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In vivo Evaluation of an Automated Pressure Sore Reducer

Linda J. Cross

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by

Linda J. Cross

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Dr. Daniel Hayes

Department of Biological and Agricultural Engineering

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Abstract

Pressure sores are soft tissue injuries resulting from prolonged, unrelieved pressure applied to body surfaces, especially on bony prominences. Mobility-impaired individuals are particularly susceptible to these sores, due to possible difficulty adjusting their body position to relieve pressure on areas of concern. Potential locations for sore development that are not adequately addressed with the current technology are on the feet and leg. Thus, a prototype was designed and built to attempt to decrease pressure sore formation over time on these areas by redistributing the contact forces resulting from universal wheelchair foot rests. The use of the automated device to routinely alter a patient's position could compensate for the inability to sense the pressure that leads to the development of sores. The effectiveness of the prototype was evaluated *in vivo* using FlexiForce® pressure sensors and Type T surface thermocouples to detect pressure redistribution and temperature resulting from forces and blood flow on the plantar region. Results from these sensors show that the prototype reduces pressure into the acceptable range and leads to a lower temperature decrease compared to a control foot on a universal footrest, indicating partial pressure relief and possibly increased blood circulation. The prototype was developed by an interdisciplinary – Mechanical and Biological Engineering – senior design team at LSU, with the biological testing aspects and analysis as the focus of this thesis.

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1 Introduction

A. Background

Pressure sores are soft tissue injuries resulting from prolonged, unrelieved pressure applied to body surfaces, especially in the area of bony prominences (Bauer, Mancoll, and Phillips 2007). Sore formation is the precursor to 84% of leg amputation cases, and 9% of sores form on the heel area, making it the greatest area of incidence besides the pelvic region. (Weinzweig 2010). The application of pressure greater than capillary pressure, around 40 mmHg at the arterial end, prevents adequate blood flow microcirculation, lymphatic circulation, and interstitial transport processes (Herrman 1999), causing oxygen and nutrient supply to decrease in the area of applied pressure. This ischemia results in tissue necrosis if held for a prolonged period of time or frequently repeated, thus resulting in a pressure sore.

The National Pressure Ulcer Advisory Panel (2007) has determined four stages of pressure sore formation: I. Non-blanchable erythema, II. Partial thickness, III. Full thickness skin loss, and IV. Full thickness tissue loss (Figure 1). Stage I pressure sores begin to occur deep within the tissue and are indicated by discoloration of the epidermis resulting from changes in tissue consistency, temperature, or sensation. In Stage II, the sore becomes superficial in the form of an abrasion, blister, or shallow crater. A Stage III pressure sore involves subcutaneous tissue necrosis resulting in full-thickness skin loss. These effects result in a deep crater that extend through the dermis and may reach the underlying fascia. In Stage IV, the pressure sore causes greater tissue necrosis and damage to the muscle, bone, or supporting structures.

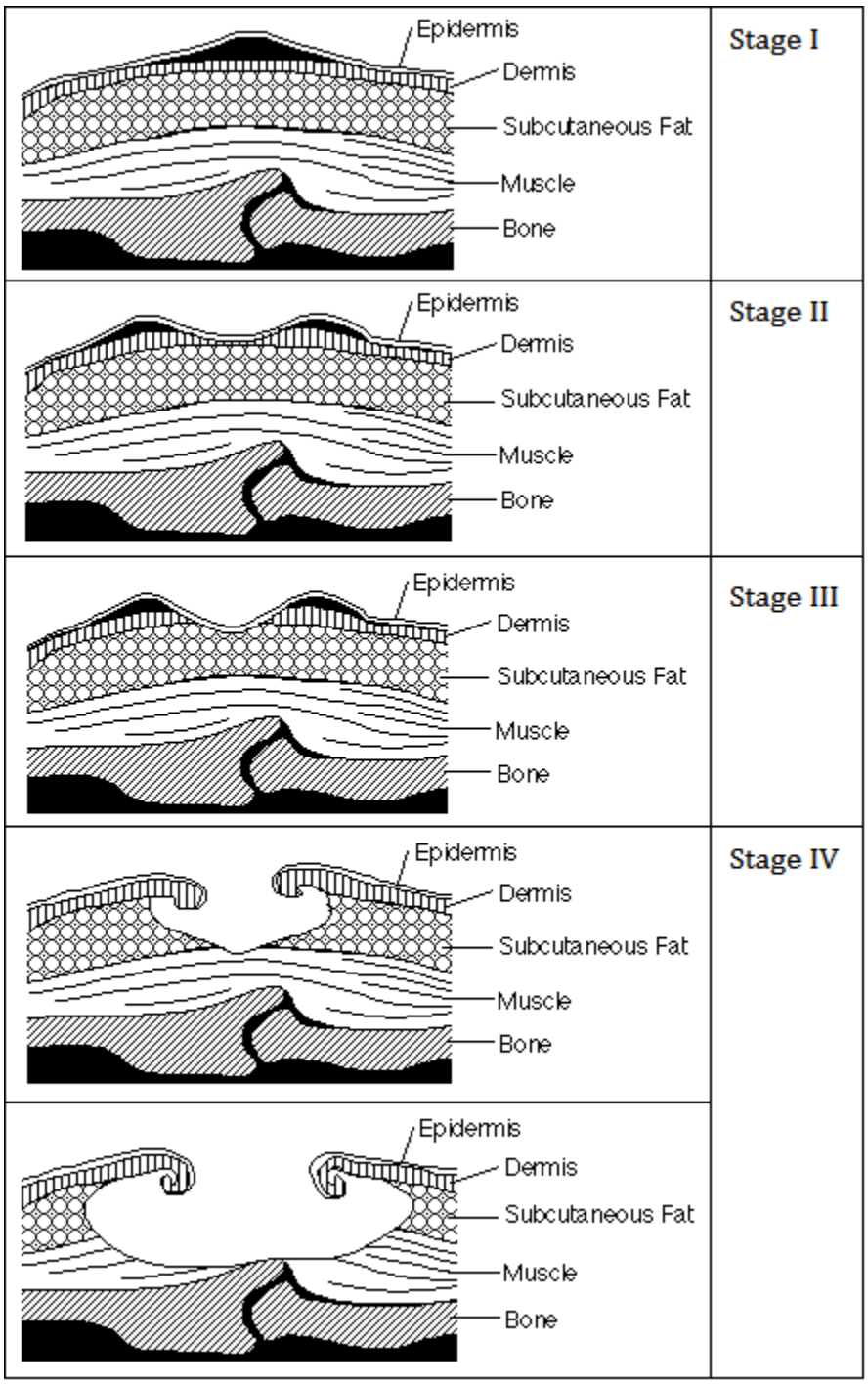

Figure 1. Stages of pressure sore formation (Statewide Spinal Cord Injury Service 2005).

Most pressure sores form over bony prominences (Bauer, Mancoll, and Phillips 2007). Locations on the foot where greatest pressures are located are the calcaneus, medial metatarsal head, and medial phalange (Yarnitzky 2006). In pressure sores, the breakdown

of tissue extends into the muscle and can extend as far down as the bone (Figure 2). Close monitoring of surface pressures will assist in detecting sores in Stage I, where the sore has begun to form within the dermis and subcutaneous regions but has not yet caused skin breakage.

Flexible sensors have made monitoring of sore formation easier since they can be incorporated onto the skin surface. In a circuit, flexible sensors measure displacement as an electrical output via conductance. Applying flexible sensors to the skin surface can allow forces and the corresponding pressures to be easily and accurately monitored without the need for implantation into the person (Bogie, Powell, and Ho 2012).

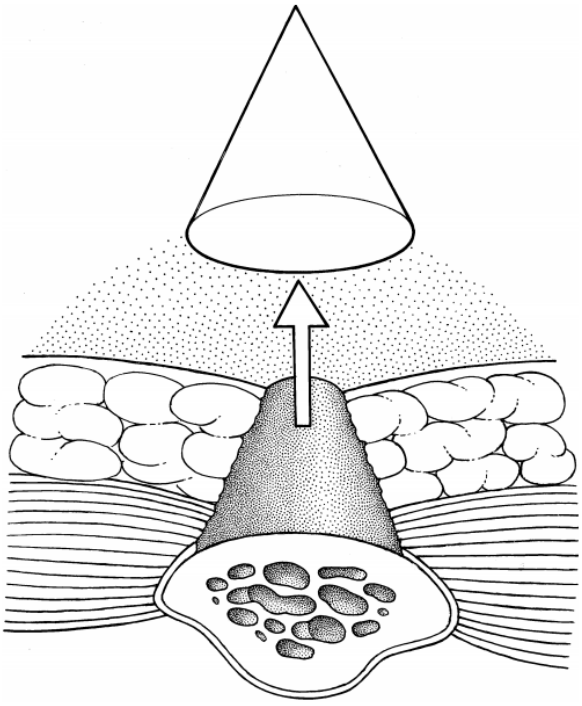

Figure 2. Cone-shaped pressure projection area deep into tissue and adjacent to bone (Bauer, Mancoll, and Phillips 2007).

Sore formation is not instantaneous. Over time it can be detected by monitoring hyperemia, return blood flow, which causes an increase in skin temperature. Although many studies investigating skin temperature as a predictor of pressure sore development have been inconsistent and inconclusive (Schubert, Perbeck, and Schubert 1994) (Sprigle and Linden *et al*. 2001) (Clark 1996), heat increase directly corresponds to an increase in blood flow, as demonstrated by Petrofsky (2012) and Cobb (2001) with measurement of blood flow with a laser Doppler sensor. Since ischemia causes pressure sores due to decrease in oxygen and nutrients (Herrman 1999), an increase in blood flow would help

prevent them. Additionally, during surgery, a low core body temperature has been associated with pressure sore development (Nixon and Brown, *et al.* 2000). High ambient temperatures, high ambient humidity, and contact with another surface can also increase skin temperature (International Review 2010).

Pressure sores are most prevalent amongst spinal cord injury patients because it is difficult for them to shift their weight and body position. Nerves that send messages to the brain indicating pain or discomfort allow a person to sense when to change his or her body position, and these messages are not relayed in spinal cord injury patients. Additionally, these patients may have difficulty adjusting their body position to relieve pressure due to lack of motor control. This lack of sensory perception and motor control causes an increase in prevalence of pressure sores in these patients. Additionally, decreased blood circulation occurs in those with spinal cord injuries, as well as in diabetics and the elderly (Petrofsky 2012; Roback 2010), partially due to endothelial cell damage, thus increasing their susceptibility to pressure sore formation. In the United States, there are about 1.6 million people who are wheelchair bound. About 250,000 of these people have a spinal cord injury, where 52% of these are paraplegic and 47% are quadriplegic. Additionally, there are 11,000 new spinal cord injuries every year. Pressure sores affect 20% of paraplegics and 26% of quadriplegics. Not only do pressure sores affect a lot of people, but also it increases their chances of death since the sores advance quickly and are difficult to treat ("Pressure Ulcers and Wound Care" 2013).

The pressure sore healing process first and foremost begins with relieving the pressure over the problem area. Poor nutrition, moisture, friction, shear, and aging skin all increase susceptibility to sore formation and can prevent the sore from healing (Lindgren 2002; Bauer, Mancoll, and Phillips 2007). The use of moist dressings improves the healing of stage II, III, and IV sores (Bergstrom and Smout, *et al*. 2005). In stage III and IV sores, healing can be improved by implementing adequate nutritional support (Bergstrom *et al*. 2005). Patients with good nutritional status have shown a significantly reduced healing time of sores (Van Rijswijk and Polansky 1994). Additionally, sores have been shown to heal faster in those who have significantly higher caloric intake (Bergstorm and Braden 1990).

