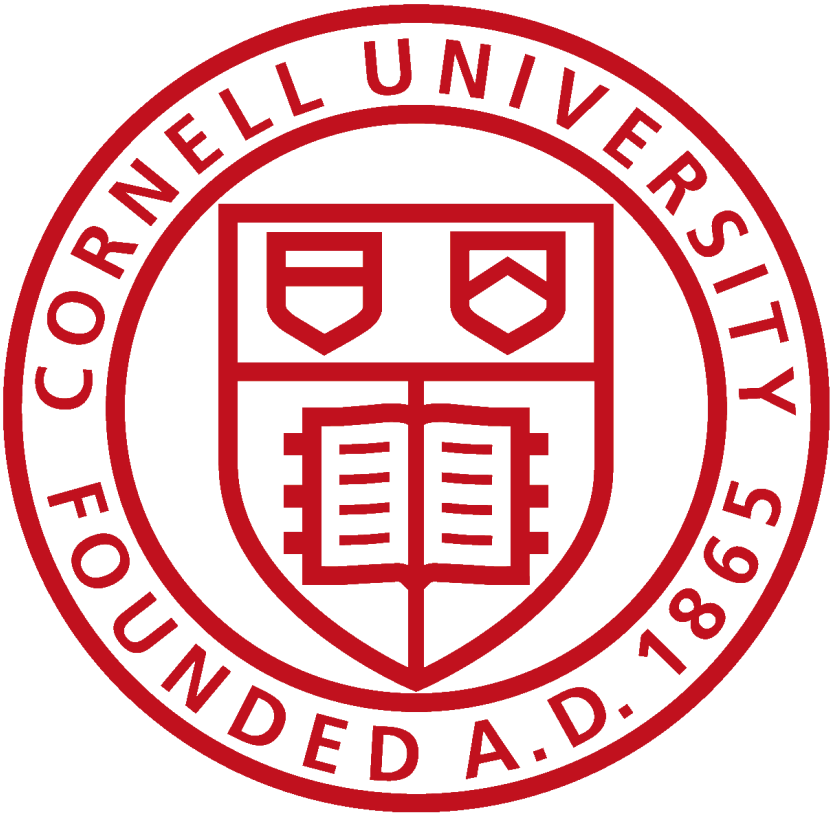

Pressure Ulcer Prevention Team

Updated Project Report

BME 5921

By Stephen Schneider, Xinchen (Nick) Zhang, and Reed Geisler

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Team Information

Stephen Schneider graduated with a B.S. in Biomedical Engineering from the University of Buffalo. Here he gained project experience designing a Nitrous Oxide detector using an Arduino microcontroller, a miniature infrared analyzer and the contact potential difference between two metals. As an undergraduate he spent several months in a regenerative medicine lab culturing and imaging stem cells for therapeutic research. Upon graduation he spent a year volunteering in a computer vision lab where he learned how to program machine learning algorithms in MATLAB to detect cancerous regions in microscopic tissue images. He is currently developing skills in C++ and Linux while also working with the Raspberry Pi microcontroller. You can view his LinkedIn at: https://www.linkedin.com/in/stephen-schneider-209b61b1

Xinchen (Nick) Zhang graduated from Purdue University. He majored in Agricultural & Biological Engineering and concentrated in Cellular & Molecular Engineering. Nick has a background in biological science and also took many courses in engineering such as Mass & Heat Transfer and Food Engineering. He has some basic experience in electricity and C programming. In the summer of 2014, Nick interned in the factory of Pfizer under the department of Medicine Quality Control in China. You can view his LinkedIn at:https://www.linkedin.com/in/xinchen-zhang-7444a1106/en

Reed Geisler finished a dual-degree in Biological Sciences and Chemistry at Cornell University while in his first semester of the Masters of Engineering in Biomedical Engineering program. Reed has worked in a lab in Cornell's College of Veterinary Medicine on drug delivery applications, and completed a summer of research at the University of Pittsburgh Medical Center in a Pharmacology research lab. His research background is primarily in drug delivery and design, though he has had previous experience with medical device development through assisting with White Light Medical's redesign of a pedicle probe for spinal fixation surgeries and Cornell iGEM's development of FishPharm (a drug applicator for salmonid fish). Outside of academics and research, Reed is heavily involved on the Cornell University campus and worked as an EMT for four years.

Acknowledgements

Amelia Abdullah recently graduated from Georgia Gwinnett College with her Bachelor's in Biology, and was a member of the M.Eng. team for the Fall 2016 semester. She has participated in three research experiences as an undergraduate and is very comfortable working in a laboratory setting. Amelia has experience working with breast cancer cells, mice, taxol, electrospinning, and PCR. She is also a certified pharmacy technician. Amelia is a hard worker, organized, approachable, and has experience in customer service. You can view her LinkedIn at: https://www.linkedin.com/in/amelia-abdullah-752a25126

An M.Eng. alumni group of Dae Hee Yun (dy88@cornell.edu), Gaurang Dimri (gpd34@cornell.edu), and Ilya Getsin (ig244@cornell.edu) acted as advisors to the project and in the second semester were the primary points of contact for feedback regarding project milestones and goals. They met with the team on a biweekly basis offering support and guidance for directions as the project evolved and periodically shifted focus over this past year, and were extremely helpful in providing additional resources and feedback for our team.

