sugama, Okuwa, Sanada, & Tabata, 2008).

To measure HRV, participants wore a Garmin Vívosmart 4. The Garmin Vívosmart 4 is a wrist device that measures HRV. The Garmin Vívosmart 4 categorizes stress levels into four different ranges, these ranges were used to evaluate the level of stress for participants in the study (Table 4).

Table 4. Garmin Vívosmart 4 stress level range and category

Stress range	Stress level
0 - 25	Resting state
26 - 50	Low stress
51 - 75	Medium stress
76 - 100	High stress

Comfort. Comfort was operationalized using an adapted version of the Tool for Assessing Wheelchair discomfort (TAWC). This assessment tool was previously validated (Crane, 2004; Crane et al., 2005), and later used in a study to examine the seating discomfort experienced by full-time wheelchair users (Crane, Holm, Hobson, Cooper, & Reed, 2007). The objective of this study was to examine the efficacy of a new user-adjustable wheelchair seating system designed to relieve discomfort for long-duration wheelchair users. Moreover, in a literature review on comfort and its measurement, two assessment tools were identified that were carefully developed and psychometrically tested; one of these assessment tools was the TAWC (Pearson, 2009).

Even though this assessment tool specifically pertains to wheelchair users, it was used for this study as no other relevant and validated tools were found that deal with the use of different support surfaces composed of air bladders that inflate and deflate, and tilting mechanisms similar to the support surface evaluated in this study.

The TAWC comprises the General Discomfort Assessment (GDA) and the Discomfort Intensity Score (DIS). The adapted GDA for this study contained six statements related to comfort and six statements related to discomfort (Appendix B). The statements were rated on a seven-point Likert scale. The GDA score had a range of 12-84 possible points. Lower scores indicated participants were comfortable and higher scores indicated participants were uncomfortable while lying down on the SBOD.

The adapted DIS for this study included ten body areas that were rated using a numeric rating scale (Appendix B). The DIS assessment allowed participants to rate

their level of comfort/discomfort regarding ten body areas and the body as a whole. The DIS score had a range of 0-30 possible points. A score of zero indicated no discomfort, while a score of 30 indicated substantial discomfort.

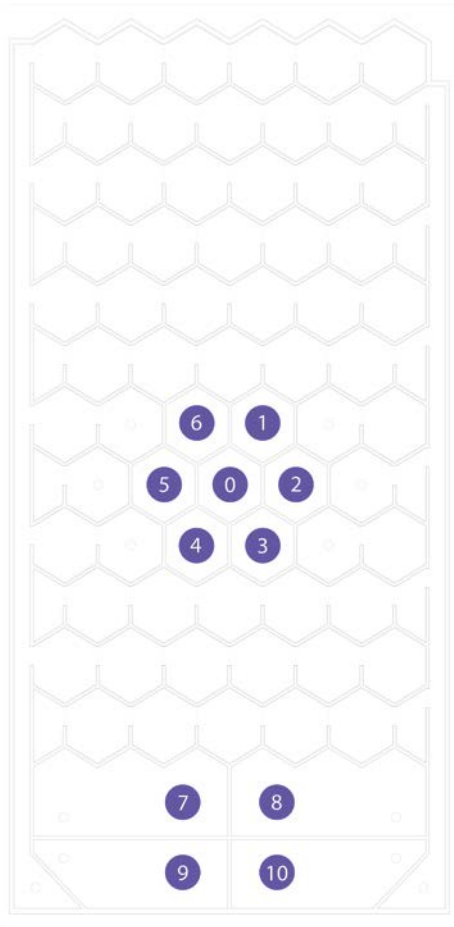
Additionally, comfort was operationalized using a structured interview method of five questions posed in spoken word by the investigator while participants were interacting with the prototype. Participants were video recorded while they laid on the SBOD and answered the five questions regarding their feelings and perceptions of the SBOD at five specific times during the pilot study (see Table 2).

Table 2. Structured Interview Method - questions and times

Question	Time
1. Are you comfortable?	When participants laid on the SBOD
2. What did you feel when the device was turning?	After the device tilted to the left
3. Do you feel comfortable?	While still being tilted to the left
4. Do you feel safe?	After the device tilted to the right
5. Do you feel any kind of pain in your body that was triggered by the device?	Before participants were told to stand up

Pressure. This independent variable was used to quantify the areas of highest pressure on the SBOD. Pressure was operationalized by measures obtained from pressure sensors located in two main areas, the lower back and

buttocks, and the heels (Figure 25). Pressure measures were recorded at four different times by a series of pressure sensors located on the device. These four times were: 1-minute after the participant laid on the device, 2-minutes after the device slightly tilted for the first time, 2-minutes after the device returned to its normal position, and 2-minutes after the device tilted for the second time.



Location	Number
Lower back and buttocks	0
	1
	2
	3
	4
	5
	6
Heels	7
	8
	9
	10

Figure 25. Pressure sensors location and number

The air cells with the pressure sensors reacted to pressure information received. When the air cells registered higher and lower pressure values, they automatically

inflated or deflated to maintain equal pressure on all body areas. The rest of the air cells in the SBOD had constant alternating pressure (see Chapter 2 for details).

Procedure

The Institutional Review Board (IRB) at Cornell University approved all phases of the study prior to the recruitment of participants. The research study was originally divided into three phases. Phases I and II consisted of studies to evaluate the SBOD in terms of the level of stress and comfort experienced among older adults. Phase III consisted of an experimental research study to evaluate the effectiveness of the SBOD for the prevention and care of pressure ulcers at the skilled nursing facility at Kendal at Ithaca. Due to resource limitations, only Phases I and II were conducted; however the experimental research study (Phase III) can be found in Appendix D.

The current study consisted of two phases. Phase I was conducted at the Human Performance and Ergonomics Laboratory at the Human Ecology Building (HEB) at Cornell University (Figure 26). For Phase I, 23 participants (female = 16, male = 7) were recruited. Phase II was conducted at Kendal at Ithaca, a continuing care retirement community located in Ithaca (Figure 27). For Phase II, 23 participants (female = 19, male = 4) were recruited.

Figure 26. Human Performance and Ergonomics Laboratory – Cornell University

Figure 27. Independent Living apartment – Kendal at Ithaca

The total duration of the study was approximately between 20 to 30-minutes per participant. Participants completed the study individually. All participants were provided with informed consent and asked to complete a consent form prior to participating in the study (Appendix C). During the first 5-minutes, consenting participants completed an anthropometrics and demographics form with general information such as height, weight, age, gender and ethnicity (Appendix C). During

the next 15-minutes, participants laid on the SBOD on a supine position. During this time, participants answered five questions using a structured interview method and were also encouraged to verbalize any additional thoughts about their experience using the SBOD. During the last 5-minutes, the participant completed the TAWC assessments (GDA and DIS) to measure their comfort (see Figure 28).

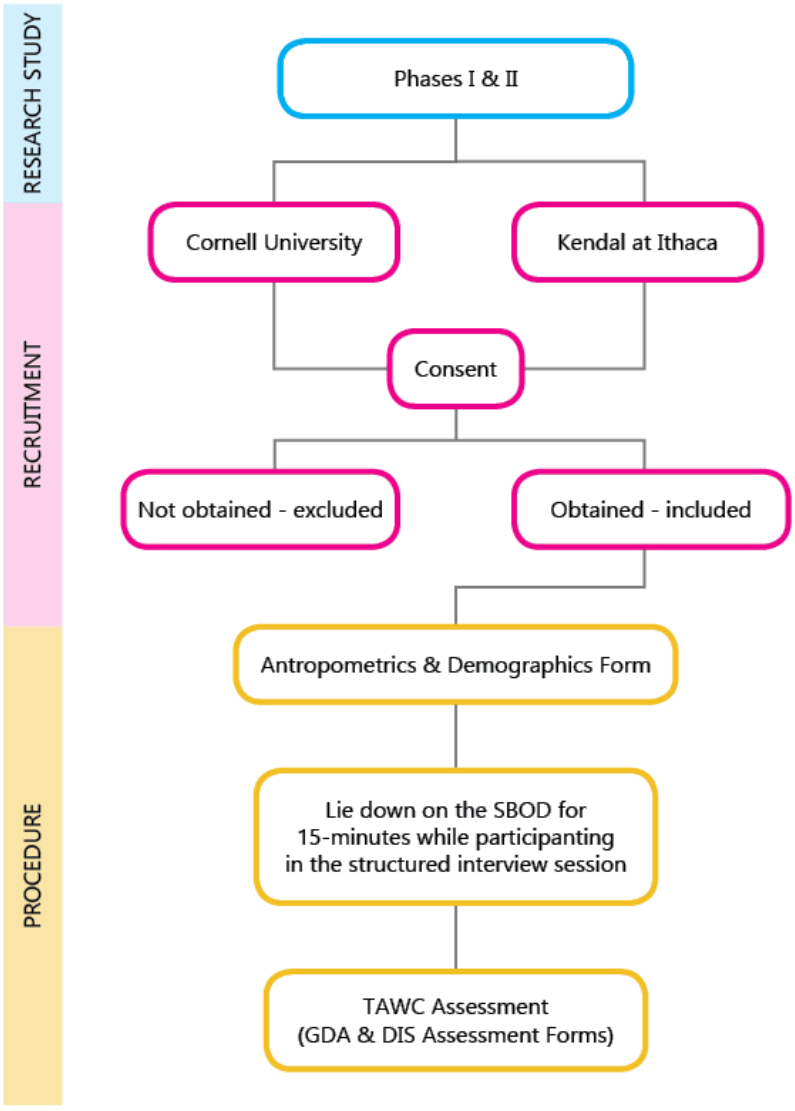


Figure 28. Procedure Diagram

When participants were lying down, they were able to feel slight changes in pressure and slight postural changes. The postural changes had the following order, supine position, left tilt, supine position, right lilt, and supine position. Each postural change lasted for 3-minutes (Figures 29 and 30).