Several studies have attempted to determine and relate parameters for pressure sore formation. The majority of these studies use animals such as dogs and pigs to create models of sore formation, and have detected an inverse relationship between pressure and time that results in sore formation. Daniel, Wheatley, and Priest (1985) demonstrated in a paraplegic pig model that 500 mmHg pressure over two hours or 100 mmHg pressure over ten hours caused muscle necrosis. Additionally, skin ulceration was seen at 11 hours with a pressure of 600 mmHg. These findings indicate that the pressure sore formation has already begun before 11 hours, and there may be a stage I pressure sore that is not readily

apparent since the necrosis begins deep within the tissue rather than on the surface. An inverse exponential relationship between pressure and time for formation of pressure sores was confirmed by Reswick and Rodgers (1976) in humans (Figure 3).

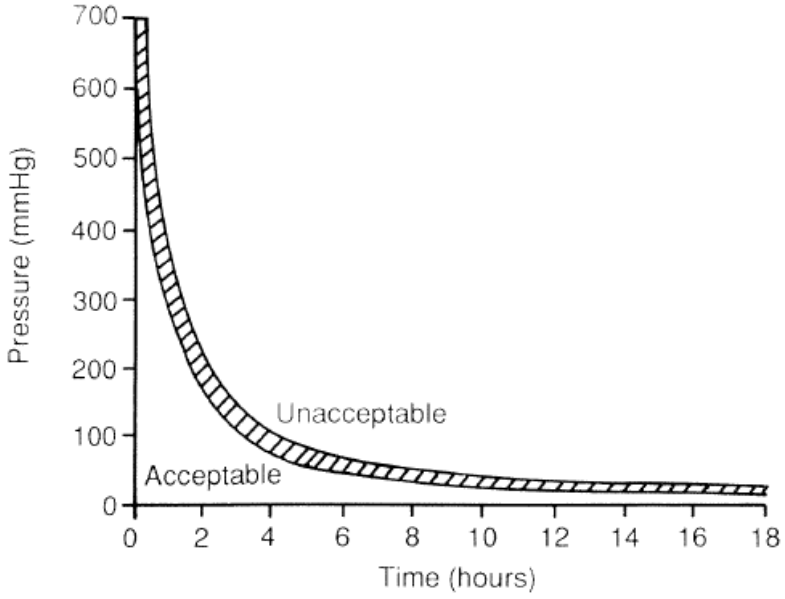

Figure 3. Pressure over time for evidence of "impending" pressure sores in seated humans The two curves are for different humidity conditions at the interface (From Reswick and Rodgers 1976).

Although the etiology of pressure sores remains complex, a general equation relating various parameters contributing to pressure sore formation was formed by Sacks (1989),

$$p_s = EK_1 + K_2\rho Q^{2/3} t^{-4/3}$$

where p_s is the pressure, E is a "lumped" elastic modulus for the tissue under load, K_1 and K_2 are constants, ρ is the tissue density, Q is local blood flow, and t is time. Ultimately this identifies a relationship of pressure to $t^{-4/3}$. Sacks (1989) confirmed the inverse exponential relationship from Reswick and Rogers (1976) with the theory from Reddy *et al.* (1981) (Figure 4).

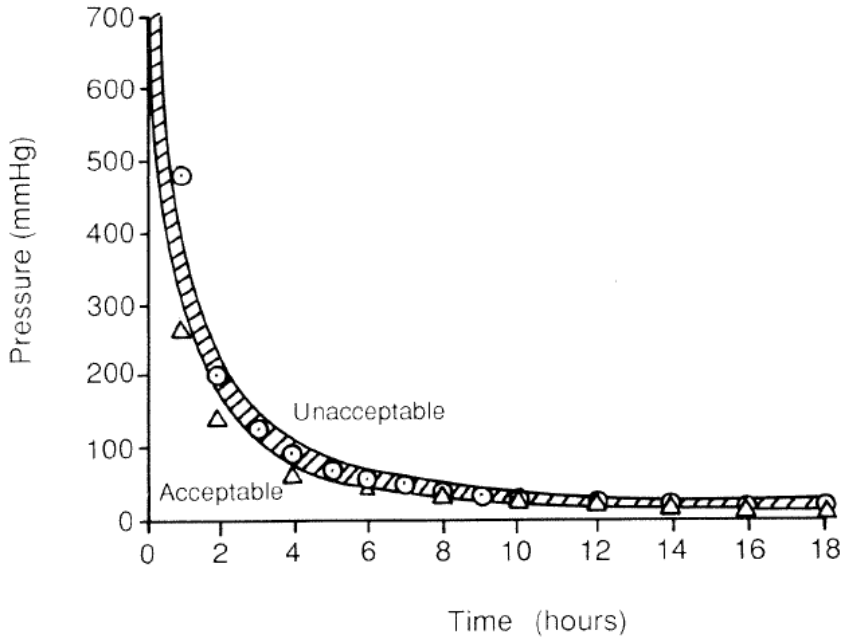

Figure 4. Combined data from Sacks (1989) of the Reswick and Rodgers curve for impending pressure sores in seated humans with the present theory and theory of Reddy.

Interstitial fluid flow and prevention of lymphatic drainage are both primary causes of pressure sores (Krouskop, 1983; Krouskop, Reddy, Spencer, & Secor, 1978; Reddy & Cochran, 1981). Nevertheless, external pressure has long been the focus of etiological investigations. A mathematical model by Reddy, Cochran, and Krouskop (1981) predicted that a pressure gradient instead of interface pressure would be more indicative of precise sore formation. This pressure indication was demonstrated and confirmed by Swain (1997) that a high interface pressure results in a proportionally larger pressure gradient. External pressure evaluations are common in the evaluation of support surfaces in clinical settings for their risk of causing pressure sores.

B. Objectives and Constraints

Potential locations for sore development that are not adequately addressed with the current technology are the feet, heel, and leg areas. Thus, the main objective of the device evaluated was to decrease pressure sore formation over time on these areas by redistributing contact forces and periodically altering the areas of contact. The use of an automated device to routinely alter a patient's position could, to some extent, compensate for the inability to sense the pressure and shear that lead to the development of sores. Guidelines to patient care recommend that if the patient is confined to a bed, position

should be changed every two hours, and if in a wheelchair a shift in weight should be done every 15 minutes (Berlowitz *et al.* 2013).

An automated leg rest device was made to be easily operable, durable, and safe in order to be marketable to wheelchair manufacturers and suppliers. The curve from Reswick and Rodgers (1976) was evaluated by several sources and determined to be indicative of impending pressure sore formation over time. Thus the main objective was for the device to reduce pressures on the plantar region into the acceptable range for values indicating impending pressure sores shown in Figure 3. The goal is to approach below capillary pressures, about 40 mm Hg, to prevent ischemia. The device was automated to cycle positions so that no particular area of the foot would remain at pressures resulting in impending pressure sores for an extended period of time.

The target market was U.S. adults with impaired mobility 20-60 years old who are confined to a wheelchair. People living with impaired mobility, such as paraplegics, are commonly susceptible to the prolonged uninterrupted pressure conditions that cause these sores. The device will ultimately be marketed to wheelchair accessory manufacturers, medical supply stores, and medical and physical therapy facilities.

The device needed to satisfy several functions to adequately fulfill the objectives and design goal. Most importantly, it needed to alternate pressure distribution enough to prevent pressure sore formation over susceptible areas by redistributing pressure over time to the acceptable range as shown in Figure 3 and reducing moisture and shearing forces on the foot. Moisture wanted to be minimized since that is a factor contributing to sore formation (Lindgren 2002; Bauer, Mancoll, and Phillips 2007). Shearing forces, which are normal mechanical forces with physiological effects, were taken into consideration because spinal cord injury patients experience clonus due to lack of muscle tone. This spasticity results in increased shear contributing to sore formation (Bauer, Mancoll, and Phillips 2007). The concept of the current automatic tilt-in-space wheelchair (Figure 5) was used to determine appropriate movement of the device.

Figure 5. Automatic wheelchair at Mobility Depot in Baton Rouge. The leg rest extends outward as it moves up parallel to the ground.

The design objective was to decrease pressure on susceptible bony prominences of the foot over time to the acceptable range of the Reswick and Rogers (1976) curve (Figure 3) and ideally below the pressure of the arterial end of capillaries, 40 mmHg (0.773 psi). Additionally, the device had to align the leg to reduce pressure sore formation from the structural components of the leg rest. The target population for the device was long-term wheelchair-confined individuals ages 20 - 60 and within 5th to 95th United States adult weight percentiles. Thus, height and weight ranges were obtained to specify allowable volunteer criteria for testing so that the device would be able to accommodate them. Minimum and maximum values were obtained by looking at each decade from 20-60 years old to determine corresponding heights and weights for the 5th to 95th percentile United States person. Thus, the range for the allowable weight was 107.2 lbs to 282.2 lbs, and the height range permitted was 59.6" to 74.4" (NCEES Fundamentals of Engineering Supplied-Reference Handbook, 2001; U.S. Health and Human Services 2012).

C. Testing Background & Theory

The design involves an automation of actuating the legs to different positions to alter the pressure distribution cyclically on the bony prominences on the feet to reduce the causation of pressure sores. Two main parameters – pressure and temperature – were measured to detect whether this reduction in pressure sore formation was achieved.

The Tekscan F-Scan® system, model 3000E (F-Scan® System, Tekscan, Inc., South Boston, MA), uses an array of 960 sensing elements which use resistive technology to provide dynamic pressure mapping of the plantar region of the foot (Figure 6). Initial qualitative pressure data was gathered using TekScan's F-Scan® system to detect regions of high pressure (Figure 7). The pressure displayed in 2D contoured form represents suspected areas of risk. Initial testing using TekScan indicated redistribution of pressures as the angle of the leg rest was altered. Pressure shifted from the lateral plantar region to the calcaneus (heel) as the leg rest was raised.

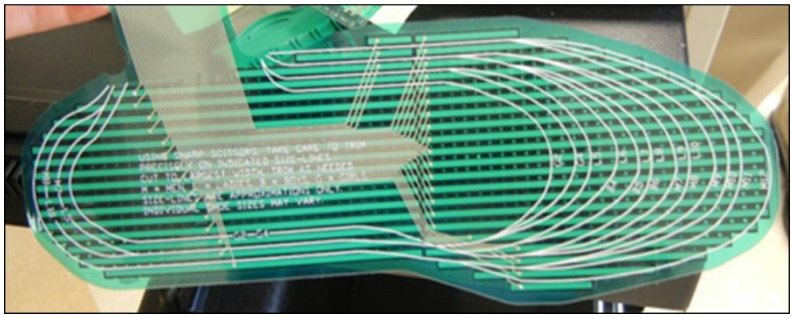

Figure 6. TekScan F-Scan® flexible pressure sensor insole

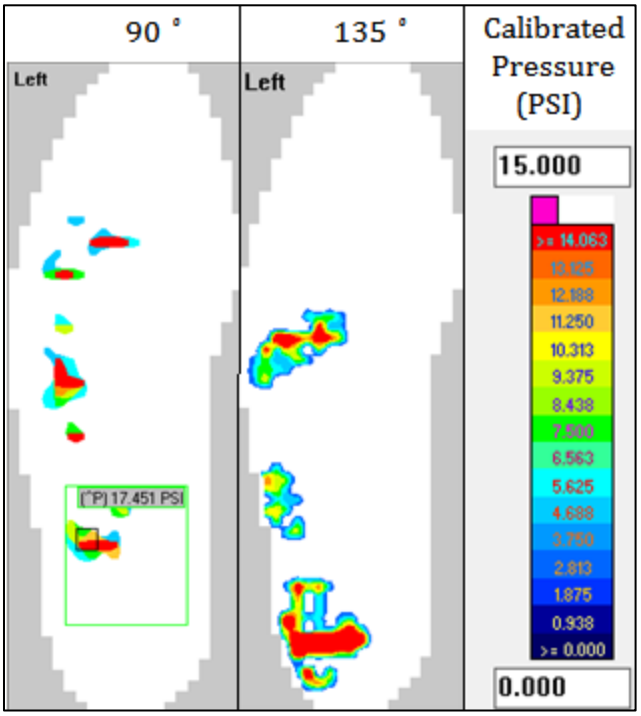

Figure 7. F-Scan® acquired data with the footplate at 90 degrees and 135 degrees with the subject barefoot.