Dr. Karim Sadik (sadik_karim@guthrie.org), a plastic and reconstructive surgeon at Guthrie Robert Packer Hospital in Sayre, PA, has been the project sponsor and our primary contact for the clinician's perspective of the device and its objectives. He allowed the team to observe patients with pressure ulcers to see how they are managed and treated, and additionally allowed observation of a skin graft surgery for treatment of late-stage pressure ulcers. His advice led us to pursue preventative mechanisms of treatment and ultimately a disposable bandage instead of focussing on mattresses and larger-scale, costly devices for mitigation and treatment of existing pressure ulcers. When considering potential features of the device (e.g. providing diagnostic information, potential utilization of transdermal drug delivery, timespan of use of the device and its existing competitors) he was able to provide realistic feedback to more appropriately focus the scope and objectives of our project.

Jack Thompson, **Dr. Newton De Faria, and the Course TAs** met weekly with the team to provide feedback and give weekly updates on course project progression and upcoming objectives. Jack was particularly helpful in managing orders for the team and with his experience in wound dressings, and Dr. De Faria was able to set up the software and much of the architecture for our device testing platforms. Guidance of the course team was essential for ensuring the success of our project.

The BME Department Staff, particularly **Belinda Floyd** and **Suzanne Koehl** for their administrative support with the program and our endeavors in the M.Eng. in BME graduate program. We are sure that a lot of work goes on behind the scenes, from planning the logistics of all seminars and department events, to ensuring that all of us are fulfilling our requirements and will be able to graduate satisfied with our experience in the program. Belinda and and Suzanne have been the most visible staff members in our experience in the program, and we are certain that all of the other staff members work very hard to ensure the success of the program as well. Thank you for your time and help!

Introduction and Project Overview

The pressure ulcer mitigation M.Eng. project team is composed of Stephen Schneider, Xinchen (Nick) Zhang, and Reed Geisler, and included Amelia Abdullah until the end of the first semester. Starting on 8/25/16, after each of the BME 5010 seminar through the year, and at critical phases of our design process, our team met at least weekly to follow the biodesign process, report on market research and potential solutions, focus our device objectives, plan our device's features, and plan, construct, and execute our device's testing and reporting. Immediately after confirming our project assignments, our project team set up a Groupme in August for use outside of our weekly meetings for more immediate project updates and coordination.

Prior to initial meetings with Dr. Karim Sadik in Guthrie Hospital, our team met with M.Eng. alums Gaurang Dimri, Dae Hee Yun, and Ilya Getsin for initial advice regarding project organization, anticipated hurdles, the process of medical device innovation and production, and ultimately the scope of our project and any retrospective advice from their own experiences within the program. In the second semester, our team met with the Ilya, Dae Hee, and Saurang on a biweekly basis, Dr. De Faria, Jack Thompson, and the BME 5921 TAs on a weekly basis, Dr. Karim Sadik through the preceptorship program, and with each other weekly to continually revisit and update our project plans and objectives.

Outside of meetings within our own team, with Dr. Sadik, with Professor De Faria, and with the aforementioned M.Eng alums, our team also met with Dr. Michael Drues to discuss long-term considerations with regard to anticipated considerations for regulation and testing compliant with FDA standards. We have also interviewed William Rodriguez, a muscular dystrophy patient for whom mitigation of pressure ulcers is a very serious concern; Ronald Schauer, the husband of a multiple sclerosis patient who had to routinely care for pressure ulcers; Barbara Abdullah, an RN that works with pressure ulcer risk assessment and treatment as part of her occupation. Meeting notes from several of these encounters can be found in Basecamp.

As a brief summary of the first semester, we spent much of our time familiarizing ourselves with pressure ulcers as well as how patients and healthcare providers alike interface with the condition with existing market options. We identified several segmented submarkets of patients such as wheelchair-bound, bedridden, geriatric, reduced mobility, and spinally compromised patients in both inpatient and outpatient settings. At first, we attempted to identify novel techniques and functionality that could be added to existing solutions (mostly inflatable mattresses and cushions that

alternately inflate over time), but found upon investigation of current options and consultation with current health practitioners that this option would prove exceptionally difficult to market against the established market. Instead, our team decided to focus on the development of a dressing for daily use, a device that could be used as a complement to inpatient standards of care as a method of preventing nosocomial development of pressure ulcers. This provides a therapeutic option that is not currently addressed by the market, provides a cheap solution for developing markets, appeals to physicians by allowing them to directly provide an intervention which will positively influence their patient satisfaction ratings, insurance companies by reducing expenditures related to the development and worsening of pressure ulcers, and patients themselves by reducing the pain and associated difficulties of pressure ulcer development and management.