Figure 29. Supine position, participant at Cornell University

Figure 30. Left tilt, participant at Kendal at Ithaca

Heart rate variability was collected at four specific times during the experimental study. The first measure was collected at the beginning of the study, when the participant was sitting down after having completed the anthropometrics and demographics form. The second measure was collected when the participant was lying on the SBOD, immediately after the SBOD had slightly tilted the participant at a ~30° angle (left tilt). The third measure was collected when the participant was still lying on the SBOD, immediately after the SBOD had slightly tilted the participant at a ~30° angle (right tilt). The degree of tilt was measured using a RISEPRO inclinometer (accuracy: 0˚ and 90˚: +/- 0.05˚). The final measure was collected at the end of the study, when the participant was sitting down after having completed the comfort/discomfort assessments.

Analytic Strategy

All the data were coded, entered and analyzed using SAS JMP (version 9.4) data analysis software.

Stress. A paired-samples t-test was conducted to compare average stress levels obtained from HRV measures, when participants were off the SBOD and when participants were on the SBOD. An independent sample t-test was conducted to compare average stress levels for participants from Cornell University and Kendal at Ithaca. Statistical significance was defined as a *p*-value of less than 0.05.

Comfort. For all analysis, if a participant missed an item on any of the assessments, that assessment was excluded from the analysis. Only complete assessments for both the GDA and DIS were considered for the analysis. The scores of

the GDA and DIS assessments were individually added. Means and standard deviations were calculated for the total sample. For each assessment, the number and percentage of participants was provided for ease of evaluation between the different statements and body parts.

Additionally, participants were video recorded while using the SBOD. The recordings pertaining the structured interview method were transcribed and analyzed. The results obtained were sorted and coded into categories. Results were reported as qualitative data.

CHAPTER 4

RESULTS

Effect of SBOD on Stress

Since data was normally distributed, a paired-samples *t*-test was conducted to compare HRV when participants were off the SBOD (sitting) and when they were lying on the SBOD. There was a statistically significant difference in HRV when participants were off the overlay device (M = 27.89, SD = 17.72) and when they were lying on the SBOD (M = 17.84, SD = 16.27), $t(45) = -5.69$, $p < .0001$ (Table 5 and Figure 31). These results suggest that the use of the SBOD had an effect on stress, such that participants lying on the SBOD experienced lower HRV than when they were sitting in a chair.

Table 5. Stress level means and standard deviations

	Cornell University	Kendal at Ithaca	Total
Mean HRV – not on device	34.65 (20.23)	21.13 (11.70)	27.89 (17.72)
Mean HRV – on device	23.17 (19.47)	12.50 (10.15)	17.84 (16.27)

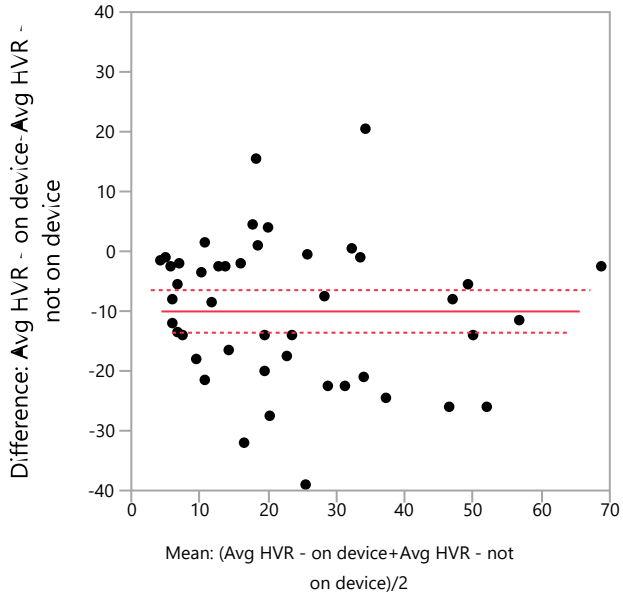


Figure 31. Paired samples *t*-test: difference mean stress level on the device versus not on the device

Additionally, an independent sample *t*-test was conducted comparing stress levels for participants from Cornell University to those from Kendal at Ithaca. There was a significant difference in HRV for participants from Cornell University (M = 28.91, SD = 18.68) and participants from Kendal at Ithaca (M = 16.82, SD = 9.65), $t(33) = -2.76$, $p = .0094$. These results suggest that participants from Kendal at Ithaca were less stressed than participants from Cornell University overall (Table 6, Figure 32).

Table 6. Stress level means and standard deviations at four specific times

	Cornell University	Kendal at Ithaca	Total
Mean HRV – time 1 (not on device)	37.09 (21.14)	21.22 (16.53)	29.15 (20.40)
Mean HRV – time 2 (left tilt)	24.13 (23.57)	13.52 (11.77)	18.83 (19.19)
Mean HRV – time 3 (right tilt)	22.22 (19.81)	11.48 (9.59)	16.85 (16.32)
Mean HRV – time 4 (not on device)	32.22 (27.41)	21.04 (18.93)	26.63 (23.97)

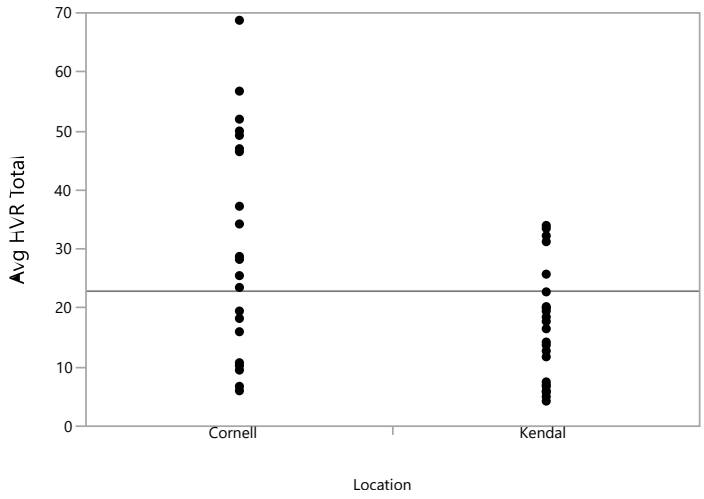


Figure 32. Independent sample t-test mean HVR by location

Effect of SBOD on Comfort

The TAWC, used in this study to measure comfort, comprises the General Discomfort Assessment (GDA) and the Discomfort Intensity Score (DIS), as previously described in Chapter 3.

GDA. The GDA was measured on a seven-point Likert scale, with lower scores indicating participants were comfortable and higher scores indicating participants were uncomfortable while lying down on the SBOD. Overall, the results suggest participants were comfortable when using the SBOD (M = 26.52, SD = 11.74) (see Table 9).

Table 9. General Discomfort Assessment (GDA) scores means and standard deviations

Statements	Cornell University	Kendal at Ithaca	Total
1. …I feel poorly positioned	1.87 (1.14)	2.17 (1.64)	2.02 (1.41)
2. …I feel like I have been in one position for too long	2.17 (1.61)	2.57 (1.83)	2.37 (1.72)
3. …I feel like I need to move or shift my position	2.70 (1.87)	2.83 (2.10)	2.76 (1.97)
4. …I feel aches, stiffness, or soreness	1.96 (1.49)	1.57 (0.90)	1.76 (1.23)
5. …I feel pressure in some part or parts of my body	3.00 (2.26)	2.87 (2.12)	2.93 (2.16)
6. …I feel uncomfortable	1.61 (1.16)	2.04 (1.30)	1.83 (1.23)
7. …I feel no pain	2.17 (1.92)	1.91 (1.62)	2.04 (1.76)
8. …I feel safe	2.17 (1.47)	1.96 (1.55)	2.07 (1.50)
9. …I feel relaxed	2.04 (1.74)	2.13 (1.74)	2.09 (1.72)
10. …I feel stable (not sliding or falling)	3.09 (2.13)	2.17 (1.15)	2.63 (1.76)
11. …I feel comfortable	1.87 (1.52)	2.13 (1.69)	2.00 (1.59)
12. …I feel good	1.87 (1.60)	2.17 (1.67)	2.02 (1.63)
Total GDA score	26.52 (12.43)	26.52 (11.29)	26.52 (11.74)

To provide an aggregate review of the data, the seven-point Likert scale was grouped into three categories “disagree”, “neither agree nor disagree”, and “agree” (Table 10).

Table 10. GDA number and percentage of participants per statement

Statements	Disagree	Neither agree nor disagree	Agree
1. …I feel poorly positioned	38 (82%)	3 (7%)	5 (11%)
2. …I feel like I have been in one position for too long	33 (72%)	4 (9%)	9 (20%)
3. …I feel like I need to move or shift my position	30 (65%)	3 (7%)	13 (28%)
4. …I feel aches, stiffness, or soreness	39 (85%)	4 (9%)	3 (7%)
5. …I feel pressure in some part or parts of my body	31 (68%)	2 (4%)	13 (29%)
6. …I feel uncomfortable	39 (85%)	4 (9%)	3 (7%)
7. …I feel no pain	6 (13%)	1 (2%)	39 (85%)
8. …I feel safe	4 (8%)	1 (2%)	41 (89%)
9. …I feel relaxed	5 (11%)	2 (4%)	39 (85%)
10. …I feel stable (not sliding or falling)	10 (21%)	1 (2%)	35 (76%)
11. …I feel comfortable	4 (9%)	1 (2%)	41 (90%)
12. …I feel good	5 (11%)	-	41 (90%)

One of the main concerns about the SBOD was safety, as the device automatically turned and repositioned participants. Out of the total sample, 41 (89%) participants felt safe while lying on the SBOD and experiencing the automated tilting. Some of the participants expressed they felt unsafe when the device was tilting, because they feared the device was going to throw them out of bed; but once they realized this was not the case, when the second tilt happened, they did not have this feeling. Moreover, 41 (89%) participants felt comfortable while lying on the device.