The data gathered supports the theory behind the design, that actuating the legs to different angles changes the pressure distribution and allows the alleviation of high pressure areas. The areas of highest pressure were noted at different locations for each angle from the F-Scan® output. With the footplate at its base position, and the knee forming a 90˚ angle, and high pressure areas were mainly located on the lateral foot. With leg rest raised to a knee angle of 135˚, high pressure locations migrated to the heel area. The 180˚ position shows a high stress area located more towards the medial plantar region. Pressure mapping was performed using the final design to identify how well it redistributed pressure.

Obstruction of blood flow causes a decrease in temperature of the surrounding tissue, which is directly correlated to the temperature of the skin over the problem area. A change of this surface temperature can predict the effects of the device on the microvasculature of the plantar regions and thus an impending pressure sore since skin temperature corresponds to changes in the blood flow and tissue (Petrofsky 2012). Human skin temperature is approximately 34˚C, lower than the core body temperature of 37 ˚C.

2 Methods

A. Device Evaluated

Concepts for the device were generated by researching current products, viewing products used at Hansen's Clinic and Mobility Depot, then brainstorming and sketching ideas. The main concepts were evaluated using a weighted Pugh selections chart, which is a decision matrix that allowed comparison of the most important criteria – reduction in pressure on sides of legs, reduction in pressure on feet, regulation of leg position, stimulation of subsurface blood circulation, ease of use, adjustability, cost, safety, and size – along with many secondary criteria. The currently used automatic tilt-in-space wheelchair served as the datum for comparison for designing the device evaluated. Based off the Pugh selections chart and conversations with patients and wheelchair product distributors, the top three concepts – an extended pad, a tilting footrest, and a telescoping footrest – were combined to produce the design (Figure 8).

A- Hanger

B- Mounting Bar

C/D- Telescoping Leg Support Bar

E-Calf Support

F- Foot Support

G-Linear Actuator

H-Mounting Brackets

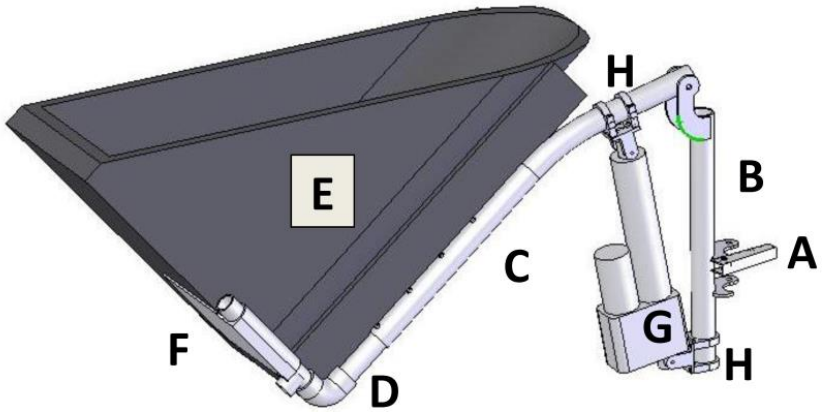

Figure 8. Designed automated pressure sore reducer.

The system is composed of mechanical components, an interface between the foot and mechanical components, and electrical components. Concentric tubing allowed for telescoping motion and adjustment of the overall length of the leg support. The pressure sore reducing device was mounted to a manual wheelchair frame via brackets cut from an aluminum plate, which supported the weight of the foot and calf and provide a foundation for the cushion on which the legs rest (Figure 9).

Figure 9. Prototype of designed automated pressure sore reducer.

The cushion that overlays the leg support was constructed primarily of lightweight memory foam with a plastazote backing and its removable cover was constructed of antimicrobial neoprene. The pad covers the foot supports and extends behind the foot and up the back of the leg to just below the knee. The padding of the leg support allows for an increased area of contact, theoretically decreasing pressures according to the equation

$$P = \frac{F}{A}$$

where P is pressure, F is force, and A is the area that the force is applied on.

The position of the leg support was adjusted using a 12 Volt linear actuator from ServoCity, which has a 4" stroke length and is capable of supporting a static load of 500 pounds. Its operating speed at no load is 0.5" per second and at max load is 0.39" per second. Built-in 10 kΩ potentiometers detected the position of the actuators as they moved and provided feedback to the control system for precise positioning of the leg rest. An Arduino Uno microcontroller board controlled the movement of the linear actuators for automatic and manual positioning modes that place the leg support at angles between 24˚ and 5˚ below horizontal, measured as shown in Figure 12. The control box was a 4" x 4" x 2" plastic housing with slots for the toggle switches, joystick modules, and ports to allow for wiring of the Arduino to the actuators and power source.

B. Testing Instrumentation

The testing system was designed to detect temperature and pressure changes on the plantar surface. Type T (copper-constantan) surface thermocouples (Surface Thermocouple with Self-Adhesive Backing, SA1 Series, OMEGA Engineering Inc., Stamford, CT) (Figure 10A) and FlexiForce® pressure sensors (FlexiForce® Sensors, Model A201, Tekscan, Inc., South Boston, MA) (Figure 10B) were chosen for their size, sensitivities, and flexibility.

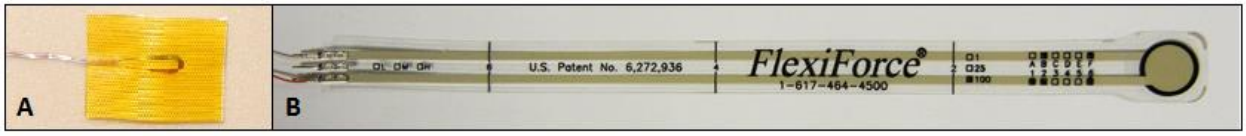

Figure 10. A) Surface Type T thermocouple used. B) FlexiForce® sensor used.

The surface Type T thermocouples were selected for their dimensions (25 L x 19 W x 0.3 mm), their measurement sensitivity (43 microV/˚C), and their continuous

temperature measurement range of -60˚C to 175˚C. Additionally, these thermocouples have a tolerance value of 1.0°C, or 0.75%, and are good for use in environments where moisture is present. Since increased temperature is a precursor for perspiration, temperature was monitored in place of moisture. The temperature measurement system allowed detection of changes of 0.1°C in skin temperature.

The thermocouples were connected to a PicoLog TC-08 data logger (USB TC-08 Thermocouple Data Logger, Pico Technology, Tyler, TX), and the software PicoLog R5.23.0 was used to acquire data from the thermocouples. The TC-08 uses stored thermocouple tables to convert output voltage into temperature, thus reducing errors resulting from analog methods of linearization.

Pressure mapping systems such as the TekScan F-Scan have difficulty obtaining accurate readings from very small pressures applied. These mapping systems are used to locate and quantify pressures resulting from the seat or from gait. The leg rest does not support all of the body weight while sitting, so pressures from smaller weights needed to be measured. Thus, TekScan's FlexiForce® sensors were used to measure pressure. TekScan's FlexiForce® sensors are able to achieve the sensitivity required for mapping smaller pressures of the feet. These are patented, ultra-thin (0.203 mm) sensors that measure pressure with superior linearity and accuracy (±3%), a 9.53 mm diameter sensing area, a length of 197 mm, a force range of up to 440 N, and operating temperatures of -40°C to 60°C. An Arduino Uno microcontroller was used to gather and record data from the FlexiForce® sensors. Four FlexiForce® sensors were wired to the Arduino Uno using a voltage divider circuit with the each sensor and a 1 MΩ resistor in series. The sensors' output was read through the analog pins of the microcontroller every 500 ms at each angle that the leg rest was positioned to as it was raised and lowered during the cycle (Appendix D).

C. *In vivo* Testing Protocol

This study was reviewed and approved by the Louisiana State University Institutional Review Board (Appendix A). Fifteen volunteers ages 20 – 52 gave their informed consent to participate in the study. Eleven of these volunteers were able-bodied persons, comprising of six males and five females. Four of these volunteers were para- and quadriplegic persons, comprising of three male and one female. Maximum and minimum heights and weights allowable for the study were determined based on the designed engineering goals for the 5th percentile female up to the 95th percentile male (U.S.

Department of Health and Human Services 2012) and are listed under "Objectives and Constraints." The volunteer profile is shown in Table 1.

Table 1. Volunteer profile ranges.

Parameter	Min	Max	Median
Height (inches)	62	74	69
Weight (lbs)	110	245	180
Age (years)	20	52	24

The volunteers were in contact with the rehabilitation prototype through their legs and feet resting on the device while sitting in a wheelchair. Physical risks included ulceration from keeping legs and feet immobile on the device, and pinch points from moving parts of the device. Psychological risks included concerns with the device causing physical problems, and social risks included being confined to a wheelchair for the testing period. There were no identified costs to the subject for participating in this research study.

Risk of pressure sores was reduced by using antimicrobial, moisture resistant, flame retardant neoprene on the device and safety of the device was taken into consideration by doing mechanical testing before human testing. Shear friction effects of the neoprene covering are minimal and the deflection of the aluminum frame was within the acceptable range for clearance following FDA regulations (Americans with Disabilities Act Title III Regulations 2010). The mechanism of the linear actuators was tested beforehand for durability and capacity. Electrical components – such as the microcontroller, 12 V battery, and potentiometers – were contained in a plastic box so that they were not exposed to the volunteers. No developing sores were recognized during the testing period to cause early cessation of the session.

Data was collected at Louisiana State University and the National Hansen's Disease Program Clinical Center in Baton Rouge. At these locations, volunteers sat for two hours in the wheelchair with the device and testing sensors attached. The recruitment pool included the senior design team members for initial testing of usability and safety, volunteers from around Baton Rouge, and patients at the National Hansen's Disease Program. The device design is intended for use by para- or quadriplegic patients between the ages of 20-60, and within the size and weight range for 5th percentile female to 95th percentile male, so all subjects must fit under those criteria. Pregnant women, incarcerated individuals, and children were excluded from the recruitment pool. There was no payment for participation in this research study.

Fifteen volunteers sat in the wheelchair with the attached device for two hours and evaluated its operability, safety, comfort, and aesthetics through survey. Four of these volunteers were unable to complete the two hour session, causing temperature results to

be analyzed for only the eleven volunteers who completed the session due to the need for temperature to equilibrate with each person and be continuously recorded for analysis of the differential during the second half of each session. Pressure and temperature were recorded during the two hours using the FlexiForce® sensors and thermocouples described under "Testing Instrumentation."

All sensors were directly placed on the plantar surface and secured with athletic tape and a stocking. Regions of the plantar pad that are of concern include the calcaneus and the tuberosity of the 5th metatarsal. One thermocouple was placed on the middle of the ball and the heel of each foot. Another thermocouple was used to record the ambient air temperature. The FlexiForce® sensors were placed with one on the tuberosity of the 5th metatarsal (henceforth referred to as "ball") and one next to the thermocouple on the tuberosity of calcaneus of each foot (henceforth referred to as "heel")(Figure 11).

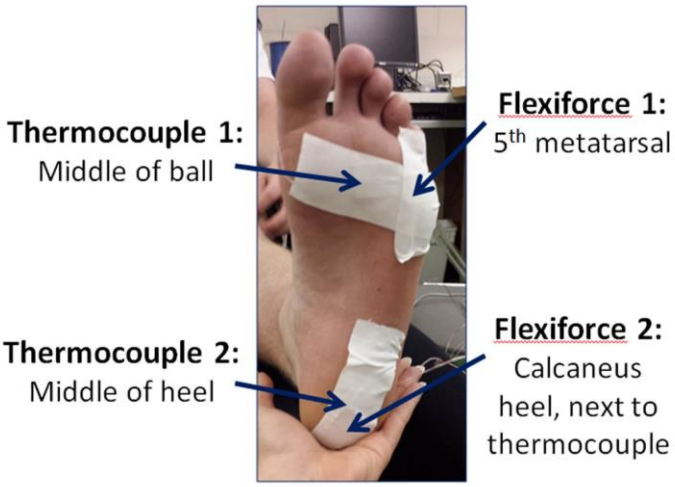

Figure 11. Placement of sensors on plantar region of left foot. Two thermocouples and two FlexiForce® sensors were placed on the bottom of each foot.