In the second semester, we designed the disposable and prophylactic pressure ulcer dressing. This required considering budget, device objectives, device components, manufacturing strategies, testing criteria, and testing platform design. For the budget, we had enough funding in the program to design a prototype, and we were given the objective of substantially improving on the existing foam pressure dressing (Mepilex sacral wound dressings) while staying below a budget of $30/weekly treatment for in-hospital use. We considered utilization of drug delivery and encoding diagnostic pressure information into our device, but ultimately decided against both aspects of the project due to complexity of mechanism, cost limitations, and a lack of demonstrated clinical benefit. Ultimately, we decided to take a purely biomechanical approach for pressure ulcer prevention and designed a layered bandage that would optimally redistribute compressive and shear forces away from common sites of pressure ulcer formation. Following successful manufacturing of our prototype, our team designed a testing platform to evaluate our device's compressive and shear forces in comparison to no treatment and the existing bandage. Results from this experimentation confirmed the success of our bandage, and can be observed later in the report.

Background

Pressure ulcers or “bedsores” are among the most common afflictions affecting geriatric and spinally impaired persons, causing tens of thousands of deaths and significantly affecting the quality of life of many others each year. According to the US Department of Health & Human Services, pressure ulcers cost $9.1-$11.6 billion per year in the US, with the cost of individual patient care ranging from $20,900 to $151,700 per pressure ulcer.[1] Due to the tremendous medical costs that pressure ulcers cause, the market for pressure relieving devices is projected to be $2.8 billion in 2020.[2] The leading contributing factors to the formation of pressure ulcers include substantial compression, shear stress, and maceration of the epidermis over approximately two hours, all of which cause tissue hypoxia and necrosis of the underlying capillary bed.

The preventative standard of care for patients at risk for developing pressure ulcers is to turn them over every two hours to ensure that bony processes against the skin (such as the sacrum, ischium, and calcaneus) do not develop pressure ulcers; this is a highly effective, but very costly preventative measure. Device-based solutions such as alternating pressure mattresses are also somewhat effective, but prohibitively expensive for in-home use and difficult to effectively maintain for in-hospital use.

One mechanism of preventing the formation of pressure ulcers would be to more evenly distribute pressure applied to bony processes of the skin, minimizing compressive forces against typically affected areas. Most commercial bandages fail to sufficiently distribute pressure because they rely on a thin foam layer for pressure distribution. Our solution is to develop a novel bandage constructed with a thicker and viscoelastic intermediate layer for pressure redistribution of high-risk areas, presenting a cost-effective method to reduce the incidence of sacral pressure ulcers, one of the most common types of pressure ulcers.

In testing our bandage, conducted shear and compressive tests to compare the pressure mitigation effectiveness of our bandage versus the standard of care bandages. By showing greater distribution of pressure away from sharp processes as shear and compressive forces are applied, our bandage prevents compression of underlying capillary beds and the resultant tissue hypoxia that causes pressure ulcers. Through pressure ulcer prevention, we can justify and recoup costs of the device by preventing the costs of pressure ulcer management and treatment from ever being incurred.

Due to the non-invasive and low-risk nature of the device and regulatory strategies of predicate medical devices, this device can be classified by the FDA as a

Class I medical device subject only to general controls, reducing cost of development and easing entry onto the market.

Background References:

1, Are we ready for this change?. Content last reviewed October 2014. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/systems/hospital/pressureulcertoolkit/putool1.html

2, Pressure Relief Devices Market (Low-tech Devices - Foam Based Mattresses, Gel Filled Mattresses, Air Filled Mattresses and Others & Hi-tech Devices - Kinetic Beds Dynamic Air Therapy Beds) - Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2014 - 2020. (2015, January 30). Retrieved May 22, 2017, from http://www.transparencymarketresearch.com/pressure-relief-devices.html

Patient and Medical Professional Perspectives

Patient Perspectives

We wanted to get feedback from patients and medical professionals on what they believe currently technology or medications are lacking in the treatment of pressure ulcers. Amelia has a friend from childhood and an aunt that are both wheelchair bound during most of their lives.

William Rodriguez is a 33 year old friend of Amelia's that was diagnosed with muscular dystrophy. William has been wheelchair bound for about 20 years. He currently has no pressure ulcers due to great patient care. His care team moves him frequently from left to right every 45 minutes to an hour. He has pillows placed between or under his knees. If a nurse notices a red spot developing on William's skin, she rubs A&D ointment. William has changed his wheelchair for growth, support of the back of his legs, and requiring the ability to adjust the head and leg rests. He is currently using the QuantumX Edge, which has a sponge type of material in the cushion. William has tried the Turn Mobile but found that this wheelchair requiring more sturdy adjustments. He claimed to feel every small bump that he would drive over and this made it painful for him.