DIS. The DIS assessment allowed participants to rate their level of comfort/discomfort regarding ten body areas and the body as a whole. The DIS score was measured on a four-point scale. A score of 0 indicated no discomfort, while a score of 3 indicated severe discomfort.

While the average DIS scores for the sample population from Cornell University (M = 0.70) versus Kendal at Ithaca (M = 0.35) vary, both scores are close to zero, suggesting that participants experienced little to no discomfort (Table 11). The majority of the sample experienced no discomfort for the most part regarding the body areas (Table 12).

Table 11. Discomfort Intensity Scores (DIS) means and standard deviations by body area

Discomfort Level	Cornell University	Kendal at Ithaca	Total
Neck	0.17 (0.49)	0.04 (0.21)	0.11 (0.38)
Upper back	0.00 (0.00)	0.04 (0.21)	0.02 (0.15)
Lower back	0.13 (0.34)	0.09 (0.29)	0.11 (0.31)
Buttocks	0.17 (0.39)	0.09 (0.29)	0.13 (0.34)
Shoulders	0.09 (2.29)	0.00 (0.00)	0.04 (0.21)
Arms	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Hands	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Legs	0.04 (0.21)	0.09 (0.29)	0.07 (0.25)
Feet	0.04 (0.21)	0.00 (0.00)	0.02 (0.15)
Heels	0.04 (0.21)	0.00 (0.00)	0.02 (0.15)
Total DIS Score	0.70 (1.15)	0.35 (0.83)	0.52 (1.01)

Table 12. DIS according to the number of participants by body area

Body area	No Discomfort level = 0	Minor Discomfort level = 1	Moderate Discomfort level = 2	Severe Discomfort level = 3
Neck	42 (91%)	3 (7%)	1 (2%)	0
Upper back	45 (98%)	1 (2%)	0	0
Lower back	41 (89%)	5 (11%)	0	0
Buttocks	40 (87%)	6 (13%)	0	0
Shoulders	44 (96%)	2 (4%)	0	0
Arms	46 (100%)	0	0	0
Hands	46 (100%)	0	0	0
Legs	43 (93%)	3 (7%)	0	0
Feet	45 (98%)	1 (2%)	0	0
Heels	45 (98%)	1 (2%)	0	0

Additionally, a correlation revealed no significant relationship between GDA scores and HRV (r = .1, p = .504). Similarly, there were no significant relationship between DIS scores and HRV (r = .1, p = .641).

Structured Interview. Participants were asked five questions of their overall feelings and emotions while lying down on the SBOD using a structured interview method at specific times during the pilot study. Once participants were lying down, the first question they answered was in terms of how comfortable they felt. Overall, 96% (n = 44) of participants felt comfortable, while 4% (n = 2) felt uncomfortable. From the participants who felt uncomfortable, one expressed to have a neck injury and the other lower back pain, prior to participating in the study. When the device tilted to the left, participants were asked how they felt when the device was turning. Of the total participants 73% (n = 34) participants felt the device was tilting, 24% (n = 11)

participants felt something was happening but could not tell what it was, 65% (*n* = 30) participants felt unsafe not knowing if the device was going to tip them over, 15% (*n* = 7) asked if the bed was a “massage bed”, and 2% (*n* = 1) participant experienced a feeling of “floating”. While participants were still tilted to the left, participants were asked if they felt comfortable, 84% (*n* = 39) participants felt comfortable while 15% (*n* = 7) felt uncomfortable. When the device tilted to the right, participants were asked if they felt safe, 95% (*n* = 44) participants felt safe, and two responses could not be accounted as the participants fell asleep. Before asking participants to get up, participants were asked if they felt any pain that was caused by the SBOD, all participants explained they felt no pain due to the device, however, 7% (*n* = 3) expressed they were in pain while lying on the SBOD, but the pain was not caused by the SBOD.

There was one interesting comment expressed by several participants that was not part of the structured interview method. When participants were asked to lie down on a supine position, 83% (*n* = 38) participants expressed that lying on a supine position was not comfortable for them, and that they preferred to lie on their side.

Pressure. Pressure measures were recorded at four different times by a series of pressure sensors located on the device as can be observed in the following table. On average, the areas that received the most pressure were located in the lower back buttocks area (Figure 33).

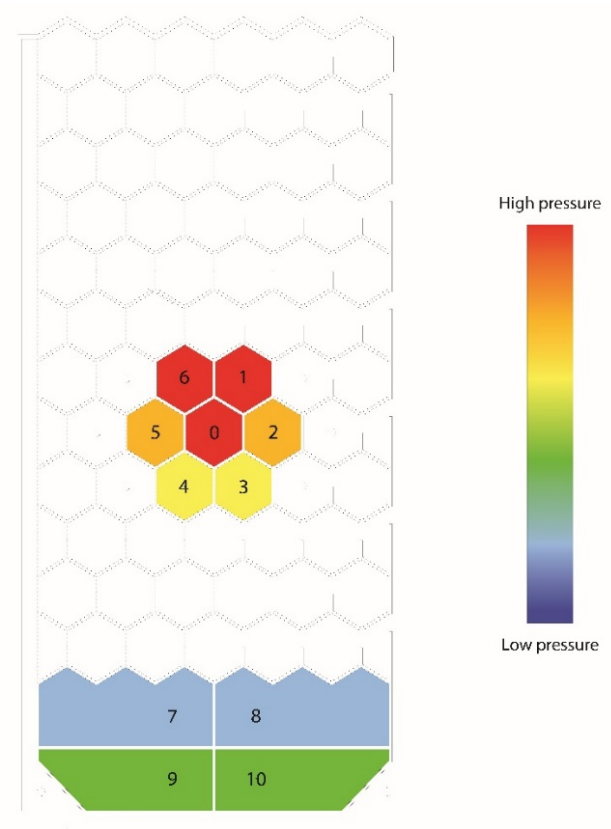


Figure 33. Areas with highest and lowest pressure on the SBOD

CHAPTER 5

DISCUSSION & CONCLUSION

The purpose of this study was to develop and evaluate a hybrid support surface prototype device (or SBOD) in terms of the level of stress and comfort experienced among older adults. It was hypothesized that the introduction of a new prototype device would affect participants in a positive way by decreasing their overall stress levels. The results obtained suggest that participants stress levels decreased significantly when they were lying on the SBOD. Overall, participants felt more relaxed and less stressed when lying on the SBOD, despite the fact that they were being introduced to a completely new and novel device. This finding supports existing results from Futamura et al. (2008), who investigated HRV while using a mattress with automated tilting (10°) versus manual turning. The results of the study indicated that participants experienced a significant reduction in mental stress during the automated tilting.

In the current study, it was additionally hypothesized that the introduction of a new prototype device would affect participants in a positive way by increasing their overall comfort level. In terms of comfort, the overall results suggest participants felt comfortable while lying on the SBOD, despite the fact that many participants expressed during the structured interview that lying on a supine position was not comfortable for them.

Pressure results suggested the lower back and buttocks were the areas that received the most pressure during the study. This coincides with the literature reviewed (Thomas, 2006); and therefore suggests these areas should be of main

concern when designing support surfaces, as these are areas where pressure ulcers are more likely to occur.

Limitations. There was a significant difference in stress level among participants from Cornell University and Kendal at Ithaca. These results suggest that participants from Kendal at Ithaca were less stressed than participants from Cornell University. This could be due to the difference in settings. The phase at Cornell University was conducted in a laboratory setting, which could have been more stressful for participants. The phase at Kendal at Ithaca was conducted at a vacant apartment setting, similar to the apartment rooms participants already live in. The familiar setting could have been less stressful for participants than a laboratory setting.

The pilot studies did not include a control group; therefore, it was hard to establish causality, rendering the study with weak internal validity. Even though the outcome variables had a positive effect on the overall perception of the SBOD, results could be misleading.

A power analysis was not conducted prior to the study. Future research should conduct a power analysis to ensure an adequate sample size.

Ideally, for more accurate results, a chest strap HRV monitor should be used. The IRB has strict rules, such that if a device used qualifies as “invasive” (as is the case of the chest strap), the device has to be approved by the Food and Drug Administration (FDA). Due to the limited resources to acquire a proper HRV monitor that was FDA approved, this study used the Garmin Vívosmart 4, as this device qualified as a “non-invasive,”

Because the study focused on older adults as the study population, results obtained might not be generalizable to other groups of people. Likewise, the setting in which the studies were conducted, a laboratory and a continuing care retirement community, are very specific and results might not be generalizable to hospital or other health settings.

Future Research

The results of this study should be considered in light of the limitations of this research study, given that only the first two phases were conducted. Even though the results of these phases reflect a promising starting point, it would be ideal to evaluate the effectiveness of the SBOD for its intended use: the prevention and healing of pressure ulcers. In the future, with the proper funding and resources, the prototype should be built according to its full functions and specifications. The prototype should be tested for its intended purpose, for the prevention and care of pressure ulcers.

Following the pilot studies, the experimental research design proposed should be conducted (Appendix D.). The pilot studies conducted in this study, along with the proposed experimental study, will comprise the basis of a series of preliminary studies that need to be conducted in the future for the purpose of establishing if a full trial will be feasible in the future. The future goal will be to conduct a randomized control trial (RCT) to evaluate the effectiveness of the support surface for pressure ulcer prevention and healing.