The leg rest cycle changed the leg rest angle (Figure 12) every fifteen minutes for two hours (Figure 13). The leg rest began fully lowered with the linear actuator fully retracted and increased by 5˚ every fifteen minutes. After sixty minutes (halfway through the test), the leg rest was at its top position (5˚ below horizontal) and was then lowered by 5˚ every fifteen minutes. At the end of the testing session, the leg rest was back to its fully lowered position, thus completing the cycle.

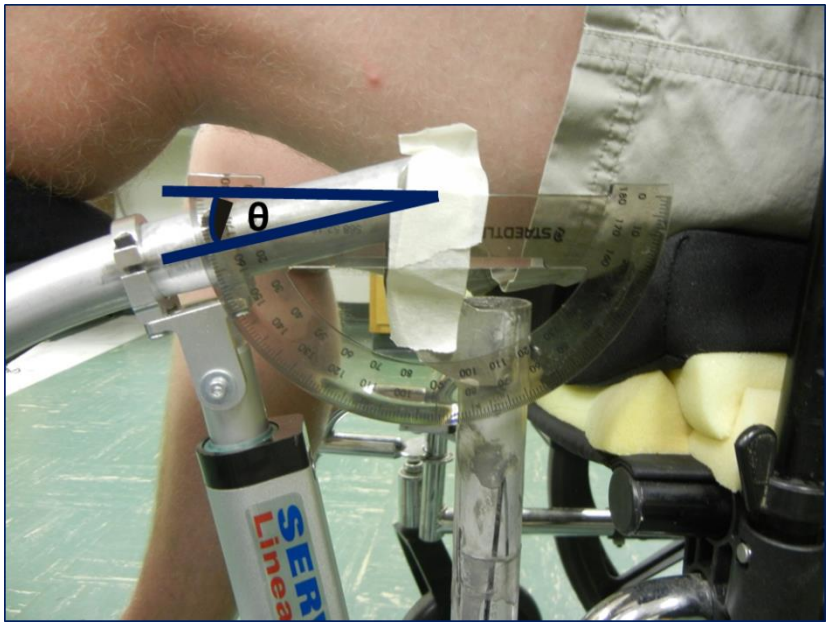

Figure 12. Angle measured on leg rest.

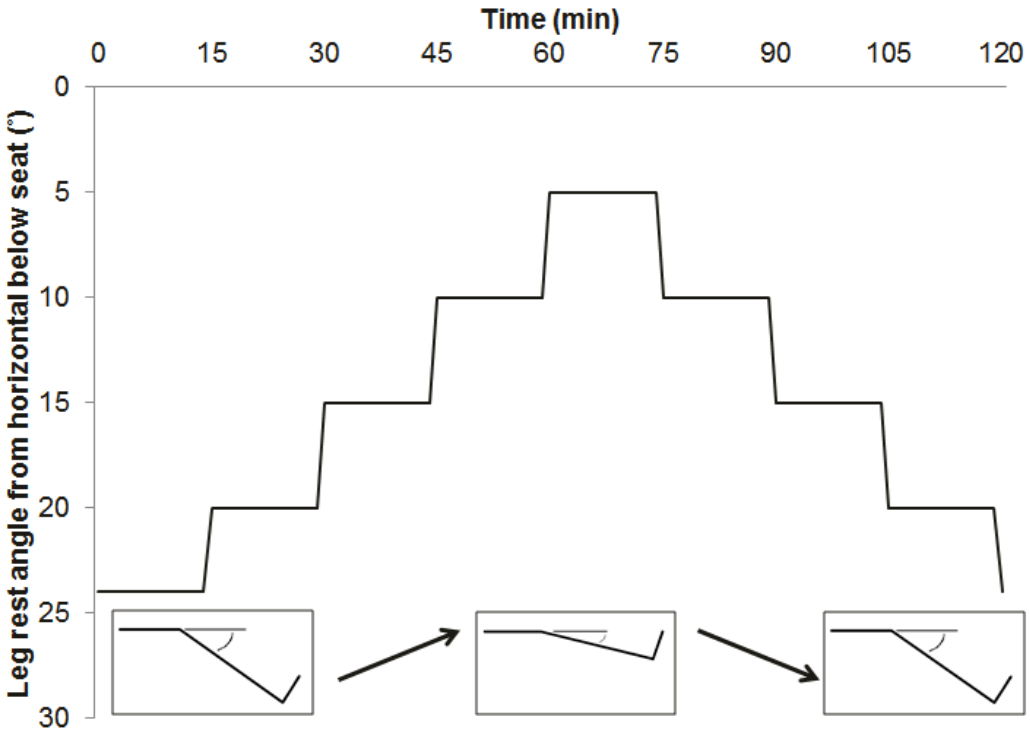

Figure 13. Increase and decrease of leg rest angle over two hour testing session.

3 Results and Analysis

Results are a compilation of data collected from fifteen volunteers who fit within the specified height and weight ranges described under "Device Constraints." The left foot rested on the prototype and the right foot rested on a universal manual wheelchair foot rest as a control.

A. Pressure

TekScan's F-Scan® system provided initial qualitative results. The TekScan F-Scan® system has a sensitivity of 75-125 psi (3878.6 mmHg – 6464.4 mmHg), far above the intended sensing range of 20 mmHg (venous end of capillaries) – 700 mmHg. The F-Scan® system was designed for gait analysis to detect pressures from a person's full weight bearing down on each foot while walking and allows easy analysis for dynamic loadings of gait, but those high pressures are not easily determinable with the leg resting in a static device. The calibration of the F-Scan® differed from that used in Figure 7 for initial analysis in Testing Background & Theory due to it not being able to read pressures while using the device. A calibration of 15 lbs body weight instead of a subject's full body weight was used during a step calibration of the sensors. Even with this smaller calibration, their sensitivity, in addition to the insole not being able to lay flat in the padding of the device, caused pressures detected by the F-Scan® to not be accurately compared to those quantified by the FlexiForce® sensors and thus the F-Scan® results served as a qualitative indication of pressure locations.

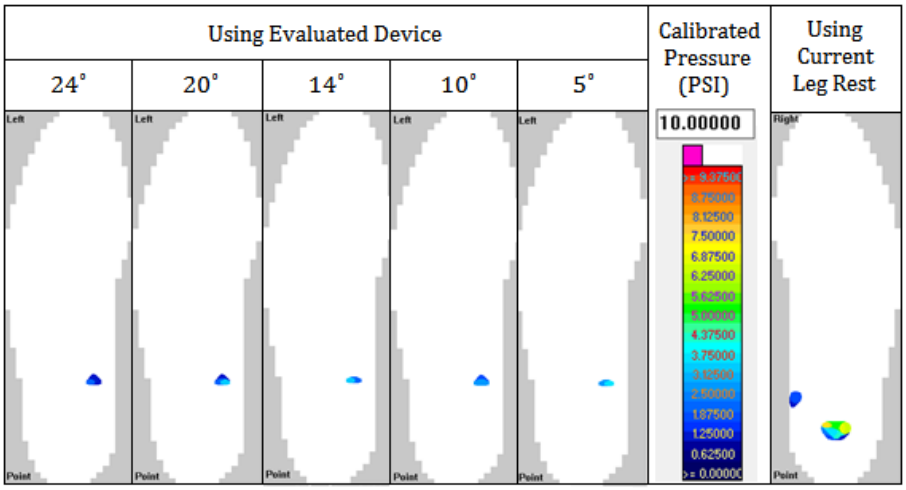

Figure 14. Pressure distribution detected by F-Scan® while using the device at various angles and while using the universal foot rest.

Slight changes in pressure distributions were detected using F-Scan® at the various angles that the evaluated device were set to, and were greater than those detected while using the universal footrest (Figure 14). Insole misalignments on each foot and possible contact areas not read by F-Scan® due to its sensitivity and measurement range may have caused the depicted location to slightly differ from actual location of the pressure of the foot (Figure 14).

Each FlexiForce® sensor was calibrated using a set of calibration weights. The sensing area of one sensor at a time was loaded from 0 grams to 205 grams. Using this method, a linear regression was obtained (Figure 15 – Figure 18) (R^2 ranging from 0.97-0.99) for each sensor from the mass and corresponding voltage outputs. The load was then multiplied by gravity to obtain force and was then divided by the sensing area of the FlexiForce® (71.33 mm^2) to obtain pressure. Values were converted to mmHg to compare to the literature. Sensors #1 and #2 were placed on the right ball and heel, respectively, which served as the control foot. Sensors #3 and #4 were placed on the left ball and heel, respectively, which served as the foot using the device.

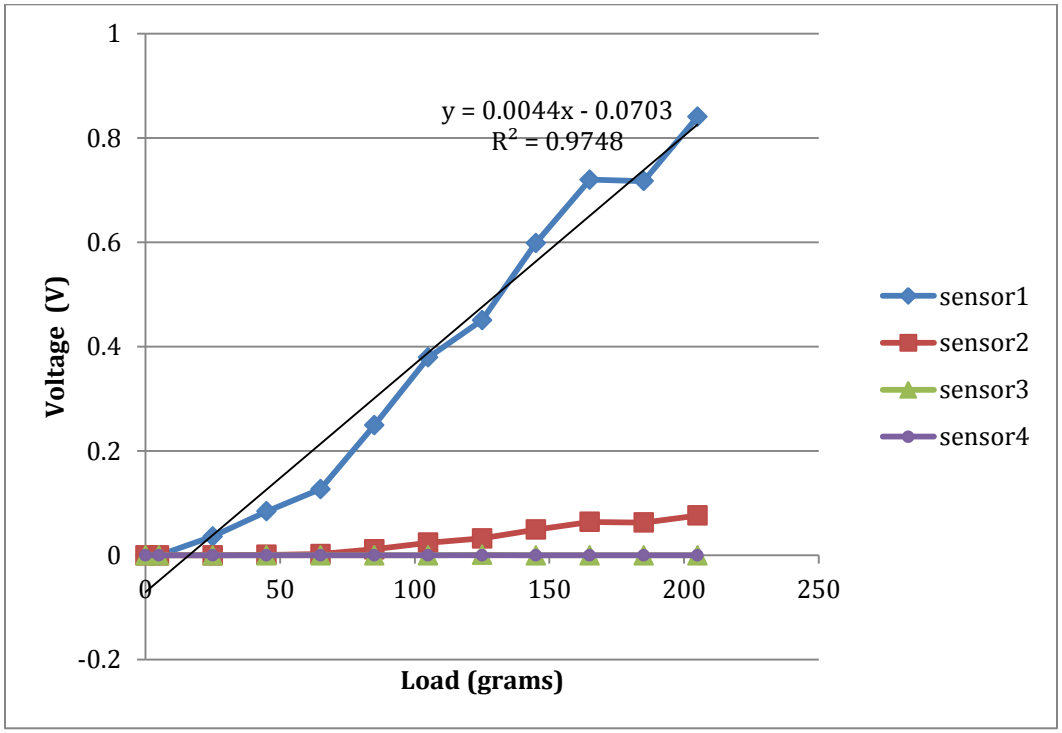

Figure 15. Increasing load on FlexiForce® sensor #1 resulting in linear voltage output with R^2 = 0.97.