Holly Schauer is Amelia's aunt who was diagnosed with multiple sclerosis. She was wheelchair bound from 1995 until she passed away in 2006. Holly had pressure ulcers on her lower back, back of upper and lower legs, and bottom. Her aids would lay her down on her side and direct a fan to her body so that the ulcers could be very dry.

They would rub Neosporin with a pain reliever on the dry ulcers. The aids and aunt Holly's husband, Roland, would move her around in her wheelchair often throughout the day to relieve any pressure directed to the same area. The aids did not use bandages on Holly and the mattress she used as an egg crate mattress. Roland did not like the egg crates because they did not help her with her pressure sores.

Medical Professionals' Perspective

Barbara Abdullah, Amelia's mother, has been a registered nurse for 11 years. She currently works at Eastside Hospital in Snellville, Georgia. Amelia interviewed her mom on the hospital's procedures for skin pressure ulcers. Upon admission, a patient is assessed from head to toe. Any wounds or redness found on the patient's skin is assessed using the Braden Scale. The wound is recorded and a picture is taken. The wound is then reassessed in 7 days. Eastside Hospital's universal skin practice involves using chlorhexidine wipes to clean the area of interest and using aloe vesta for broken skin. Nurses, nurse aids, technicians, and family members are instructed not to massage over boney areas. For patients that require diapers, the diapers are changed often throughout the day. Patients are required to participate in some sort of movement in order to maintain activity levels. Pillows are used for cushioning boney areas and limb support. Heel floaters are used to prevent degradation of the patient's heel. For patients that are at a higher risk of developing pressure ulcers, the patient is turned every 2 hours, required to participate in more activities, seen by a dietician, and have a higher intake of vitamins. At Eastside Hospital, the mattress used for patients at a high risk of developing a pressure ulcer is the Maxy Air by Hill-rom. This particular mattress filters the air through the back of the mattress, which reduces the heating and degradation of the patient's skin. Nurses use various dressings, topicals, and wound draining systems to treat pressure ulcers. The dressings used are wet to dry dressing, Aquaseal, and Duoderm. The topicals used are hydrogel and aloe vesta. Santyl is used only for patients developing necrosis. A wound vac is used for drainage of the ulcer. It is changed every 2 days and usually worn for a longer period of time depending on the severity of the wound. At Eastside Hospital, the Progressive unit has a turning team, where 2 nurses go around the unit and turn patients every 2 hours to help reduce the development of pressure ulcers. The policy at this hospital, and many other hospitals, is that a patient does not usually stay in the hospital upon the development of a pressure ulcer. Patients and their families are instructed on how to do dressing for the wound. The patient follows up with a wound care center or their primary care physician. Insurance does not cover pressure ulcer treatment if it is developed at the hospital because it signifies poor patient care.

Dr. Karim Sadik is a plastic surgeon at Guthrie Hospital in Sayre, Pennsylvania. He often encounters pressure ulcer patients as part of his daily practice, and is the

clinical sponsor of the M.Eng. team. His experience with pressure ulcer repair surgeries and other treatments for late-stage pressure ulcers has indicated that preventative solutions would be most ideal for patient outcomes, as surgeries for late-stage pressure ulcers have high failure rates and often result in unintended complications. He mentioned that Guthrie's current protocol for high-risk ulcer patients (according to the Braden Scale) involves transferring the patient to Clinitron beds and administering Mepilex foam dressings to the patient. He advised against pursuing novel mattresses and wheelchair-based devices due to oversaturation of these markets and limited potential to successfully market these devices in competition with existing solutions, and encouraged the team to emphasize dressings as the best opportunity for our project. This recommendation was primarily due to the portability and ease of use of dressings in both clinical and home settings, their ability to complement current standards of care such as air-fluid mattresses, their low cost relative to other mechanisms of treatment, the lack of established and effective competition in the market for pressure ulcer dressings, and the ability to "market to the limbic system" by offering healthcare professionals an intervention that they could personally provide. This last point is especially important in the increasingly patient satisfaction-dependent reimbursement system: by providing a direct intervention in addition to offering pressure ulcer mattresses, patients will more confidently feel as though their physician is competently providing care and their experience will improve as a result.

System Requirements

Because the device could not be clinically tested before the termination of the M.Eng. program, we decided to evaluate our device using an in vitro model system for compressive and shear forces. Experimental design and results are included later in this report. We decided to focus our device on sacral pressure ulcers, one of the most common types of pressure ulcers, and focused on reduction of pressure observed at bony prominences. We were able to show that on physiological ranges of weight, the Mepilex bandage reduced observed pressure to approximately 2.4 Newtons/cm^2 and and our device reduced observed pressure to approximately 2.0 Newtons/cm^2 when a load applied to skin alone would have resulted in an observed pressure of 2.7 Newtons/cm^2 (approximately the amount of pressure that would result in a pressure ulcer if left for an extended period of time). While both the existing standard and our prototype device reduced pressure, our device would be more preferable to the other device because it would be more successful in reducing incidence of pressure ulcers in markedly obese patients or patients with very poor skin conditions.