Additionally, it is important to note that the postural changes were more frequent during the experimental phase than in a typical health setting. Ideally, postural changes would only occur during nighttime every two hours

(Association for the Advancement of Wound Care, 2010; European Pressure Ulcer Advisory Panel et al., 2014; MacGregor, 2010), and less so during daytime depending on the needs and condition of the patient.

Conclusion

Despite the billions of dollars spent to treat pressure ulcers, they are still a significant burden for patients, caregivers, and the healthcare system as a whole. Pressure ulcers can be prevented by avoiding constant pressure that can compromise tissue viability. Frequent postural changes and incontinence check-ups can aid in the prevention of pressure ulcer development.

Support surfaces are devices that can help with the prevention and care of pressure ulcers. There are three types of support surfaces, reactive, active, and hybrid. While most of the literature available focuses on reactive and active support surfaces, there are very few studies available on hybrid support surfaces.

This thesis focused on the design and development of a hybrid support surface prototype for the prevention and healing of pressure ulcers. The hybrid support surface prototype or SBOD provided two main functions: automated localized pressure sensing technology to detect and reduce areas in the body that have high pressure; and, automated turning and repositioning. These functions were found to be essential for the prevention and care of pressure ulcers.

This study concerned the development and evaluation of a hybrid support surface prototype, intended for the prevention and care of pressure ulcers, in terms of the level of stress and comfort experienced among older adults. Overall results from this study

suggest participants had lower stress levels and felt comfortable while lying on the SBOD.

Despite the study limitations, this study will contribute to existing knowledge and research on hybrid support surfaces for the care and prevention of pressure ulcers that have novel features and smart technologies. These novel features and smart technologies could become the next generation of hybrid support surfaces, to prevent and help with the healing process of pressure ulcers as well as to assist caregivers who take care of patients with pressure ulcers. Automated tilting SBODs can potentially help alleviate the burden that manual tilting poses on caregivers. Likewise, the smart automated individual air cell mechanism could prevent the development of pressure ulcers, and its manual control can help care for already existing pressure ulcers by offloading the pressure in any given area.

REFERENCES

About Adult BMI. (2017, August 29). Retrieved June 24, 2019, from Centers for Disease Control and Prevention website: https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html

Agency for Healthcare Research and Quality. (2011). Preventing Pressure Ulcers in Hospitals [Text]. Retrieved April 20, 2018, from Agency for Healthcare Research and Quality website: https://www.ahrq.gov/professionals/systems/hospital/pressureulcertoolkit/putool1.html

Agrawal, K., & Chauhan, N. (2012). Pressure ulcers: Back to the basics. *Indian Journal of Plastic Surgery*, *45*(2), 244. https://doi.org/10.4103/0970-0358.101287

Association for the Advancement of Wound Care. (2010). *Association for the Advancement of Wound Care Guideline of Pressure Ulcer Guidelines* (p. 14). Retrieved from https://s3.amazonaws.com/aawc-new/memberclicks/AAWCPressureUlcerGuidelineofGuidelinesAug11.pdf

Bansal, C., Scott, R., Stewart, D., & Cockerell, C. J. (2005). Decubitus ulcers: A review of the literature: Decubitus ulcers. *International Journal of Dermatology*, *44*(10), 805–810. https://doi.org/10.1111/j.1365-4632.2005.02636.x

Bharucha, J. B., Seaman, L., Powers, M., Kelly, E., Seaman, R., Forcier, L., … Wang, L. (2018). A Prospective Randomized Clinical Trial of a Novel, Noninvasive Perfusion Enhancement System for the Prevention of Hospital-Acquired Sacral

Pressure Injuries. . . *Journal of Wound, Ostomy and Continence Nursing*, *45*(4), 310–318. https://doi.org/10.1097/WON.0000000000000450

Braden, B., & Bergstrom, N. (1988). *Braden Scale*. Retrieved from https://www.in.gov/isdh/files/Braden_Scale.pdf

Branom, R., & Rappl, L. M. (2001). "Constant Force Technology" versus Low-Air-Loss Therapy in the Treatment of Pressure Ulcers. *Ostomy/Wound Management*, *47*(9), 38–46.

Brown, S. (2018, October). *Restorative sleep affects both the mind and body*. Presented at the LeadingAge Annual Meeting and EXPO, Philadelphia.

Callahan, P. (2019, February). *A Patient's Perspective*. Presented at the Pressure Ulcer Summit, Atlanta.

Campos, M. (2017, November 22). Heart rate variability: A new way to track well-being [Blog]. Retrieved June 25, 2019, from Harvard Health Publishing website: https://www.health.harvard.edu/blog/heart-rate-variability-new-way-track-well-2017112212789

Chai, C. Y., Sadou, O., Worsley, P. R., & Bader, D. L. (2017). Pressure signatures can influence tissue response for individuals supported on an alternating pressure mattress. *Journal of Tissue Viability*, *26*(3), 180–188. https://doi.org/10.1016/j.jtv.2017.05.001

Cooper, K. L. (2013). Evidence-Based Prevention of Pressure Ulcers in the Intensive Care Unit. *Critical Care Nurse*, *33*(6), 57–66. https://doi.org/10.4037/ccn2013985

Crane, B. (2004). *Development and validation of the wheelchair seating discomfort assessment tool (WcS-DAT)E*. 226.

Crane, B., Holm, M. B., Hobson, D., Cooper, R. A., & Reed, M. P. (2007). A Dynamic Seating Intervention for Wheelchair Seating Discomfort: *American Journal of Physical Medicine & Rehabilitation*, *86*(12), 988–993. https://doi.org/10.1097/PHM.0b013e3181583ed9

Crane, B., Holm, M., Hobson, D., Cooper, R., Reed, M., & Stadelmeier, S. (2005). Test-Retest Reliability, Internal Item Consistency, and Concurrent Validity of the Wheelchair Seating Discomfort Assessment Tool. *Assistive Technology*, *17*(2), 98–107. https://doi.org/10.1080/10400435.2005.10132100

Creehan, S. (2019, February). *Science, Clinical Evidence, and Health Economics in PU Prevention*. Presented at the Pressure Ulcer Summit, Atlanta.

Davis, K. G., & Kotowski, S. E. (2015). Role of Bed Design and Head-of-Bed Articulation on Patient Migration: *Journal of Nursing Care Quality*, *30*(3), E1–E9. https://doi.org/10.1097/NCQ.0000000000000115

Defloor, T. (2000). The effect of position and mattress on interface pressure. *Applied Nursing Research*, *13*(1), 2–11. https://doi.org/10.1016/S0897-1897(00)80013-0

Defloor, T., De Bacquer, D., & Grypdonck, M. (2005). The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. *International Journal of Nursing Studies*, *42*(1), 10. Retrieved from Health Reference Center Academic.

Demarré, L., Beeckman, D., Vanderwee, K., Defloor, T., Grypdonck, M., & Verhaeghe, S. (2012). Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: A randomised-controlled clinical trial. *International Journal of Nursing Studies*, *49*(4), 416–426. https://doi.org/10.1016/j.ijnurstu.2011.10.007

Demarré, L., Verhaeghe, S., Van Hecke, A., Grypdonck, M., Clays, E., Vanderwee, K., & Beeckman, D. (2013). The effectiveness of three types of alternating pressure air mattresses in the prevention of pressure ulcers in Belgian hospitals: PREVENTION OF PRESSURE ULCERS. *Research in Nursing & Health*, n/a-n/a. https://doi.org/10.1002/nur.21557

European Pressure Ulcer Advisory Panel, National Pressure Ulcer Advisory Panel, & Pan Pacific Pressure Injury Alliance. (2014). *Prevention and treatment of pressure ulcers: Quick reference guide*. Retrieved from http://www.epuap.org/wp-content/uploads/2016/10/quick-reference-guide-digital-npuap-epuap-pppia-jan2016.pdf

Find & compare doctors, hospitals & other providers - Medicare. (n.d.). Retrieved April 12, 2018, from Medicare.gov website: https://www.medicare.gov/forms-help-resources/find-compare-doctors-hospitals-other-providers

Fletcher, J., Gefen, A., Jones, L., Sanada, H., & Irvine, M. (2015). *Hybrid Support Surfaces Made Easy*. Retrieved from Wounds International website: https://www.woundsinternational.com/download/resource/6074

Futamura, M., Sugama, J., Okuwa, M., Sanada, H., & Tabata, K. (2008). Evaluation of Comfort in Bedridden Older Adults Using an Air-Cell Mattress with an Automated Turning Function. *Journal of Gerontological Nursing*, *34*(12), 20–26. https://doi.org/10.3928/00989134-20081201-09

Gefen, A. (2009). Reswick and Rogers pressure-time curve for pressure ulcer risk.Part 1. *Nursing Standard*, *23*(45), 64–74.

Gray, D., Cooper, P., Bertam, M., Duguid, K., & Pirie, G. (2008). A clinical audit of the Softform Premier Active™ mattress in two acute care of the elderly wards. *Wounds UK*, *4*(4), 4.

Gray, D. G., & Smith, M. (2000). Comparison of a new foam mattress with the standard hospital mattress. *Journal of Wound Care*, *9*(1), 29–31. https://doi.org/10.12968/jowc.2000.9.1.25944

Grindley, A., & Acres, J. (1996). Alternating pressure mattresses: Comfort and quality of sleep. *British Journal of Nursing*, *5*(21), 1303–1310. https://doi.org/10.12968/bjon.1996.5.21.1303

Hines, V. (2018, September). *Challenges of Home Care*. Presented at the Kendal at Ithaca, Ithaca.