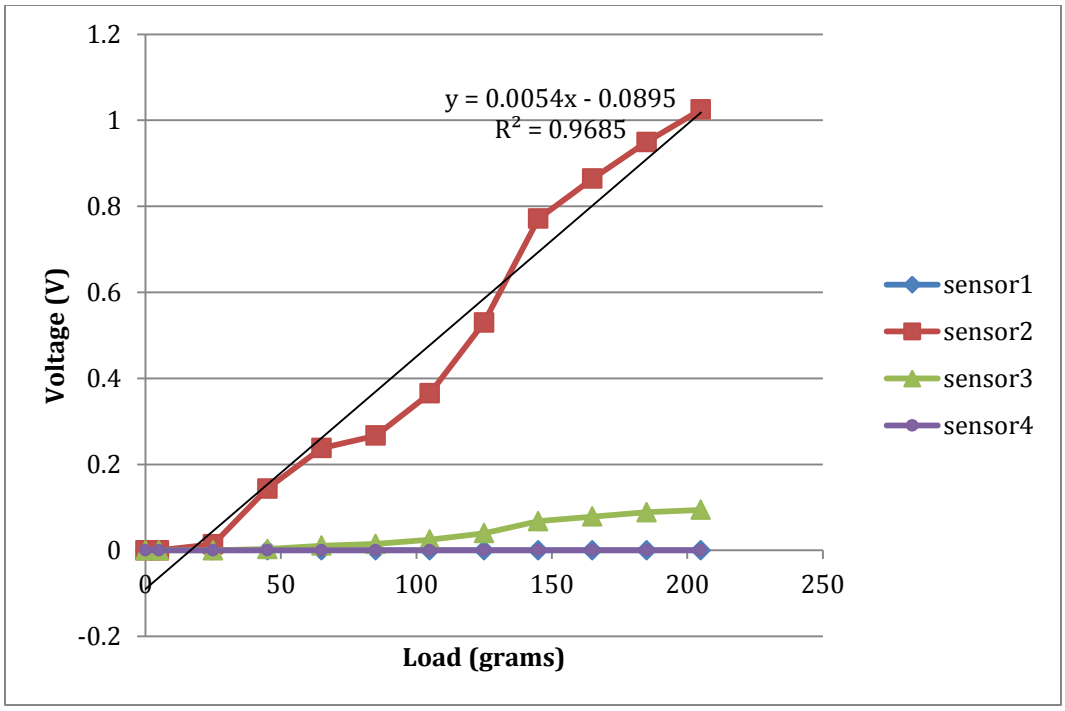

Figure 16. Increasing load on FlexiForce® sensor #2 resulting in linear voltage output with $R^2 = 0.97$.

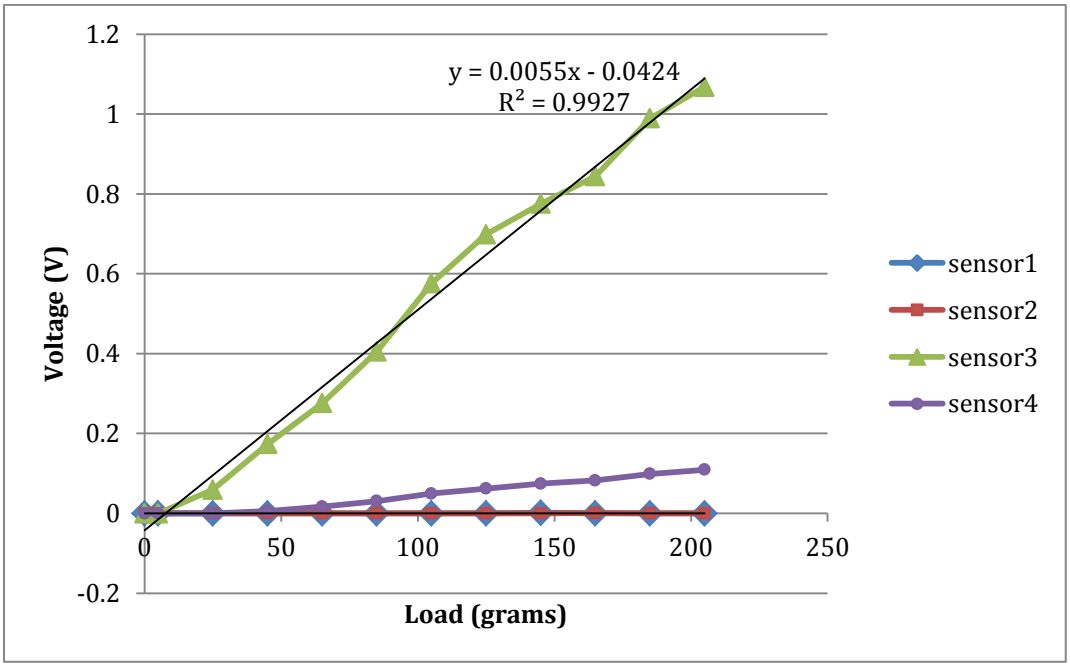

Figure 17. Increasing load on FlexiForce® sensor #3 resulting in linear voltage output with $R^2 = 0.99$.

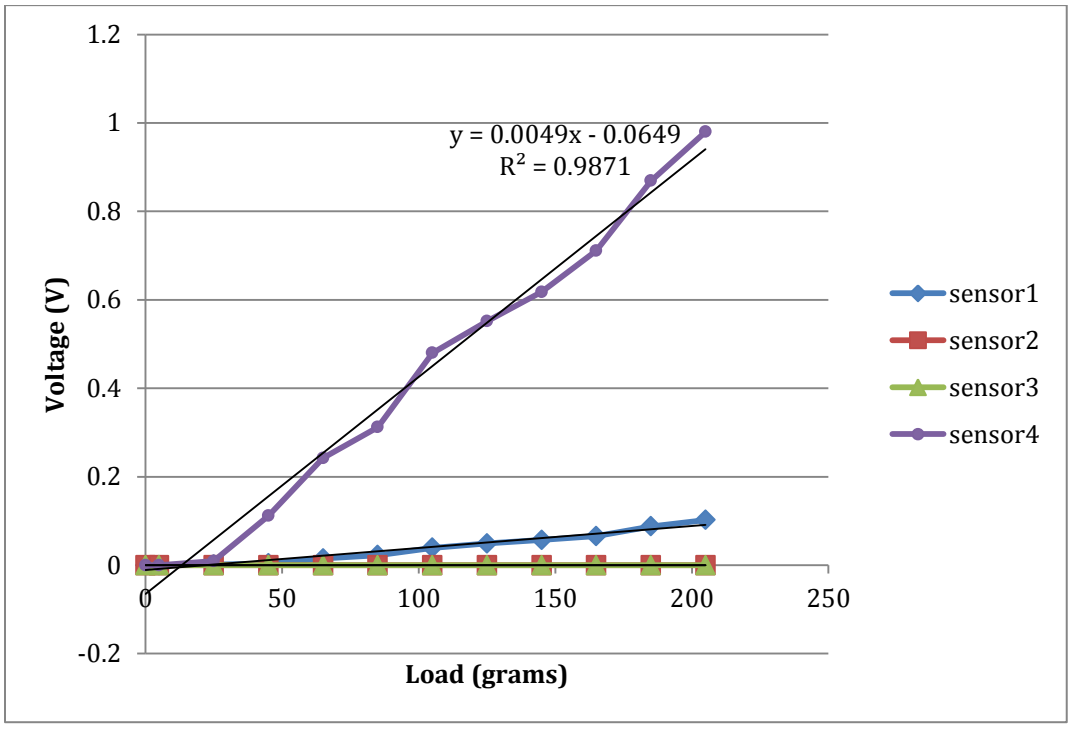

Figure 18. Increasing load on FlexiForce® sensor #4 resulting in linear voltage output with $R^2 = 0.99$.

FlexiForce® pressure sensors produced pressure data for the 5th metatarsal (ball) and calcaneus (heel) of the left foot using the device and the right foot control on a universal foot rest. The left foot on the device leg rest was moved to 24, 20, 14, 10, and 5 degrees below horizontal during the testing session (Figure 13). Since the recruitment pool included volunteers who were not para- or quadriplegic, the data may incorporate noise due to accidental volunteer movements during the two hour testing session. Possible error from movement was reduced by averaging pressure data at each angle during a period the volunteer was stable. The data for each angle was averaged across volunteers and is shown in Figure 19 for the ball of each foot and Figure 20 for the heel of each foot.

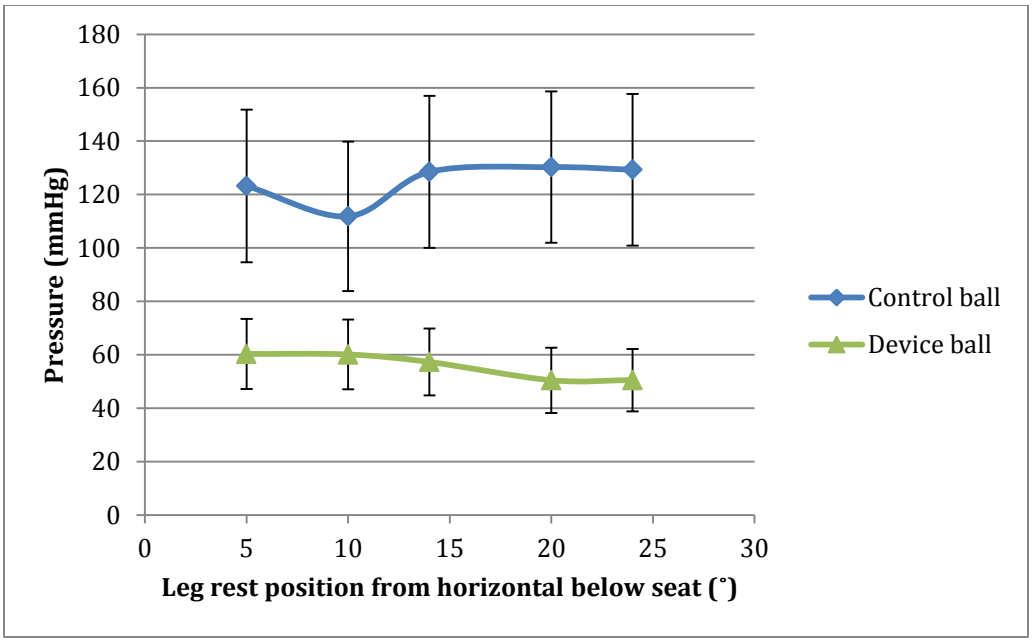

Figure 19. Pressure comparison between the ball of the left foot with the device attached and ball of the right foot without the device attached.

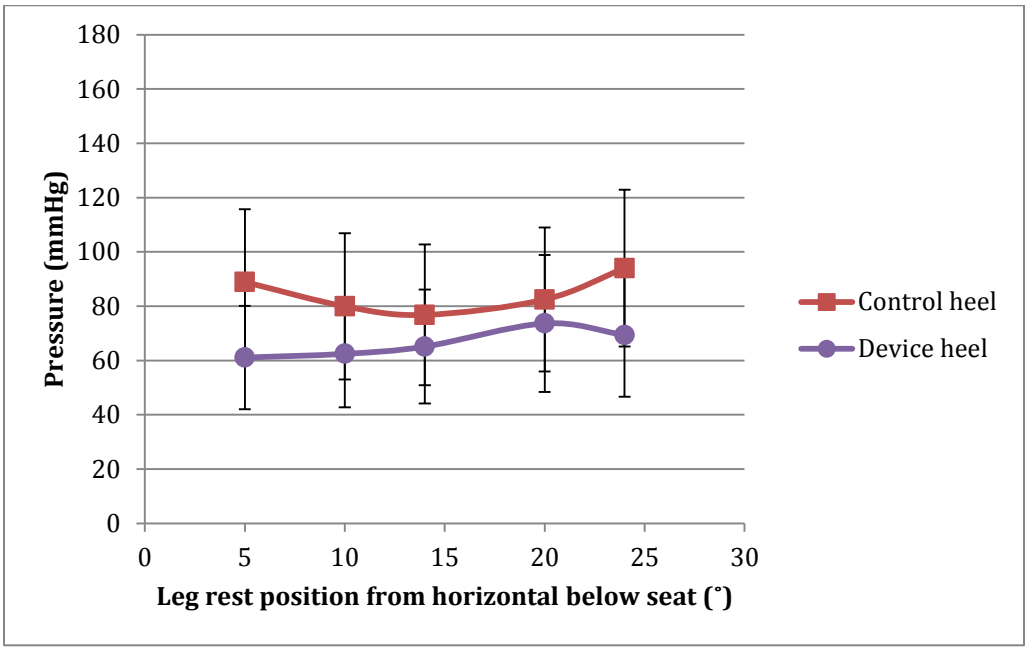

Figure 20. Pressure comparison between the heel of the left foot with the device attached and the heel of the right foot without the device attached.