Our device's function can be split into three major layers. The outer layer was chosen to have a low coefficient of friction and little water retention to mitigate shear forces and to ensure that the bandage can be worn for extended periods of time (up to 1 week). The middle layer was composed of the Akton Viscoelastic Gel, which conformed to applied pressures and substantially redistributed pressure applied from compressive forces. This layer was wrapped in an adhesive, cotton-like material to enhance breathability of the dressing. The bottom, wound-contact layer was a Mepitel Safetac silicone adhesive dressing, the same dressing used by Mepilex, which allowed for secure and breathable attachment to the skin with non-traumatic removal when changing dressings. The wound contact layer is responsible for 75% of the cost of the device (at post-market rates) and alternatives are currently being explored. One of the most promising alternatives is DuploMED's Soft-Stick adhesive dressing, a pressure-sensitive adhesive that is designed as a more cost-effective alternative to silicone dressings for non-traumatic adhesives for medical applications.

As a purely mechanical device, no notable interface or software requirements were necessary beyond those used for designing our testing platform, which was done with a LabView setup that took inputs from various force-sensitive and stretch-sensitive resistors to measure compressive and shear forces.

Pathophysiology of Pressure Ulcers

A pressure ulcer is the development of localized tissue trauma, or constriction of healthy capillary flow, where soft tissue is compressed between bony and external surfaces for an extended period of time.[2] Healthy capillary pressure ranges from 20 to 40 mmHg, while the average is 32 mmHg. Pressure ulcers can develop within 2 to 6 hours.[3] There are three main causes of pressure ulcer formation: sustained pressure, friction, and shear. Sustained pressure occurs when the pressure exerted on a boney surface exceeds the pressure of the blood flowing in that area. The lack of blood flow decreases the amount of nutrients flowing to that area. The most common areas for this occurrence include the spine, tailbone, shoulder blades,hips, heels, and elbows.[4] Friction occurs when one body rubs against another.[6] Friction can occur if the patient's skin is somehow dragged and there is damage to the skin. Shear is when the patient's skin and material surface are moving in opposite directions causing stress to the skin.[4]

There are two well-known ways to assess the severity of pressure ulcer development risk. The scales used are the Braden scale and the Norton scale. The Braden scale consists of 6 broad clinical categories: sensory perception, moisture, activity, mobility, nutrition, and friction and shear. If the patient's assessment by the nurse receives a score lower than 18, the patient is at risk of developing a pressure ulcer. The Norton scale has 5 broad clinical categories:physical condition, mental state, activity, mobility, and incontinence. If the patient's assessment by the nurse receives a score lower than 16, the patient is at risk of developing a pressure ulcer.The patients who are most at risk for developing pressure ulcers are patients that lack mobility & daily activities, have sensitive skin, loss of bladder control, lack healthy nutrition, and are elderly.[3]

There are 4 stages of development of pressure ulcers. In stage 1, the wounds are closed wounds and the skin is not broken. The skin is painful and appears red and blanched. The skin of the area of interest is warmer than the surrounding area. The area may also present as firm or soft. In stage 2, the skin is broken, tender, and painful. The sore area expands deeper into the tissues. The area appears to be scraped, blistered, or there may be a crater on skin.Sometimes the blisters are filled with clear colored liquid. In stage 3, the ulcer has extended deeper into skin layers. The crater in the skin is deeper. Also, the fat layer becomes visible. In Stage 4, the ulcer extends deeper into the muscle and bone layer. The muscle and bone can be visible and can lead to damage of tendons and joints.

Pathophysiology of Pressure Ulcer References:
1. Paice, Judith A. Physical Aspects of Care. Oxford: Oxford University Press, 2015
2. "Treatment of Pressure Ulcers Guideline Panel." Treatment of Pressure Ulcers. Rockville: Agency for Healthcare Policy and Research. 1994 Dec. No. 15. Web. < https://www.ncbi.nlm.nih.gov/books/NBK63895/>
3. Lyder, Courtney H. "Pressure ulcer prevention and management." Jama 289.2 (2003): 223-226
4. Pieper, Barbara, Diane Langemo, and Janet Cuddigan. "Pressure ulcer pain: a systematic literature review and national pressure ulcer advisory panel white paper." Ostomy/wound management 55.2 (2009): 16.
5. Antokal, Steven, et al. "Friction Induced Skin Injuries–Are They Pressure Ulcers? A National Pressure Ulcer Advisory Panel White Paper." (2012).

Current methods to Prevent Pressure Ulcers

There are a variety of existing pressure ulcer treatment strategies. These include pressure relieving mattresses, debris removal therapies, and tissue regeneration and repair strategies.

I) Pressure relieving

Air-fluidized beds

The bed/mattress is covered in silicone-coated ceramic beads that move with circulation of warm air, creating the characteristics of a fluid. Air-fluidized mattresses can release pressure to some extent which prevent the exacerbation of injury. Due to the fluidic nature of these beds, patients usually can’t get off by themselves. This bed is usually used for patients that can’t move at all. These beds are usually reserved for patients that have already developed posterior pressure ulcers and are highly expensive.