Kim, H. G., Cheon, E. J., Bai, D. S., Lee, Y. H., & Koo, B. H. (2018). Stress and Heart Rate Variability: A Meta-Analysis and Review of the Literature. *Psychiatry Investigation*, *15*(3), 235–245. https://doi.org/10.30773/pi.2017.08.17

Lachenbruch, C., Ribble, D., Emmons, K., & VanGilder, C. (2016). Pressure Ulcer Risk in the Incontinent Patient: Analysis of Incontinence and Hospital-

Acquired Pressure Ulcers From the International Pressure Ulcer Prevalence™ Survey. *Journal of Wound, Ostomy and Continence Nursing*, *43*(3), 235–241. https://doi.org/10.1097/WON.0000000000000225

Land, L., Evans, D., Geary, A., & Taylor, C. (2000). A clinical evaluation of an alternating-pressure mattress replacement system in hospital and residential care settings. *Journal of Tissue Viability*, *10*(1), 6–11. https://doi.org/10.1016/S0965-206X(00)80014-5

Levine, M. (2018, July 23). [Phone interview].

Lynch, R. M., & Freund, A. (2000). Short-term efficacy of back injury intervention project for patient care providers at one hospital. *AIHAJ; Fairfax*, *61*(2), 290–294.

MacGregor, L. (2010). *International Review: Pressure Ulcer Prevention - pressure, shear, friction, and microclimate context* [A consensus document]. London: Wounds International.

Malbrain, M., Hendriks, B., Wijnands, P., Denie, D., Jans, A., Vanpellicom, J., & De Keulenaer, B. (2010). A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients. *Journal of Tissue Viability*, *19*(1), 7–15. https://doi.org/10.1016/j.jtv.2009.12.001

McNichol, L., Watts, C., Mackey, D., Beitz, J. M., & Gray, M. (2015). Identifying the Right Surface for the Right Patient at the Right Time: Generation and Content Validation of an Algorithm for Support Surface Selection. *Journal of Wound,*

Ostomy and Continence Nursing, *42*(1), 19–37. https://doi.org/10.1097/WON.0000000000000103

Moore, J. (2016, June 24). Heart Rate Variability vs. Heart Rate. Retrieved June 25, 2019, from Heart Rate Variability Educational Courses website: https://hrvcourse.com/heart-rate-variability-vs-heart-rate/

Moore, Z., Cowman, S., & Conroy, R. M. (2011). A randomised controlled clinical trial of repositioning, using the 30° tilt, for the prevention of pressure ulcers. *Journal of Clinical Nursing*, *20*(17–18), 2633–2644. https://doi.org/10.1111/j.1365-2702.2011.03736.x

Moore, Z., Cowman, S., & Posnett, J. (2013). An economic analysis of repositioning for the prevention of pressure ulcers. *Journal of Clinical Nursing*, *22*(15–16), 2354–2360. https://doi.org/10.1111/j.1365-2702.2012.04310.x

Nixon, J., Cranny, G., Iglesias, C., Nelson, E. A., Hawkins, K., Phillips, A., … Cullum, N. (2006). Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial. *BMJ: British Medical Journal*, *332*(7555), 1413–1415.

Occupational Safety and Health Administration. (2010). Retrieved March 27, 2018, from Healthcare - Safe Patient Handling website: https://www.osha.gov/SLTC/healthcarefacilities/safepatienthandling.html

Park, K. H., & Park, J. (2017). The Efficacy of a Viscoelastic Foam Overlay on Prevention of Pressure Injury in Acutely Ill Patients. *Journal of Wound*,

Ostomy and Continence Nursing, *44*(5), 440–444. https://doi.org/10.1097/WON.0000000000000359

Paschall, F. (2018, November 7). [Phone interview].

Pearson, E. (2009). Comfort and its measurement – A literature review. *Disability and Rehabilitation: Assistive Technology*, *4*(5), 301–310. https://doi.org/10.1080/17483100902980950

Phillips, L. (2007). Interface pressure measurement: Appropriate interpretation of this simple laboratory technique used in the design and assessment of pressure ulcer management devices. *Primary Intention*, *15*(3).

Rosenthal, M. J., Felton, R. M., Nastasi, A. E., Naliboff, B. D., Harker, J., & Navach, J. H. (2003). Healing of advanced pressure ulcers by a generic total contact seat: 2 randomized comparisons with low air loss bed treatments11No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit upon the author(s) or upon any organization with which the author(s) is/are associated. *Archives of Physical Medicine and Rehabilitation*, *84*(12), 1733–1742. https://doi.org/10.1016/S0003-9993(03)00435-0

Russell, T. (2003). Pressure ulcers and lateral rotation beds: A case study. *Journal of WOCN*, *30*(3), 143–145. https://doi.org/10.1067/mjw.2003.124

Shmerling, H. H. (2017). How's your heart rate and why it matters? Retrieved June 25, 2019, from Harvard Health Publishing website: https://www.health.harvard.edu/heart-health/hows-your-heart-rate-and-why-it-matters

Stotts, N. A., Rodeheaver, G. T., Thomas, D. R., Frantz, R. A., Bartolucci, A. A., Sussman, C., … Maklebust, J. (2001). *An Instrument to Measure Healing in Pressure Ulcers: Development and Validation of the Pressure Ulcer Scale for Healing (PUSH). 56A*(12).

The National Pressure Ulcer Advisory Panel. (1998). *PUSH Tool 3.0*. Retrieved from http://www.npuap.org/resources/educational-and-clinical-resources/push-tool/

The National Pressure Ulcer Advisory Panel. (2007). *Support Surface Standards Initiative*. Retrieved from http://www.npuap.org/resources/educational-and-clinical-resources/support-surface-standards-initiative-s3i/

Theaker, C., Kuper, M., & Soni, N. (2005). Pressure ulcer prevention in intensive care – a randomised control trial of two pressure-relieving devices. *Anaesthesia*, *60*(4), 395–399. https://doi.org/10.1111/j.1365-2044.2004.04085.x

Thomas, D. R. (2006). Prevention and Treatment of Pressure Ulcers. *Journal of the American Medical Directors Association*, *7*(1), 46–59. https://doi.org/10.1016/j.jamda.2005.10.004

Tilley, A. R. (2002). *The measure of man and woman: human factors and design* (Rev. ed.). New York: Wiley.

Van Leen, M., Hovius, S., Neyens, J., Halfens, R., & Schols, J. (2011). Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical trial in a Dutch nursing home. *Journal of Tissue Viability*, *20*(1), 30–34. https://doi.org/10.1016/j.jtv.2010.04.001

Van Leen, M., Hovius, S., Neyens, J., & Schols, J. (2013). *Pressure Relief With Visco-Elastic Foam or With Combined Static Air Overlay? A Prospective, Crossover Randomized Clinical Trial in a Dutch Nursing Home*. *25*(10), 7.

Vanderwee, K., Grypdonck, M. H. F., De Bacquer, D., & Defloor, T. (2007). Effectiveness of turning with unequal time intervals on the incidence of pressure ulcer lesions. *Journal of Advanced Nursing*, *57*(1), 59–68. https://doi.org/10.1111/j.1365-2648.2006.04060.x

Vanderwee, K., Grypdonck, M. H. F., & Defloor, T. (2005). Effectiveness of an alternating pressure air mattress for the prevention of pressure ulcers. *Age and Ageing*, *34*(3), 261–267. https://doi.org/10.1093/ageing/afi057

VanGilder, C., MacFarlane, G. D., Harrison, P., Lachenbruch, C., & Meyer, S. (2010). *The Demographics of Suspected Deep Tissue Injury in the United States: An Analysis of the International Pressure Ulcer Prevalence Survey 2006–2009*. *23*(6), 8.

Vasihadou, A., Karvountzis, G. G., Soumilas, A., Roumehotis, D., & Theodosopoulou, E. (1995). Occupational low-back pain in nursing staff in a Greek hospital. *Journal of Advanced Nursing*, *21*(1), 125–130. https://doi.org/10.1046/j.1365-2648.1995.21010125.x

Vitale-Aussem, J. (2018, September 10). [Phone interview].

Winnipeg Regional Health Authority. (2012, November). *Pressure ulcer prevention and treatment: Clinical Practice Guideline*. Retrieved from http://www.wrha.mb.ca/extranet/eipt/files/EIPT-013-004.pdf

Woelfel, S. (2019, February). *Offloading and Repositioning/Safe Patient Handling*. Presented at the Pressure Ulcer Summit, Atlanta.

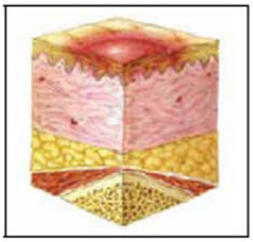
APPENDIX A

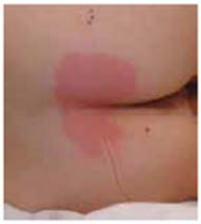
International NPUAP/EPUAP Pressure Ulcer Classification System

Category/Stage I: Nonblanchable Erythema

Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category/Stage I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" individuals (a heralding sign of risk).



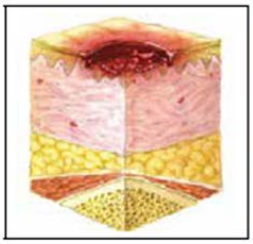


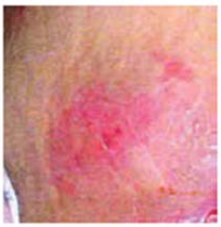
Category/Stage II: Partial Thickness Skin Loss

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

Presents as a shiny or dry shallow ulcer without slough or bruising.* This Category/Stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation.