Table 2. Population Averages for ball of foot (mmHg)

Location	Leg rest position (˚ below horizontal)				
	24˚	20˚	14˚	10˚	5˚
Device ball	50.5 ± 11.7	50.5 ± 12.2	57.3 ± 12.5	60.1 ± 13.0	60.3 ± 13.1
Control ball	129.3 ± 28.4	130.3 ± 28.3	128.5 ± 28.5	111.8 ± 28.0	123.2 ± 28.6

Table 3. Population averages for heel of foot (mmHg)

Location	Leg rest position (˚ below horizontal)				
	24˚	20˚	14˚	10˚	5˚
Device heel	69.4 ± 22.7	73.7 ± 25.3	65.1 ± 21.0	62.4 ± 19.7	61.1 ± 19.0
Control heel	94.0 ± 28.9	82.5 ± 26.5	76.8 ± 25.9	79.9 ± 27.0	88.9 ± 26.8

Table 4. Pressure difference between control and device ball.

	Leg rest position (˚ below horizontal)				
	24˚	20˚	14˚	10˚	5˚
Difference in ball	78.8	79.8	71.2	51.7	62.9
P value	0.0058	0.0036	0.0102	0.0657	0.0431
Significance ($P < 0.05$)	Yes	Yes	Yes	No	Yes

Table 5. Pressure difference between control and device heel.

	Leg rest position (˚ below horizontal)				
	24˚	20˚	14˚	10˚	5˚
Difference in heel	24.6	8.8	11.7	17.5	27.8
P value	0.3512	0.7553	0.7446	0.2820	0.1173
Significance ($P < 0.05$)	No	No	No	No	No

Pressure data of the ball and heel of the control foot and the foot using the device were compared as shown in Table 2 – Table 5 with standard error and a paired two-tailed Student t-test to determine significance. The difference was obtained and compared between the ball and heel of each foot (Table 4 and Table 5). Significance ($P<0.05$) was found between the control and device ball at a majority of the leg rest positions: 24˚, 20˚, 14˚, and 5˚.

B. Temperature

Each thermocouple was calibrated using an ice bath. A Vernier wide-range temperature probe (Wide-Range Temperature Probe, Vernier Software & Technology, LLC, Beaverton, OR), which obtains a ±0.1°C accuracy, stability, and repeatability by using resistance temperature detection, was used for measurement of the ice bath temperature, as read by a LabQuest interface. Distilled water was placed in a beaker with ice until the temperature stabilized, at 4.4˚C. Each thermocouple was placed in the ice bath and their output recorded through the PicoLog TC-08 data logger after stabilization. During data analysis, the difference of the values obtained through each calibration was added to each sensor's temperature readings.

Temperature data was obtained over two hours for eleven volunteers able to stably sit for the entire session in the manual wheelchair with the device attached. The temperature differential for the last half of the cycle was analyzed (lowering of the leg rest over one hour in 15 minute increments from the leg rest at its top angle of 5˚ from horizontal to its starting position of 24˚ from horizontal as shown in Figure 13) due to thermal equilibration of each foot in its new environment occurring during the beginning of each session.

Figure 21 shows the average temperature differential of the eleven volunteers. Ambient air remained relatively stable, while the control ball and heel decreased about 1.72°C and 1.75°C, respectively, and the ball and heel while using the device decreased 0.33°C and 0.01°C, respectively (Figure 21; Table 6).

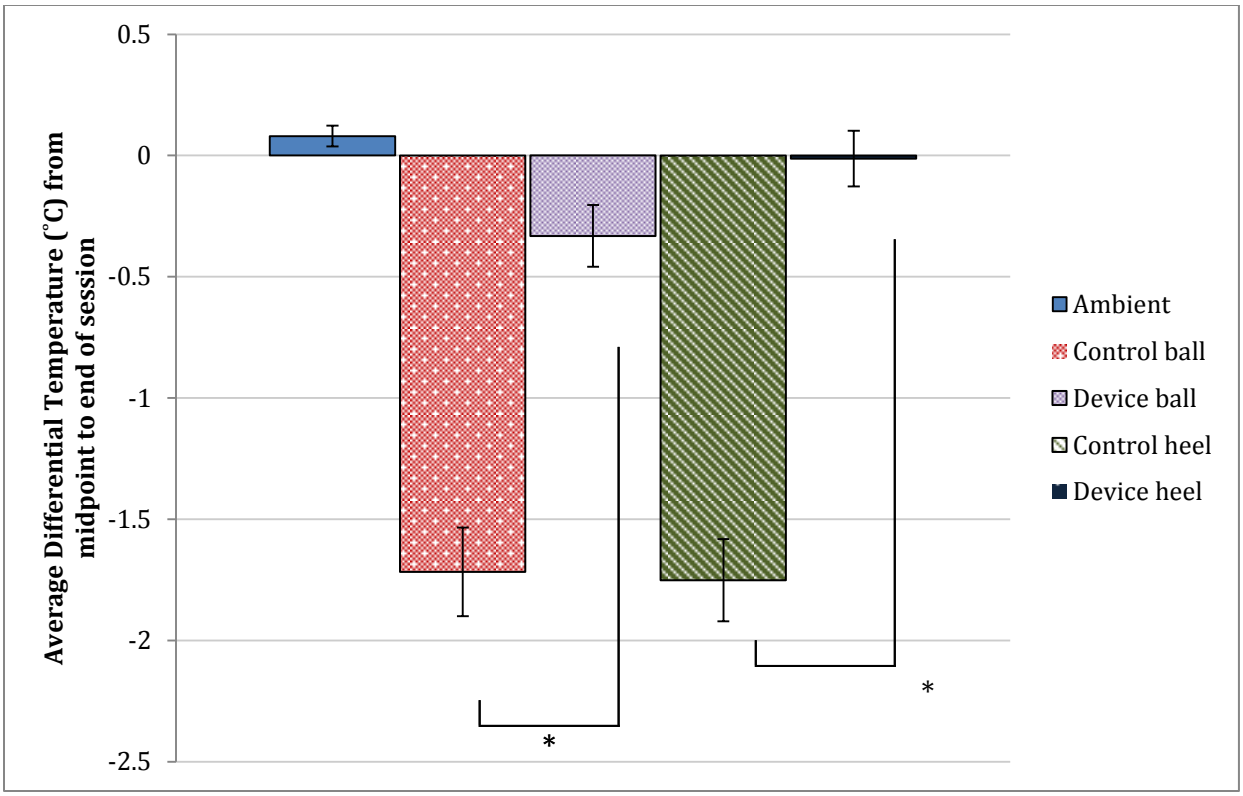

Figure 21. Average temperature differential between control and device ball and control and device heel. *Standard error and a Student's two-tailed t-test shows significance between ball and heel compared between feet (P<0.01).

Table 6. Population averages for temperature differential at each location measured.

Location	Average Differential Temperature (˚C) from midpoint to end of session
Ambient air	0.08 ± 0.04
Device Ball	-0.33 ±0.13
Control Ball	-1.72 ± 0.18
Device Heel	-0.01 ± 0.12
Control Heel	-1.75 ± 0.17

Table 7. Temperature differential between control and device ball.

	Average Differential Temperature (°C) from midpoint to end of session
Difference	-1.39
P value	0.0023
Significance (P < 0.01)	Yes

Table 8. Temperature differential between control and device heel.

	Average Differential Temperature (°C) from midpoint to end of session
Difference	-1.74
P value	0.000151
Significance (P < 0.01)	Yes

Temperature data of the ball and heel of the control foot and the foot using the device were compared with standard error and a paired two-tailed Student t-test to determine significance. The difference was obtained and compared between the ball and heel of each foot (Table 7 and Table 8). Significance (P<0.01) was found between both the control and device ball and the control and device heel.

C. Survey results

Volunteers evaluated the device aspects of comfort, ease of use, noise level, aesthetics, timing of cycles, and leg rest adjustability on a scale of 1 to 5, with 5 being extremely satisfied. The response ratings ranged from 4 to 5 for comfort and timing of cycles, and from 3 to 5 for ease of use, noise level, aesthetics, and leg rest adjustability. The average for each aspect was from 4-5, which corresponded to highly to extremely satisfied (Figure 22). General comments made by limited mobility volunteers included a little difficulty pushing the switch into automatic mode and pushing the switch to adjust the leg rest position once in manual mode. Another volunteer noted that no muscle spasms were experienced while using the device, and that the device had a great range of motion. One volunteer commented that the warmth of the foot using the device would help with the spasms and relaxing the leg, and a caretaker noted that the device would also help to

reduce blood clots. None of the volunteers had preexisting pressure sores, and none had indications of inflammation during or immediately after the testing session.

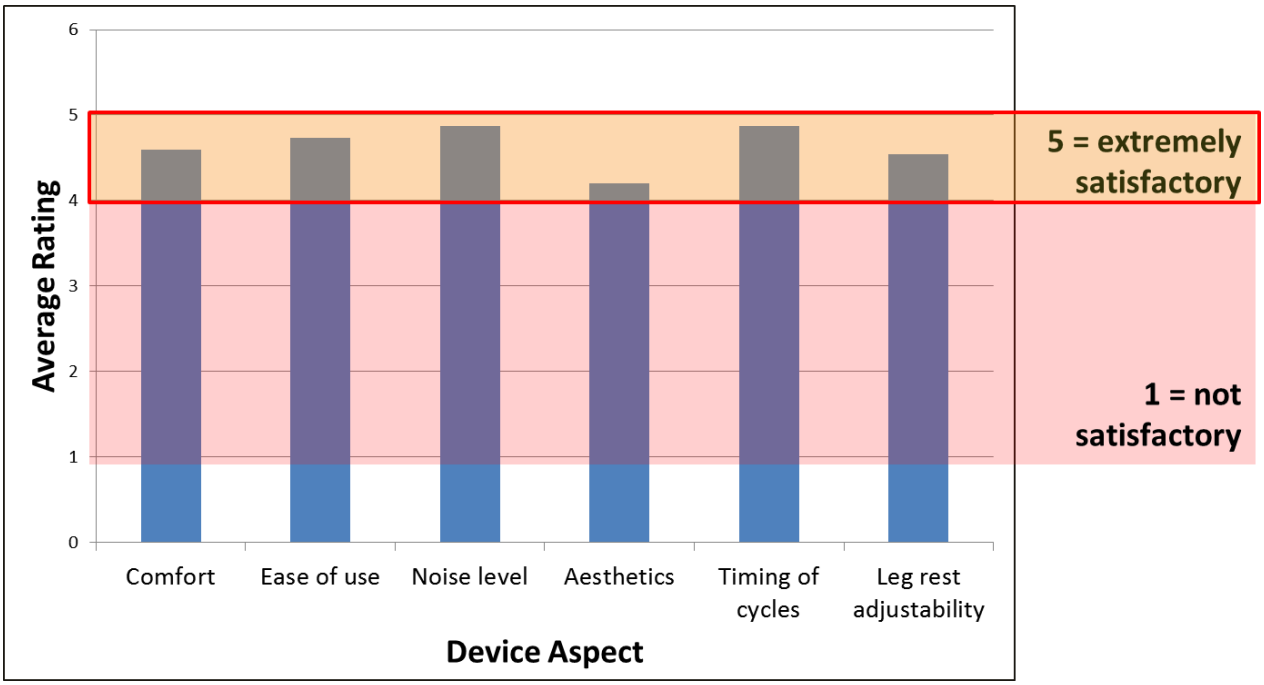

Figure 22. Survey responses of fifteen volunteers rating aspects of the device after testing session.

4 Discussion

Comparing the pressure values obtained to those found in the literature, the control foot pressures were found to not be significant from those pressures at the time they were measured when overlapped with the Reswick and Rogers (1976) curve (Figure 23). The pressure on the control ball was significant from the pressure on the ball using the device. At 15 minutes, each location was significant from the pressure noted to result in an impending pressure sore (Table 9). The data was then compared over the two hour duration of the testing session. The control ball was not significantly different when compared to 150 mmHg, the threshold of the unacceptable range of pressures at two hours, and thus the control data indicates a pressure sore may be impending from using the universal wheelchair foot rest for two hours (Table 10), while use of the device results in prevention of that sore formation.