Alternating-pressure surfaces

The mattress has multiple layers and subunits that can be inflated and deflated.Alternate sacs are inflated and deflated, which provides alternating pressure change for the patient. This mattress also prevents the exacerbation of injury but no direct treatment of any already-developed pressure ulcers. The effect of therapy is not significant.

Low-air-loss beds

Mattresses that consist of inflatable upright sacs of semi-permeable fabric. Inflation of sacs will increase the contacting surface between patient and mattress. Some patients report it is hard to get off from the bed individually. The effect of therapy is not clear.

II) Debris Removal

Dextranomer paste

The paste composed by porous beads 0.1 mm to 0.3 mm in diameter. The paste is hydrophilic and can absorb wound debris and bacteria. The therapy is not significant.

III) Tissue Regeneration

Electrotherapy

The treatments of electrotherapy include many types: pulsed electromagnetic therapy,negative-polarity and positive polarity. Electrical fields generated by placing electrodes near awound. Electrical current enhance microcirculation and protein synthesis to heal the wound. In addition, this method can also increase blood flow which increases macrophages in local to clean up debris. Experiments prove effectiveness of this method.

Therapeutic ultrasound

The application of ultrasound to a wound with a transducer and water-based gel. The power of ultrasound waves is relative low to avoid additional damage to patients. Therapeutic ultrasound works through three mechanisms. First, ultrasound can increase blood flow to speed up tissue regeneration. Second, ultrasound can mitigate pains from swelling and edema. In addition, the massage effect of ultrasound softens the tissue to facilitate regeneration.

Topical negative pressure

Continuous negative pressure applied to a wound through an open-cell dressing. A vacuum is applied on the wound through a special sealed dressing. Negative pressure improves tissue regeneration by sucking away waste (fluid) near wound and increase blood supplement to the wound. Negative pressure is very popular and useful treatment for pressure ulcer.

Surgery

Surgical repair is the direct treatment option for pressure ulcers and is usually reserved for severe ulcers (phase 3,4). The necrotic wound under skin is excavated and tissue is taken from another site (or from an ex vivo graft) and new tissue will fill up the wound again over months. However, surgical intervention has high rates of failure and requires patients to spend up to several months in-hospital recovering from the surgery.

Pressure Ulcer Treatment Reference:

Reddy M. Pressure ulcers: treatment. Systematic review 1901. BMJ Clinical Evidence.http://clinicalevidence.bmj.com.proxy.library.cornell.edu/x/systematic-review/1901/overview.html 2015 December. Accessed 2016 2th December.

Pressure Ulcer Prevention

Pressure ulcer is a disease caused by pressure and shear stress. The parts of body with high local pressure and shear stress result in compromised function of the microvasculature in that area, leading to hypoxia and malnutrition. After pressure ulcers develop, they are hard to cure because those observed pressure ulcers are already necrotic and the ulcer as a whole is in stage 2, 3 or 4, where damage is irreversible. In current standards of care, the only method of removing stage 3 and 4 ulcers is surgery; the only other option is daily management of the wound. Although the injured area is usually small based on external observation, the necrotic tissue usually is not superficial; the effects of increased pressure will be most significant near hard tissue (cancellous bone), so the most severely compromised tissues in a pressure ulcer are internal. As a result, surgery leaves a cavity on the damaged tissue, sometimes damaging tissues such as the underlying bone itself.

Whether or not the pressure ulcer is surgically repaired, the quality of life of the patient is hugely compromised. As a result, prevention of pressure ulcer formation must be emphasized over treatment of pressure ulcers. Since the cause of pressure ulcer is based on pressure from compression and shear stress, relieving the pressure permanently or episodically is the key to prevent ulcer pressure. In this part, several preventions are introduced. Although none of these methods can guarantee 100 percent prevention, they can decrease the total cost of pressure ulcer across United states. It should be noted that some of the prevention methods are same to treatment method, because usually prevention can facilitate pressure ulcer treatment.

Identify potential risks

Although some patients develop pressure without conscious, they also have the responsibility to identify potentials risks in the environment. Can the patient move by himself? Is the patient obese? Does the patient have adequate nutrition, or do they have any underlying conditions affecting the circulatory system? By asking more and more question, potential risks can be identified and the pressure on the skin can be managed. Some hospitals evaluate how risky patients are going to develop pressure ulcer and give better preventing methods to patients are more susceptible. Although the risk factors are weighted based on their importance, every risk factor should be taken into consideration for pressure ulcer prevention: age, obesity of patient (BMI), movability of patient (disability), nutrition condition(other disease, especially skin disease) and whether incontinence.

Special mattress / bed

Special mattresses for immobilized patient can greatly relieve the pressure on hip, heel,shoulder and head where usually suffer more pressure than other parts. Water bed, low air low mattress, and Clinitron beds are the special mattress / beds that can release the peak pressure.Note that even only for waterbed there are different designs which lead to different performance.