**Bruising indicates suspected deep tissue injury.*

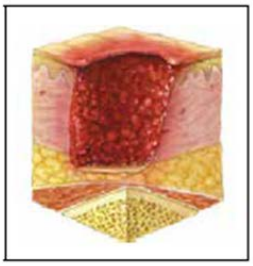


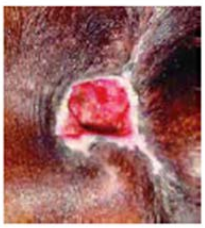


Category/Stage III: Full Thickness Skin Loss

Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

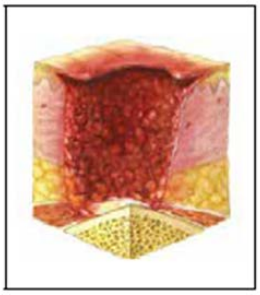




Category/Stage IV: Full Thickness Tissue Loss

Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.

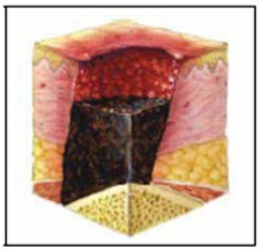
The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.

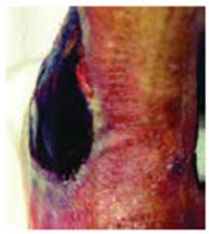


Unstageable: Depth Unknown

Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore Category/Stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as 'the body's natural (biological) cover' and should not be removed.

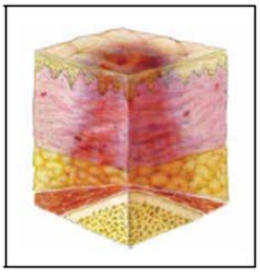




Suspected Deep Tissue Injury: Depth Unknown

Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.



APPENDIX B

General Discomfort Assessment (GDA)

Participant: ____

Phase I: Pilot Study 1 - Cornell University

General Comfort/Discomfort Assessment*

Please rate your answer on the following scale (place a mark in the appropriate box)	**Strongly disagree**	**Disagree**	**Partly disagree**	**Neither agree nor disagree**	**Partly agree**	**Agree**	**Strongly agree**
While lying down on the bed overlay device…							
…I feel poorly positioned							
…I feel like I have been in one position for too long							
…I feel like I need to move or shift my position							
…I feel aches, stiffness, or soreness							
…I feel pressure in some part or parts of my body							
…I feel uncomfortable							
…I feel no pain							
…I feel safe							
…I feel relaxed							
…I feel stable (not sliding or falling)							
…I feel comfortable							
…I feel good							

Discomfort Intensity Score (DIS)

Participant: _____

Discomfort Intensity Score*

On a scale from 0 to 3 (0 = no discomfort and 3 = severe discomfort) please rate the amount of comfort/discomfort you felt in the different body areas caused by lying on the bed overlay device.

Body areas	Rating	Please describe your discomfort (for example: aching, burning, pressure, or others). If no discomfort is experienced, leave blank.
Neck		
Upper back		
Lower back		
Buttocks		
Shoulders		
Arms		
Hands		
Legs		
Feet		
Heels		
Overall Discomfort Level (General discomfort level)		

APPENDIX C

Consent Form

A study to evaluate the perceived level of comfort of a bed overlay device known

We are asking you to participate in a research study. This form is intended to give you information about the study and answer any of your questions.

Project Title: Development and evaluation of a hybrid support surface for the prevention and care of pressure ulcers among older adults

Principal Investigator: Paulina Villacreces
Design and Environmental Analysis
pmv52@cornell.edu

Faculty Advisor: Keith Evan Green
Design and Environmental Analysis
keg95@cornell.edu

What the study is about

The purpose of this pilot study is to evaluate your perceived level of comfort when using SmartRest. SmartRest is a bed overlay device, similar to an alternating pressure pad, used for the prevention and care of pressure ulcers.

What we will ask you to do

For this study, you will be asked to wear a wristband watch that will measure your heart rate and stress levels while lying down on SmartRest, a bed overlay device, for 15-minutes. While lying down, you will experience slight position changes and you will be asked to answer a few questions on your perceived comfort. After this, you will be asked to rate your level of comfort by filling out two paper surveys, which will take no more than 5-minutes. The study will take a total of 20-minutes.

Risks and discomforts

We do not anticipate any risks from participating in this research.

Benefits

You will receive no direct benefit from this study. However, findings from this study may help to improve the design and functionality of devices for pressure ulcers.

Compensation for participation

You will receive a $5 gift card from Ithaca Bakery at the end of the study.

Audio/Video Recording/Photographs

You will be video/voice recorded during the first 15-minutes of the study when you are lying down on the bed overlay device.

Photographs may be taken to document the research process. We ask you to grant us the right to make use of and publish these photos in academic conference presentations, thesis research, or journal papers for academic purposes only. Your identity will be kept confidential.

Please check a box and sign below if you are willing to be video/voice recorded and have your photograph taken. You may still participate in this study if you are not willing to be video/voice recorded or have your photo taken.

- ☐ I am willing to be video/voice recorded
- ☐ I am willing to have my photograph taken.
- ☐ I do not want to be video/voice recorded
- ☐ I do not want to have my photograph taken.

Signed: _____

Date: _____

Privacy/Confidentiality/Data Security

You will not be asked to provide any personal information. The photographs taken during this study will not contain identifying information about the participants. The researchers will keep identifying information, if any, separate from the study.

Taking part is voluntary

Your involvement is voluntary, and you may refuse to participate before the study begins, discontinue at any time during the study, or skip any procedures that may make you feel uncomfortable with no penalty to you, and no effect on your relationship with the university or other organization or service that may be involved with the research.

If you have questions

The main researcher conducting this study is *Paulina Villacreces, a graduate student at Cornell University.* Please ask any questions you have now. If you have questions later, you may contact *Paulina Villacreces* at *pmv52@cornell.edu* or at +1 (607) 280-1054. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Institutional Review Board (IRB) for Human Participants at 607-255-5138 or access their website at http://www.irb.cornell.edu. You may also report your concerns or complaints anonymously through Ethicspoint online at www.hotline.cornell.edu or by calling toll free at 1-866-293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature_____ Date_____

Your Name (printed)_____

Signature of person obtaining consent_____ Date_____

Printed name of person obtaining consent_____

This consent form will be kept by the researcher for five years beyond the end of the study.

Participant: _____

Anthropometrics and Demographics

Anthropometrics

Weight: ____
Height: ____

Demographics

1. What is your age? _____

2. Which of the following would you say best describes your gender?
___ Male
___ Female
___ Transgender
___ I prefer not to say

3. Which of the following would you say best describes your race or ethnicity? Check all that apply.
___ White or Caucasian
___ Black or African American
___ Hispanic or Latino
___ Asian or Asian American
___ American Indian or Alaska Native
___ Native Hawaiian or Other Pacific Islander
___ Multiple Races/Ethnicities
___ Other
___ I prefer not to say

APPENDIX D

Future Research Study

The approved research methodology for Phase III is included in this study for future reference. In the future, with the proper funding and resources, the prototype will be modified to fit the noise level standards and proceed with the full research study as planned and approved by the IRB.

The purpose of this experimental study is to evaluate the effectiveness of a SBOD for the prevention and healing of pressure ulcers, among older adults living at a skilled nursing facility.

Research Questions

1. Among older adults living at a skilled nursing facility, does a smart SBOD affect:
    a) the prevention and healing of pressure ulcers?
    b) the level of stress?
    c) the quality of sleep?
    d) the level of comfort?
2. How does the smart SBOD improve on existing alternatives?

Hypotheses

1. The smart SBOD is more effective than the Vive alternating pressure pad at improving wound healing times for pressure ulcers.
2. The smart SBOD is more effective than the Vive alternating pressure pad at providing: a) lower stress levels, b) better quality of sleep, and c) more comfort.

3. The smart SBOD is easier to use and preferred over the Vive alternating pressure pad.

This research study will use an experimental research design. The previous research conducted in this study, along with this experimental study, comprise the basis of a series of preliminary studies conducted specifically for the purposes of establishing if a full trial will be feasible in the future. The future goal will be to conduct a randomized control trial (RCT).

The primary outcome of this experimental research study will be to evaluate the effectiveness of a smart SBOD concerning pressure ulcer incidence, specifically wound healing times. The secondary outcome will be to evaluate the effectiveness of a smart SBOD in terms of participants' level of stress, sleep quality and comfort.

Participants

For this research study, 5-10 participants will be recruited by the Director of Marketing and Admissions and the nursing staff from Kendal at Ithaca, who will be directly communicating with the residents about the study, conducting the necessary assessments prior to participation, and providing the consent form.

All participants must meet the inclusion criteria in order to participate in the study. All participants will undergo pressure ulcer assessment, using the Braden Scale (Braden & Bergstrom, 1988) to predict pressure ulcer risk and condition (Appendix E).

Inclusion criteria:

1. Older adults aged 50 years or older

2. Residing in the skilled nursing facility of a continuing care retirement community
3. Who:
    a. have an existing stage 2 pressure ulcer, or
    b. are bedridden, or
    c. are unable to reposition on their own
4. Have a bed that allows the placement and testing of the support surface

Exclusion Criteria:

1. Older adults who:
    a. have existing stage 3 & 4 pressure ulcers and deep tissue injuries
    b. have positioning restrictions
    c. are cognitively impaired
    d. have certain conditions that are highly associated with pressure ulcer risk (diabetes, vascular disease, and others).

Participants who meet the inclusion criteria will be invited to participate in the study and will be provided a consent form. If participants agree to participate and sign the consent forms, they will be able to participate in the study.

Research Design

This study will compare a hybrid and an active support surface. The support surfaces used for this study will be the smart SBOD and the Vive alternating pressure pad. Both support surfaces are bed overlays that go on top of a bed mattress.