Future testing sessions with mobility impaired people should be lengthened to analyze pressure and temperature over the typical time spent sitting in a wheelchair, approximately twelve hours a day. This would most likely show a clearer difference in the amount of time that the evaluated device allows for use compared to the universal foot rest before pressure sore formation.

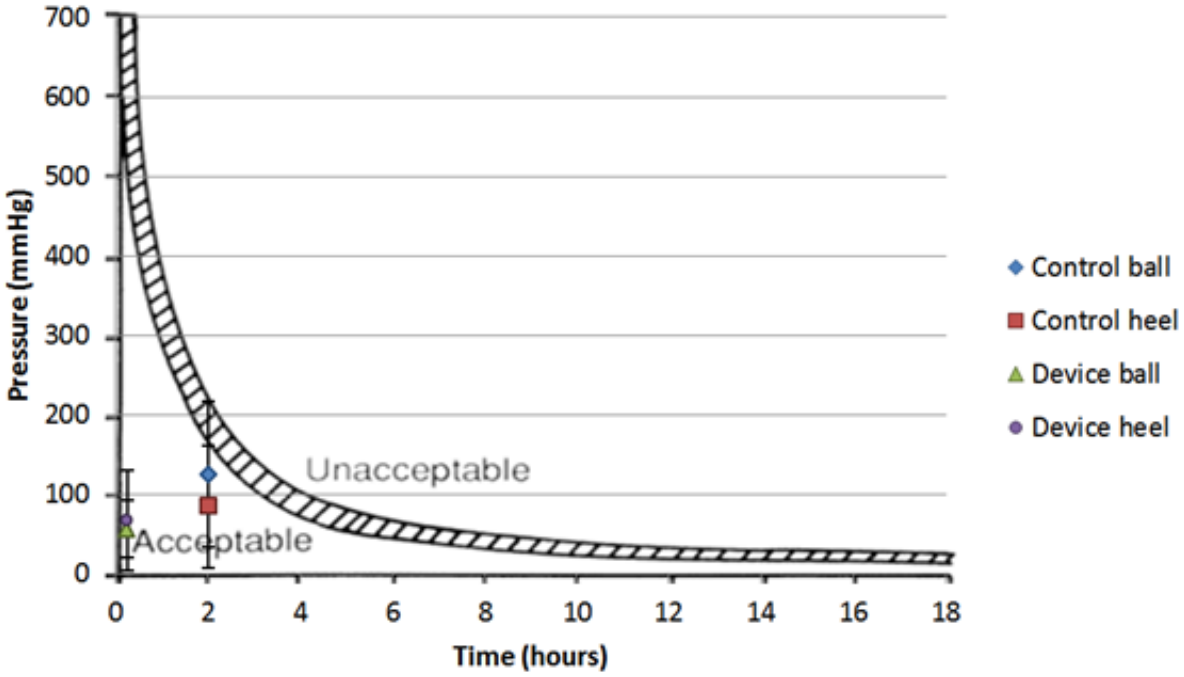

Figure 23. Pressure readings for the control and device ball and heel overlaid on literature graph (Sacks 89) for "impending" pressure sores. Standard deviation is shown for the 15 volunteers.

Table 9. Significance of data compared to literature value (450 mmHg) for impending pressure sore prediction at 15 minutes.

Location	P value	Significance to unacceptable pressure at 15 minutes (450 mmHg) (P < 0.01)
Control ball	1.45E-43	Yes
Control heel	1.96E-52	Yes
Device ball	5.00E-79	Yes
Device heel	4.88E-60	Yes

Table 10. Significance of data compared to literature value (150 mmHg) for impending pressure sore prediction at two hours.

Location	P value	Significance to unacceptable pressure at 2 hours (150 mmHg) (P < 0.05)
Control ball	0.0203	No
Control heel	2.61E-10	Yes
Device ball	4.82423E-35	Yes
Device heel	7.2601E-18	Yes

As the device was intended to reduce ischemia and thus improve circulation to prevent pressure sore formation, the decline in temperature and thus blood flow of the volunteers' feet was a concern. The greater decline in temperature of both the ball and heel of the control foot indicates a decrease in blood flow to those regions. Some volunteers noted their feet, especially the control foot, getting cold. Since this temperature decline was not as prevalent in the device foot, this differential may be indicative that the foot maintained greater blood flow from use of the device. The testing system was able to produce accurate (± 0.1°C) results to compare temperature changes between using the device and not using the device, and was able to be transposed between volunteers of varying dimensions by reattaching them on the areas of concern instead of making one universal insole.

The device and *in vivo* results have several implications for individuals with limited mobility. No muscle spasms were observed during device operation on limited mobility individuals, indicating that the leg rest operating speed between 0.5" per second at no load and 0.39" per second at max load every 15 minutes is not too sudden or often. Additionally, the smaller decline in temperature of the foot using the device may help with clonus by relaxing the leg. Improved blood flow from varying the leg rest position would not only prevent ischemia, it may also aid in reduction in blood clots. Additionally, this device may improve joint flexibility through repeated movement of the legs. This may reduce incidences of clonus in spinal cord injury patients and thus reduce the shear effects that are a factor in pressure sore formation.

5 Conclusions

A pressure sore reducing leg rest prototype which repositioned the leg every 15 minutes was evaluated for biological effectiveness. FlexiForce® sensors showed that the device achieved a significant ($P<0.01$) decrease in pressure on the ball of the foot. The device obtained a pressure of 55.7 ± 35.8 mmHg on the ball and 66.3 ± 63.4 mmHg on the heel, compared to the universal foot rest which resulted in a pressure of 124.6 ± 92.0 mmHg on the ball and 84.4 ± 77.2 mmHg on the heel. Thus, the prototype obtained pressures that indicate reduced pressure sore formation when changing the position every 15 minutes as compared to the pressures of the control at 2 hours of use. Additionally, there was significance between the temperature differential for both the ball and heel of the control foot and the foot using the device. The decreased temperature differential in the foot using the device is indicative that the prototype allowed for more consistent blood flow to the skin compared to the control foot. This pressure and temperature data indicate that the device does reduce risk of pressure sore formation. Testing volunteers responded that they were highly satisfied with the device, resulting in average ratings between 4 and 5 (extremely satisfied) for various device aspects.

Several developments could be made to improve the device's effectiveness. A useful development to the device would be an interface system to optimize the movement cycle based on anthropometric data of the user. A feedback system in communication with sensors would potentially detect impending sore formation and provide feedback into the system to change the foot's position. Additional pressure sensors could be used to test more locations to determine if pressure was redistributed to other areas of the body, such as to the calf or ischial tuberosities. To improve similarities of the use of the device to a real world setting, the testing session could be lengthened to analyze pressure and temperature over the typical time spent sitting in a wheelchair, approximately twelve hours a day. This would most likely show a clearer difference in the amount of time that the evaluated device allows for use before pressure sore formation compared to the universal foot rest.

6 Acknowledgments

Thank you first and foremost to my senior design team – Amy Pinner, Paul Mathews, and Stephen Montelepre – for helping design and build the automated pressure sore reducer prototype. Additionally, thank you to my advisors Anna Dugas, CAPT Dave Giurintano, AJ McPhate, and Daniel Hayes for suggesting countless improvements and offering guidance. I would like to thank my family and the LSU Honors College for encouragement and LTC Bart Kemper, P.E., and Krista Kemper for their advice regarding design and construction of the device. Thank you to the LSU Department of Biological and Agricultural Engineering and the LSU Department of Mechanical Engineering for use of their facilities for testing and device construction. Additionally, thank you Kemper Engineering Services, LLC, and the Tiger Athletic Foundation for funding. A special thank you goes out to Dr. Ronnie Mathews, John Figarola, and Dane Hupp at the National Hansen's Disease Program in Baton Rouge, and Eddie Austin at the Baton Rouge General Clinic for use of their facilities and helping me get in contact with patients who have limited mobility. And, of course, thank you to all of the volunteers who tested the device!

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8 Appendix

A. IRB Approval

ACTION ON PROTOCOL APPROVAL REQUEST

Institutional Review Board
Dr. Robert Mathews, Chair
130 David Boyd Hall
Baton Rouge, LA 70803
P: 225.578.8692
F: 225.578.5983
irb@lsu.edu | lsu.edu/irb

TO: David Giurintano
Mechanical Engineering

FROM: Robert C. Mathews
Chair, Institutional Review Board

DATE: January 17, 2014
RE: **IRB#** 3444

TITLE: Design of an Automated Pressure Sore Reducer

New Protocol/Modification/Continuation: New Protocol

Review type: Full __X__ Expedited ___ **Review date:** 12/13/2013

Risk Factor: Minimal ___X___ Uncertain _____ Greater Than Minimal_____

Approved* _____X_____ **Disapproved** _____

Approval Date: 12/13/2013 **Approval Expiration Date:** 12/12/2014

Re-review frequency: (annual unless otherwise stated)

Number of subjects approved: 50

Protocol Matches Scope of Work in Grant proposal: (if applicable) _____

***Approval Note:**

By: Robert C. Mathews, Chairman _____

PRINCIPAL INVESTIGATOR: PLEASE READ THE FOLLOWING –
Continuing approval is CONDITIONAL on:

1. Adherence to the approved protocol, familiarity with, and adherence to the ethical standards of the Belmont Report, and LSU's Assurance of Compliance with DHHS regulations for the protection of human subjects*
2. Prior approval of a change in protocol, including revision of the consent documents or an increase in the number of subjects over that approved.
3. Obtaining renewed approval (or submittal of a termination report), prior to the approval expiration date, upon request by the IRB office (irrespective of when the project actually begins); notification of project termination.
4. Retention of documentation of informed consent and study records for at least 3 years after the study ends.
5. Continuing attention to the physical and psychological well-being and informed consent of the individual participants including notification of new information that might affect consent.
6. A prompt report to the IRB of any adverse event affecting a participant potentially arising from the study.
7. Notification of the IRB of a serious compliance failure.
8. SPECIAL NOTE:

**All investigators and support staff have access to copies of the Belmont Report, LSU's Assurance with DHHS, DHHS (45 CFR 46) and FDA regulations governing use of human subjects, and other relevant documents in print in this office or on our World Wide Web site at http://www.fas.lsu.edu/osp/irb*

Application for Approval of Projects Which Use Human Subjects

This application is used for projects/studies that cannot be reviewed through the exemption process.

Institutional Review Board
Dr. Robert Mathews, Chair
130 David Boyd Hall
Baton Rouge, LA 70803
P: 225.578.8692
F: 225.578.5983
irb@lsu.edu | lsu.edu/irb

– Applicant, Please fill out the application in its entirety and include two copies of the competed application as well as parts A-E, listed below. Once the application is completed, please submit to the IRB Office for review and please allow ample time for the application to be reviewed. Expedited reviews usually takes 2 weeks. Carefully completed applications should be submitted 3 weeks before a meeting to ensure a prompt decision.