Pressure ulcer prevention gel /pad

Soft gel is another pressure releasing strategy. Usually the hydrogel pad is attached to patient's heel and hip to release pressure and the pad should be changed every day. Example DermaGel Hydrogel Sheet.

Repositioning

Pressure ulcer may be developed when local tissue is hypoxic over 2-3 hours, so repositioning is a cheap and simple strategy to prevent ulcer. For patients who can’t turn themselves, other people can help them to turn every 2-3 hours. The gold standard of care in-hospital is to have nurses or other patient care staff reposition patients every two hours.

Nutrition

Nutrition is the key component of everyone’s health and it is also important for pressure ulcer prevention. First of all, patients who have ulcer usually have a significant lack of protein intake. Also since nutrition relate to skin health to some extent. In addition, obesity is another factor directly relate to nutrition that can promote pressure ulcer. In a sum, a good nutritional regimen is important including proper hydration and a balanced diet with supplemental protein.

Pressure Ulcer Prevention Reference:
Mcleland, A. (2015). Prevention of Pressure Ulcer (1st ed., pp. 271-279). Springer BerlinHeidelberg.

Stakeholder Analysis

Patients

More than 2.5 million people in the United States develop pressure ulcers annually, and a significantly larger proportion of the population is at risk for developing them. In aggregate, pressure ulcer treatment costs between $9.1 and $11.6 billion dollars in the United States. Pressure ulcers are associated with severe pain, and an estimated 60,000 patients die annually as a result of complications related to pressure ulcer management and treatment. Costs of pressure ulcer management raise significantly in later stages of pressure ulcers, and treatments such as skin grafts are extremely costly and have high rates of failure. The interests of patients can be categorized into safety, cost, convenience, opportunity cost, and perceived risk.

Clinical Outcomes: Simply put, patients want their medical issue to be resolved. This involves not only eliminating the source of the problem, but also reducing any long-lasting side effects of the medical problem and avoiding any unintended consequences of seeking treatment. These may include physical pain and recovery time as a result of treatment, cosmetic changes to the patient, and the introduction of other medical concerns. The current standards of care for pressure ulcers do not adequately satisfy patients' desired clinical outcomes; surgical repair often fails, and many existing devices introduce other complications resulting from their use. As an example of this, alternating pressure mattresses may be loud or uncomfortable when changing which segment of the mattress is inflated, resulting in loss of sleep and general discomfort of the patient. Our dressing would not introduce any secondary side effects resulting from its use, and the external layer of the bandage itself may be designed to roughly match the skin tone of the patient to reduce any cosmetic effects that it would introduce.

Safety: Procedures with known complications may appear routine and acceptable from care providers’ perspectives, but many patients may opt not to undergo procedures due to apparent risks or lowered quality of life after treatment. In the case of pressure ulcers, surgical repair of pressure ulcers offers patients the ability to

completely repair the ulcer. However, even if the surgery were completely covered by insurance, many patients would opt not to undergo surgical repair due to the necessity of keeping pressure entirely off of the site of repair and remaining in the hospital for several months after the surgery. Even after undergoing this procedure, many patients that undergo surgical repair will result in rejection of the repair, which ultimately results in a larger and more severe pressure ulcer than the original ulcer that was repaired. In designing a new treatment for pressure ulcers, it is therefore important to ensure that the severity and incidence of complications are minimized. Our team's solution is to design a dressing that minimizes risk of pressure ulcer development, which is safer for patients due to minimal risk and severity of complications, simple administration and removal, and retained patient agency over the utilization of this intervention to minimize their probability of pressure ulcer development.

Cost: Many novel medical devices and therapeutics are not initially covered by insurance due to their perceived experimental nature. In order to facilitate development and initial testing of our device, as well as encourage its early adoption, low costs are essential. In addition, provision of a cheaper alternative or supplement to existing pressure ulcer technologies expands the potential market of buyers to many countries outside of the United States. Current costs of pressure ulcer management are upwards of $50,000 per patient, up to as high as $130,000 average costs associated with Stage IV pressure ulcers. Therefore, a cheap device that even moderately reduces the incidence of pressure ulcers would substantially reduce costs over time. Patients are particularly sensitive to the cost of healthcare, because even in the case of insurance coverage, many patients will still need to pay for a portion of their treatment. Our dressing solution offers patients the opportunity to reduce development and progression of pressure ulcers for a minimal cost.

Convenience: In short, patients avoid treatments that significantly inconvenience them or worsen their quality of life. These factors can include the availability of the device, its ease of use, and unintended side effects of the treatment. For existing devices in the treatment of pressure ulcers (such as alternating-pressure mattresses), many are not ideal or are extremely difficult to design for home use. For devices such as wheelchair cushions, many patients may elect not to adopt them for the simple reason that the patient may feel embarrassed to use them. Our dressing would offer convenience to the patient by involving simple daily application and removal, and allows the patient to cover their pressure ulcer discreetly to prevent personal embarrassment. Many existing devices such as alternating pressure mattresses also have undesirable secondary effects such as requiring a loud motor or imposing physical discomfort to the patient. Neither of these would be concerns with our dressing because it does not (in its current design) require active motor components.