The smart SBOD has three main functions. The first function is to provide localized pressure sensing technology to detect and reduce areas in the body that have high pressure. The second function is to provide automated turning and repositioning. The third function is to provide incontinence alerts. The support surface will provide automated turning and repositioning every 2-hours. This support surface will be the intervention variable for this study.

The Vive alternating pressure pad provides uniform alternating pressure. With this support surface nursing staff at Kendal will have to turn and reposition participants every 2-hours. This support surface will be the control variable for this study.

To ensure that the changes in pressure ulcer condition are not impacted by the time participants spend sitting, all participants will be provided with a ROHO Mosaic cushion. These types of cushions are usually used for people who have a high risk of pressure ulcer development.

Qualitative and quantitative methods were combined for a mixed-methods approach to evaluating the support surfaces. Pressure ulcer incidence (wound healing times) will be assessed using the PUSH Tool. To assess the influence of the support surfaces on stress and quality of sleep, heart rate variability (HRV) and sleep will be monitored during nighttime. To assess the influence of the support surfaces on comfort, quality of sleep, and support surfaces preference, a validated scale (TWAC), a quality of sleep and a support surface assessments will be used.

Pressure Ulcer Incidence. Pressure ulcer incidence or wound healing times will be assessed using the Pressure Ulcer Scale for Healing - PUSH Tool 3.0 (The National

Pressure Ulcer Advisory Panel, 1998) (Appendix E). The PUSH Tool has been previously validated (Stotts et al., 2001), and the study concluded that it was a practical tool that provided clinically valid data in terms of pressure ulcer healing. The PUSH will be used because it allows to monitor pressure ulcer healing over time and can differentiate a healing wound from a non-healing wound.

Stress. HRV will be used to operationalize stress. To measure HRV, participants will wear a Garmin Vívosmart 4. The Garmin Vívosmart 4 is a wrist device that measures HRV and categorizes those measure into stress levels.

Quality of Sleep. The Garmin Vívosmart 4 will also monitor quality of sleep. The Garmin Vívosmart 4 has a feature for advanced sleep monitoring, that tracks light, deep and REM stages of sleep, as well as movement throughout the night. Tracking the quality of sleep among participants will be important in this study, to evaluate and compare automated versus manual turning and positioning.

Quality of Sleep will also be assessed using a Quality of Sleep Assessment, previously used in an RCT that focused on the development of a methodology to assess patient comfort and quality of sleep to compare two alternating air pressure mattresses (Grindley & Acres, 1996), and were adapted to be used in the current study (Appendix F).

Comfort. The TAWC will be used to evaluate support surface comfort/discomfort. The TAWC is composed by the General Discomfort Assessment (GDA) and the Discomfort Intensity Score (DIS) as previously described in the pilot studies.

Support Surface. Support surface preference will be assessed using a Quality of Sleep Assessment, previously used in an RCT that focused on the development of a methodology to assess patient comfort and quality of sleep to compare two alternating air pressure mattresses (Grindley & Acres, 1996), and were adapted to be used in the current study (Appendix F).

Procedure

Phase III will consist of an experimental research design that will be carried out at the skilled nursing facility, at Kendal at Ithaca, a continuing care retirement community. All participants will be given a consent form prior to participating in the study (Appendix E). Once the consent forms are received the study will begin. Participants who give voluntary consent will be asked to complete an anthropometrics and demographics form with general information such as height, weight, age, gender and ethnicity (Appendix E). Nursing staff will be responsible for documenting participants' relevant diagnoses, and pressure ulcer stage (Appendix E)

Participants will be randomly assigned with either of two support surfaces that will be used for this study for a period of one week (7-days). Participants will use both the Vive alternating pressure pad and the smart SBOD for one week, and they will be randomly assigned to the order they use the support surfaces (alternating pressure pad first then the smart SBOD or vice versa). The total time for the research study per participant will be two weeks (14-days).

Pressure ulcer care will be provided by the nursing staff at Kendal at Ithaca following their standard protocols, which will depend on the pressure ulcer stage and condition of each participant. Additionally, incontinence checks will be provided on a

regular basis for the Vive alternating pressure pad. The smart SBOD will provide incontinence alerts to nursing staff, who will assist participants upon receiving the alerts.

Nursing staff at Kendal will be responsible for providing three pressure ulcer assessments using the PUSH Tool to assess pressure ulcer healing and healing times. The first assessment will be done at the beginning of the study to record the pressure ulcer condition, the second will be done at the end of the first seven days of the study, and the third one will be done at the end of the study, on the 14^{th} day. Nursing staff will be responsible of keeping record of the pressure ulcer condition and healing times using the PUSH Tool. Nursing staff will only report information concerning wound healing and healing times. This information will be used to determine the effectiveness between the support surfaces.

The heart rate variability (stress level) and sleep quality will be monitored and collected all throughout the study, during nighttime when participants will be lying on the different support surfaces. The Garmin Vívosmart 4, a wrist device, will be used to collect these measures as previously described in this study.

The GDA, DIS and sleep quality assessments will be completed on a daily basis. The support surface preference assessment will be completed two times during the study; at the end of the 7^{th} and 14^{th} days.

Additionally, another support surface preference assessment was adapted (Grindley & Acres, 1996) to evaluate nursing staff preference and ease of use of the different support surfaces (Appendix F). This assessment will be completed once at the end of the study by the nursing staff at Kendal.

APPENDIX E

Braden Scale

BRADEN SCALE – For Predicting Pressure Sore Risk

SEVERE RISK: Total score ≤ 9 **HIGH RISK**: Total score 10-12 **MODERATE RISK**: Total score 13-14 **MILD RISK**: Total score 15-18				DATE OF ASSESS ➡				
RISK FACTOR	**SCORE/DESCRIPTION**				1	2	3	4
SENSORY PERCEPTION Ability to respond meaningfully to pressure-related discomfort	**1. COMPLETELY LIMITED** – Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation, **OR** limited ability to feel pain over most of body surface.	**2. VERY LIMITED** – Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness, **OR** has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	**3. SLIGHTLY LIMITED** – Responds to verbal commands but cannot always communicate discomfort or need to be turned, **OR** has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	**4. NO IMPAIRMENT** – Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.				
MOISTURE Degree to which skin is exposed to moisture	**1. CONSTANTLY MOIST**– Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	**2. OFTEN MOIST** – Skin is often but not always moist. Linen must be changed at least once a shift.	**3. OCCASIONALLY MOIST** – Skin is occasionally moist, requiring an extra linen change approximately once a day.	**4. RARELY MOIST** – Skin is usually dry; linen only requires changing at routine intervals.				
ACTIVITY Degree of physical activity	**1. BEDFAST** – Confined to bed.	**2. CHAIRFAST** – Ability to walk severely limited or nonexistent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	**3. WALKS OCCASIONALLY** – Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.	**4. WALKS FREQUENTLY**– Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours.				
MOBILITY Ability to change and control body position	**1. COMPLETELY IMMOBILE** – Does not make even slight changes in body or extremity position without assistance.	**2. VERY LIMITED** – Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	**3. SLIGHTLY LIMITED** – Makes frequent though slight changes in body or extremity position independently.	**4. NO LIMITATIONS** – Makes major and frequent changes in position without assistance.				
NUTRITION Usual food intake pattern [1]NPO: Nothing by mouth. [2]IV: Intravenously. [3]TPN: Total parenteral nutrition.	**1. VERY POOR** – Never eats a complete meal. Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement, **OR** is NPO[1] and/or maintained on clear liquids or IV[2] for more than 5 days.	**2. PROBABLY INADEQUATE** – Rarely eats a complete meal and generally eats only about ⅓ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement **OR** receives less than optimum amount of liquid diet or tube feeding.	**3. ADEQUATE** – Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) each day. Occasionally refuses a meal, but will usually take a supplement if offered, **OR** is on a tube feeding or TPN[3] regimen, which probably meets most of nutritional needs.	**4. EXCELLENT** – Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.				
FRICTION AND SHEAR	**1. PROBLEM**- Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures, or agitation leads to almost constant friction.	**2. POTENTIAL PROBLEM**– Moves feebly or requires minimum assistance. During a move, skin probably slides to some extent against sheets, chair, restraints, or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	**3. NO APPARENT PROBLEM** – Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair at all times.					
TOTAL SCORE	**Total score of 12 or less represents HIGH RISK**							

ASSESS	DATE	EVALUATOR SIGNATURE/TITLE	ASSESS.	DATE	EVALUATOR SIGNATURE/TITLE
1	/ /		3	/ /	
2	/ /		4	/ /	

NAME-Last First Middle	Attending Physician	Record No.	Room/Bed

Form 3166P BRIGGS, Des Moines, IA 50306 (800) 247-2343 www.BriggsCorp.com
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BRADEN SCALE

NATIONAL PRESSURE ULCER ADVISORY PANEL

Pressure Ulcer Scale for Healing (PUSH)

PUSH Tool 3.0

Patient Name _____ Patient ID# _____

Ulcer Location _____ Date _____

Directions:

Observe and measure the pressure ulcer. Categorize the ulcer with respect to surface area, exudate, and type of wound tissue. Record a sub-score for each of these ulcer characteristics. Add the sub-scores to obtain the total score. A comparison of total scores measured over time provides an indication of the improvement or deterioration in pressure ulcer healing.