– A Complete Application Includes All of the Following:
(A) Two copies of this completed form and two copies of part B thru F.
(B) A brief project description (adequate to evaluate risks to subjects and to explain your responses to Parts 1&2)
(C) Copies of all instruments to be used.
*If this proposal is part of a grant proposal, include a copy of the proposal and all recruitment material.
(D) The consent form that you will use in the study (see part 3 for more information.)
(E) Certificate of Completion of Human Subjects Protection Training for all personnel involved in the project, including students who are involved with testing or handling data, unless already on file with the IRB. Training link: (http://phrp.nihtraining.com/users/login.php)
(F) IRB Security of Data Agreement: (https://sites01.lsu.edu/wp/ored/files/2013/07/Security-of-Data-Agreement.pdf)

1) Principal Investigator*: CAPT David Giurintano **Rank** Professor
*PI **must be** an LSU Faculty Member

Dept: Mechanical Engineerir **Ph:** 225-810-8528 **E-mail:** dgiurintano@lsu.edu

2) Co Investigator(s): please include department, rank, phone and e-mail for each
Linda Cross, BE, student, 312-287-7013, lcross4@lsu.edu
Amy Pinner, ME, student, 269-547-9444, apinne2@lsu.edu
Paul Mathews, ME, student, 225-963-2337, pmathe8@lsu.edu
Stephen Montelepre, ME, student, 504-259-4109, smonte4@lsu.edu

IRB# 3444 LSU Proposal #
Full ◉ Expedited
Complete Application
Human Subjects Training
IRB Security of Data Agreement

3) Project Title: Design of an Autonomated Pressure Sore Reducer

4) Proposal Start Date: 2/1/2014 **5) Proposed Duration Months:** 2

6) Number of Subjects Requested: 50 **7) LSU Proposal #:**

8) Funding Sought From: Kemper Engineering Services, LLC

STUDY APPROVED BY:
Dr. Robert C. Mathews, Chairman
Institutional Review Board
Louisiana State University
130 David Boyd Hall
225-578-8692 / www.lsu.edu/irb
Approval Expires: 12/12/2014

ASSURANCE OF PRINCIPAL INVESTIGATOR named above
I accept personal responsibility for the conduct of this study (including ensuring compliance of co-investigators/co-workers) in accordance with the documents submitted herewith and the following guidelines for human subject protection: The Belmont Report, LSU's Assurance (FWA00003892) with OHRP and 45 CFR 46 (available from http://www.lsu.edu/irb). I also understand that copies of all consent forms **must be maintained at LSU for three years after the completion of the project.** If I leave LSU before that time, the consent forms should be preserved in the Departmental Office.

Signature of PI _____ Date 12/2/13

ASSURANCE OF STUDENT/PROJECT COORDINATOR named above. If multiple Co-Investigators, please create a "signature page" for all Co-Investigators to sign. Attach the "signature page" to the application.

I agree to adhere to the terms of this document and am familiar with the documents referenced above.

Signature of Co-PI (s) attached Date _____

Consent Form for Testing of an Automated Pressure Sore Reducer

1. Study Title: Automated Pressure Sore Reducer

2. Performance Site: Louisiana State University and National Hansen's Disease Clinical Center in Baton Rouge

3. Investigators: CAPT David Giurintano, Linda Cross, Amy Pinner, Paul Mathews, Stephen Montelepre. The investigator listed below is available to answer questions about the research:

M-F, 8:00 a.m. - 4:00 p.m.

Linda Cross | 312-287-7013 | lcross4@lsu.edu

4. Purpose of the Study: The purpose of this research project is to evaluate the comfort, safety, durability, pressure distribution, operability, and aesthetics of an automated pressure sore reducing device designed by an interdisciplinary senior design team at LSU.

5. Subject Inclusion: Individuals, ages 20-60, who are within the size and weight range for 5th percentile female to 95th percentile male.

6. Number of Subjects: 50

7. Study Procedures: Each subject will sit and maneuver in a wheelchair that has the device attached for 2 hours.

8. Benefits: There are no direct benefits to the subjects. However, information gained from the study may provide valuable feedback for modification of the device to more effectively prevent pressure sore formation and improve the operability of the device.

9. Risks/Discomforts: There may be slight discomfort from sitting in the wheelchair and a slight possibility of ulceration on the contact areas or pinching at the device's moving points. These risks/discomforts are minimized by cycling areas of pressure and covering the moving points with an interface.

10. Injury/Illness: In the unlikely event of injury resulting from the device, contact Linda Cross, Senior Design Team member, 312-287-7013. You will be referred for treatment, but the expense of medical treatment will be your responsibility. No compensation is available in case of study-related illness or injury.

11. Right to Refuse: Subjects may choose not to participate or to withdraw from the study at any time with no jeopardy to their treatment by their respective doctors or other penalty at the present time or in the future.

12. Privacy: The LSU Institutional Review Board (which oversees university research with human subjects) and Kemper Engineering Services, LLC may inspect and/or copy the study records.

Results of the study may be published, but no names or identifying information will be included in the publication.

Other than as set forth above, subject identity will remain anonymous. No identifying information will be attached to the data of each subject.

13. Financial Information: There is no cost to the subjects, nor is there any compensation for participating in the study.

14. Signatures:

The study has been discussed with me and all my questions have been answered. I may direct additional questions regarding study specifics to the investigators. If I have questions about subjects' rights or other concerns, I can contact Robert C. Mathews, Institutional Review Board, (225) 578-8692, irb@lsu.edu, www.lsu.edu/irb. I agree to participate in the study described above and acknowledge the investigator's obligation to provide me with a signed copy of the consent form.

Subject Signature:_____ Date:_____

Please contact us if you have questions about this form.

Institutional Review Board
Dr. Robert Mathews, Chair
130 David Boyd Hall
Baton Rouge, LA 70803
P: 225.578.8692
F: 225.578.5983
irb@lsu.edu | lsu.edu/irb

STUDY APPROVED BY:
Dr. Robert C. Mathews, Chairman
Institutional Review Board
Louisiana State University
130 David Boyd Hall
225-578-8692 / www.lsu.edu/irb
Approval Expires: 12/12/2014

ɔved:

ACTION ON PROTOCOL APPROVAL REQUEST

Institutional Review Board
Dr. Robert Mathews, Chair
130 David Boyd Hall
Baton Rouge, LA 70803
P: 225.578.8692
F: 225.578.5983
irb@lsu.edu | lsu.edu/irb

TO: David Giurintano
Mechanical Engineering

FROM: Robert C. Mathews
Chair, Institutional Review Board

DATE: March 20, 2014
RE: **IRB#** 3444
TITLE: Design of an Automated Pressure Sore Reducer

New Protocol/Modification/Continuation: Modification

Brief Modification Description: Changes to instrumentation

Review type: Full ___ Expedited _X_ **Review date:** 3/21/2014

Risk Factor: Minimal ___X___ Uncertain _____ Greater Than Minimal_____

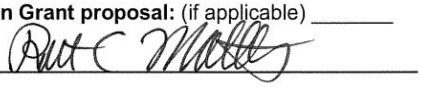
Approved___X___ **Disapproved** _____

Approval Date: 3/21/2014 **Approval Expiration Date:** 12/12/2014

Re-review frequency: (annual unless otherwise stated)

Number of subjects approved: 50

Protocol Matches Scope of Work in Grant proposal: (if applicable) _____

By: Robert C. Mathews, Chairman 

PRINCIPAL INVESTIGATOR: PLEASE READ THE FOLLOWING –
Continuing approval is CONDITIONAL on:

1. Adherence to the approved protocol, familiarity with, and adherence to the ethical standards of the Belmont Report, and LSU's Assurance of Compliance with DHHS regulations for the protection of human subjects*
2. Prior approval of a change in protocol, including revision of the consent documents or an increase in the number of subjects over that approved.
3. Obtaining renewed approval (or submittal of a termination report), prior to the approval expiration date, upon request by the IRB office (irrespective of when the project actually begins); notification of project termination.
4. Retention of documentation of informed consent and study records for at least 3 years after the study ends.
5. Continuing attention to the physical and psychological well-being and informed consent of the individual participants including notification of new information that might affect consent.
6. A prompt report to the IRB of any adverse event affecting a participant potentially arising from the study.
7. Notification of the IRB of a serious compliance failure.
8. SPECIAL NOTE:

**All investigators and support staff have access to copies of the Belmont Report, LSU's Assurance with DHHS, DHHS (45 CFR 46) and FDA regulations governing use of human subjects, and other relevant documents in print in this office or on our World Wide Web site at http://www.lsu.edu/irb*

B. Consent Form

Consent Form for Testing of an Automated Pressure Sore Reducer

1. Study Title: Automated Pressure Sore Reducer

2. Performance Site: Louisiana State University and National Hansen's Disease Clinical Center in Baton Rouge

3. Investigators: CAPT David Giurintano, Linda Cross, Amy Pinner, Paul Mathews, Stephen Montelepre. The investigator listed below is available to answer questions about the research:
M-F, 8:00 a.m. - 4:00 p.m.
Linda Cross | 312-287-7013 | lcross4@lsu.edu

4. Purpose of the Study: The purpose of this research project is to evaluate the comfort, safety, durability, pressure distribution, temperature, operability, and aesthetics of an automated pressure sore reducing device designed by an interdisciplinary senior design team at LSU.

5. Subject Inclusion: Individuals, ages 20-60, who are within the size and weight range for 5th percentile female to 95th percentile male.

6. Number of Subjects: 50

7. Study Procedures: Each subject will sit and maneuver in a wheelchair that has the device attached for 2 hours.

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Subject Signature:_____ Date:_____

Please contact us if you have questions about this form.

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C. Volunteer Testing Survey

Patient No:_____

Date/Time:_____/_____

Our team of mechanical and biological engineering majors, studying at Louisiana State University, have designed a fully automated wheelchair leg rest that aims to prevent pressure sore formation. Our device will cycle the leg rest through a preset range of positions in order to maintain a desired measure of pressure distribution induced at the contact surface on the lower body. We are interested in your feedback on this topic and appreciate your time.

Height _____ Weight _____ Age _____ Male/Female _____

Please indicate the level of satisfaction you have regarding the following aspects of this device					
1=not satisfactory	**5=extremely satisfactory**				
1. Comfort	1	2	3	4	5
2. Ease of use	1	2	3	4	5
3. Noise level	1	2	3	4	5
4. Aesthetics	1	2	3	4	5
5. Timing of cycles	1	2	3	4	5
6. Leg rest adjustability	1	2	3	4	5
7. Did you experience any discomfort?		YES		NO	
8. Do you have a need for this device?		YES		NO	
9. Have you ever experienced pressure sores?		YES		NO	
10. Do you already own an automatic wheelchair?		YES		NO	
11. Would you prefer an automated leg rest over a manual leg rest?		YES		NO	
12. Would you buy a device like this if affordable?		YES		NO	
What market price would you expect for this device? (circle one)					
< $1,500 **$1,500 - $3,000** **> $3,000**					

Please list any additional comments:

D. Arduino Uno Code for FlexiForce® sensors

```
//reads analog pins and prints voltage value
float voltage1,voltage2,voltage3,voltage4;
const float q = 5.0/1023;

void setup()
{
 Serial.begin(9600);  // Start serial at 9600 baud
}
   void loop()
{
 int sensorPreValue1 = analogRead(A0);  // Read the input on analog pin 0
  int sensorPreValue2 = analogRead(A1);  // Read the input on analog pin 1
  int sensorPreValue3 = analogRead(A2);  // Read the input on analog pin 2
  int sensorPreValue4 = analogRead(A3);  // Read the input on analog pin 3
 delay(100); // hopefully this will help fix the crossover between sensors

   int sensorValue1 = analogRead(A0);  // Re-reading the inputs
 float voltage1 = sensorValue1 * q;  // Convert the analog reading (which goes from 0 -
1023) to a voltage (0 - 5V)
  int sensorValue2 = analogRead(A1);
 float voltage2 = sensorValue2 * q;
  int sensorValue3 = analogRead(A2);
 float voltage3 = sensorValue3 * q;
  int sensorValue4 = analogRead(A3);
 float voltage4 = sensorValue4 * q;

 Serial.print ("AnalogRead = ");
 Serial.print( sensorValue1 );
 Serial.print( ",");
 Serial.print( sensorValue2 );
 Serial.print( ",");
 Serial.print( sensorValue3 );
 Serial.print( ",");
 Serial.print( sensorValue4 );

 Serial.print(", Voltage = " );  //prints voltage values
```

```
  Serial.print( voltage1 );
  Serial.print( ",");
  Serial.print( voltage2 );
  Serial.print( ",");
  Serial.print( voltage3 );
  Serial.print( ",");
  Serial.print( voltage4 );
  Serial.println (" volts");

  delay(500);   // Wait 500 milliseconds; slows down output for easier reading
}
```