LENGTH X WIDTH (in cm^2)	0 0	1 < 0.3	2 0.3 – 0.6	3 0.7 – 1.0	4 1.1 – 2.0	5 2.1 – 3.0	Sub-score
		6 3.1 – 4.0	7 4.1 – 8.0	8 8.1 – 12.0	9 12.1 – 24.0	10 > 24.0	
EXUDATE AMOUNT	0 None	1 Light	2 Moderate	3 Heavy			Sub-score
TISSUE TYPE	0 Closed	1 Epithelial Tissue	2 Granulation Tissue	3 Slough	4 Necrotic Tissue		Sub-score
							TOTAL SCORE

Length x Width: Measure the greatest length (head to toe) and the greatest width (side to side) using a centimeter ruler. Multiply these two measurements (length x width) to obtain an estimate of surface area in square centimeters (cm^2). Caveat: Do not guess! Always use a centimeter ruler and always use the same method each time the ulcer is measured.

Exudate Amount: Estimate the amount of exudate (drainage) present after removal of the dressing and before applying any topical agent to the ulcer. Estimate the exudate (drainage) as none, light, moderate, or heavy.

Tissue Type: This refers to the types of tissue that are present in the wound (ulcer) bed. Score as a "4" if there is any necrotic tissue present. Score as a "3" if there is any amount of slough present and necrotic tissue is absent. Score as a "2" if the wound is clean and contains granulation tissue. A superficial wound that is reepithelializing is scored as a "1". When the wound is closed, score as a "0".

- **4 – Necrotic Tissue (Eschar):** black, brown, or tan tissue that adheres firmly to the wound bed or ulcer edges and may be either firmer or softer than surrounding skin.
- **3 – Slough:** yellow or white tissue that adheres to the ulcer bed in strings or thick clumps, or is mucinous.
- **2 – Granulation Tissue:** pink or beefy red tissue with a shiny, moist, granular appearance.
- **1 – Epithelial Tissue:** for superficial ulcers, new pink or shiny tissue (skin) that grows in from the edges or as islands on the ulcer surface.
- **0 – Closed/Resurfaced:** the wound is completely covered with epithelium (new skin).

NATIONAL PRESSURE ULCER ADVISORY PANEL

Pressure Ulcer Healing Chart

To monitor trends in PUSH Scores over time

(Use a separate page for each pressure ulcer)

Patient Name_____ Patient ID# _____

Ulcer Location _____ Date _____

Directions:

Observe and measure pressure ulcers at regular intervals using the PUSH Tool.
Date and record PUSH Sub-scores and Total Scores on the Pressure Ulcer Healing Record below.

Pressure Ulcer Healing Record														
Date														
Length x Width														
Exudate Amount														
Tissue Type														
PUSH Total Score														

Graph the PUSH Total Scores on the Pressure Ulcer Healing Graph below.

PUSH Total Score	Pressure Ulcer Healing Graph													
17														
16														
15														
14														
13														
12														
11														
10														
9														
8														
7														
6														
5														
4														
3														
2														
1														
Healed = 0														
Date														

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PUSH Tool Version 3.0: 9/15/98

APPENDIX F

Quality of Sleep Assessment

Quality of Sleep Assessment*

For this set of questions, you will be asked to report your perceived quality of sleep (please check one box only).

1. How long (in total) did you sleep for last night?

   7 hours or more ☐
   5-6 hours ☐
   4 hours or less ☐

2. How many times did you wake up last night?

   Did not wake ☐
   Once ☐
   Twice ☐
   3 times or more ☐

3. How well did you sleep last night?

   Well ☐
   Average ☐
   Badly ☐

4. How would you describe the mattress with respect to comfort?

   Comfortable ☐
   Uncomfortable ☐
   Neither ☐

*Adapted from: Grindley, A (1996). Alternating pressure mattresses: comfort and quality of sleep. *British journal of nursing*, 5 (21), 1303.

Support Surface Preference Assessment (Participants)*

For this set of questions, you will be asked to report your support surface preference (please check one box only).

1. Which support surface was more comfortable?

First support surface	☐
Second support surface	☐
No preference	☐

2. Which support surface did you sleep better on?

First support surface	☐
Second support surface	☐
No preference	☐

3. Overall, which of the two support surfaces do you prefer?

First support surface	☐
Second support surface	☐
No preference	☐

*Adapted from: Grindley, A (1996). Alternating pressure mattresses: comfort and quality of sleep. *British journal of nursing*, 5 (21), 1303.

Support Surface Preference Assessment (Nursing Staff)*

For this set of questions, you will be asked to report your support surface preference (please check one box only).

1. Which support surface was easier to use?

   Alternating pressure pad ☐
   SmartRest ☐
   No preference ☐

Why? _____

2. In your opinion, which of the two support surfaces provides better care for patients with pressure ulcers?

   Alternating pressure pad ☐
   SmartRest ☐
   No preference ☐

Why? _____

3. Which support surface would you recommend to patients with pressure ulcers?

   Alternating pressure pad ☐
   SmartRest ☐
   Other _____ ☐
   None ☐

Why? _____

4. Overall, which of the two support surfaces do you prefer?

   Alternating pressure pad ☐
   SmartRest ☐
   No preference ☐

Why? _____

APPENDIX G

Consent Form

A study to evaluate the effectiveness of SmartRest, a support surface that provides prevention and care of pressure ulcers

We are asking you to participate in a research study. This form is intended to give you information about the study and answer any of your questions.

Project Title:	Study to evaluate how a smart support surface affects the prevention and healing of pressure ulcers, the level stress and comfort, and the quality of sleep, among older adults living in skilled nursing facilities
Principal Investigator:	Paulina Villacreces Design and Environmental Analysis pmv52@cornell.edu
Faculty Advisor:	Keith Evan Green Design and Environmental Analysis keg95@cornell.edu

What the study is about

The purpose of this study is to evaluate the effectiveness of a support surface for the prevention and healing of pressure ulcers, as well as to evaluate the level of stress and comfort, and quality of sleep of older adults living at skilled nursing facilities who use these types of support surface. The support surface to be evaluated is "SmartRest".

What we will ask you to do

For this study, you will be asked to evaluate two support surfaces that will be provided to you. This study will take a total of two weeks (14 days).

During the first week (7 days), along with the current pressure ulcer care protocols in place at Kendal at Ithaca, you will be asked to use the alternating pressure pad, on your bed during nighttime, when you go to sleep. We will also ask you to wear a wristband watch that will track your stress levels and quality of sleep during nighttime. During the first week, you will be asked to rate your level of comfort and quality of sleep by filling out a two paper surveys, which will take no more than 5-minutes every day.

During the second week (7 days) we will ask you to use SmartRest, as a support surface on your bed during nighttime, when you go to sleep. wristband watch that will track your stress levels and quality of sleep during nighttime. During the second week, we will ask you to rate your level of comfort and quality of sleep by filling out two paper surveys, which will take no more than 5-minutes every day. At the end of the study you will fill out another assessment regarding support surface preference.

Risks and discomforts

You may experience mild physical discomfort associated with the use of SmartRest, which is why we ask you to rate your level of comfort daily. Moreover, nursing staff at Kendal at Ithaca, will provide three pressure ulcer assessments to ensure there is no risk of pressure ulcer development. If there is any sign of risk of pressure ulcer development with the use of SmartRest, the study will immediately end.

Benefits

You will receive no direct benefit from this study. However, findings from this study may help to improve the design and functionality of support surfaces for pressure ulcers.

Compensation for participation

You will receive a $5 gift card from Ithaca Bakery or cash amount at the end of the study.

Photographs

Photographs may be taken to document the research process. We ask you to grant us the right to make use of and publish these photos in whole or in part in academic conference presentations, academic conference, or journal papers for academic purposes only. The participant does not have the right to inspect or approve the published matter that incorporates the photos.

Please check a box and sign below if you are willing to have your photograph taken. You may still participate in this study if you are not willing to have your photo taken.

☐ I am willing to have my photograph taken.
☐ I do not want to have my photograph taken.

Signed: _____

Date: _____

Privacy/Confidentiality/Data Security

You will not be asked to provide any personal information. The photographs taken during this study will not contain identifying information about the participants. The researchers will keep identifying information, if any, separate from the study.

Taking part is voluntary

Your involvement is voluntary, and you may refuse to participate before the study begins, discontinue at any time during the study, or skip any procedures that may make you feel uncomfortable with no penalty to you, and no effect on your relationship with the university or other organization or service that may be involved with the research.

If you have questions

The main researcher conducting this study is *Paulina Villacreces, a graduate student at Cornell University.* Please ask any questions you have now. If you have questions later, you may contact *Paulina Villacreces* at *pmv52@cornell.edu* or at +1 (607) 280-1054. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Institutional Review Board (IRB) for Human Participants at 607-255-5138 or access their website at http://www.irb.cornell.edu. You may also report your concerns or complaints anonymously through Ethicspoint online at www.hotline.cornell.edu or by calling toll free at 1-866-293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature_____ Date_____

Your Name (printed)_____

Signature of person obtaining consent_____ Date_____

Printed name of person obtaining consent_____

This consent form will be kept by the researcher for five years beyond the end of the study.

Anthropometrics, Demographics, Diagnoses, and Pressure

Ulcer Stage and Condition Form

Anthropometrics, Demographics, Diagnoses, and Pressure Ulcer Stage and Condition

Anthropometrics

Weight: ____
Height: ____

Demographics

1. What is your age? _____

2. Which of the following would you say best describes your gender?
___ Male
___ Female
___ Transgender
___ I prefer not to say

3. Which of the following would you say best describes your race or ethnicity? Check all that apply.
___ White or Caucasian
___ Black or African American
___ Hispanic or Latino
___ Asian or Asian American
___ American Indian or Alaska Native
___ Native Hawaiian or Other Pacific Islander
___ Multiple Races/Ethnicities
___ Other
___ I prefer not to say

Diagnosis

Please list any diagnoses that are relevant to this study.

_____
_____
_____

Pressure Ulcer Stage and Condition

Please write the current stage and condition of the pressure ulcer.

_____
_____
_____