Opportunity cost: It is also important to consider what the next best option for patients would be. Because a pressure ulcer dressing would be convenient, quick to apply and remove, and relatively inexpensive, the opportunity costs associated with utilization of our device are minimal. In contrast, alternating pressure mattresses are both very costly and have the potential to substantially inconvenience patients. Surgical repair of late-stage pressure ulcers offers an extremely high opportunity cost, not only due to the fiscal cost of the operation and hospital stay, but also due to the several months spent in-hospital and therefore without the agency to continue one's life outside of the hospital.

Perceived risk: Distinguishable from the actual safety concerns of devices and treatments, perceived risk is a result of what the patient believes can go wrong. In the case of surgery, for example, many patients may be afraid of in-surgery complications and mistakes that can occur even in well-established procedures with minimal risk. In adjustable mattresses and alternating pressure mattresses, many patients may fear the potential for a critical failure or loss of power occurring while they are asleep, impacting performance of the mattress. In contrast, applying a pressure ulcer dressing would be little different from applying any other familiar bandage – this is a common method of treatment that the vast majority of patients would already feel familiar and comfortable with. Therefore, perceived risk from a pressure ulcer dressing would be minimal.

Physicians and Other Care Providers

Physicians are also heavily affected by the current status of pressure ulcer management. More than 17,000 lawsuits are filed against physicians annually with claims related to pressure ulcers. This makes pressure ulcers the second most common claim in medical malpractice lawsuits, second only to wrongful death lawsuits. Therefore, improper management of pressure ulcers results in higher premiums of malpractice insurance for physicians in addition to the expected frustration of not having access to appropriate equipment and therapy to prevent and mitigate development of pressure ulcers. Care providers' interests can be categorized into ensuring the agency and accountability of their patients, their patients' clinical outcomes, reimbursement concerns, risks, opportunity costs, and changes to their workflow.

Agency and Accountability: As a core factor of medical ethics, physicians are responsible for representing the best interests of their patients by balancing risks, benefits, and costs to the best of their ability. Our device would satisfy physician agency by providing a cheap, supplemental tool to physicians to provide for their patients. Additionally, a benefit of the physician providing dressings to the patient is that it improves the physician-patient relationship: a patient would be more likely to feel as though their care provider is more invested in their care if they are given a dressing,

rather than if they are merely transported to an alternating pressure mattress. This is especially important to physicians in a healthcare market that is increasingly reliant on patient perception of satisfaction with their physician's care.

Clinical outcomes: In partnership with agency, clinicians are obligated to choose the treatment plans for their patients that best optimize benefits, risk, and cost of the intervention provided. In the context of our device, it can be used as a cheap, supplemental treatment to existing standards that would introduce no significant risk to the patient. With significant benefit, low cost, and negligible risk to the patient, physicians and other care providers would likely be very willing to adopt our device.

Economic impact: Physicians are also concerned with how they will be reimbursed for utilizing a medical device, whether the medical device requires substantial training, whether it significantly disrupts existing workflow, requires purchasing of expensive medical equipment, or renders their current technologies obsolete. Our device would be reimbursed under the same codes as most other medical bandages, would require no major training as its application will be similar to applying any other bandage, does not disrupt existing workflow because it can be removed and applied each day when pressure ulcers are routinely cleaned and managed, does not require expensive secondary technologies, and can be used to supplement their current technologies (rather than render them obsolete). Therefore, our pressure dressing would only provide positive economic impacts on the physician or other caregiver's role.

Risks: With any newly designed product, there is an increased level of clinical uncertainty regarding its efficacy when it is first utilized. Because our device is primarily focused on mitigating development of (and preventing formation of) pressure ulcers, rather than eliminating ulcers that are already present, the success of our device would rely heavily on rigorous clinical testing showing a reduction in development of pressure ulcers without the development of unintended side effects. Physician and care provider risks may also be attributed to changes in liability for the development of medical conditions. Because many cases of litigation occur as a direct result of developing pressure ulcers in-hospital, successful application of our device would substantially decrease potential liability by preventing these ulcers from forming (or at least slowing their progression to more manageable levels). Therefore, with proper clinical testing, our device can be shown to substantially decrease risk for physicians.

Opportunity cost: The physician or care provider's time taken to administer the treatment must also be taken into consideration. Because pressure ulcers are already managed in-hospital, including administration of our dressing would only take a few seconds out of a nurse's or CNA's time to cover up the pressure ulcer after regular daily management. This implies that the time investment necessary in applying a pressure ulcer dressing would be absolutely minimal. This effect is made even more financially justifiable by the fact that hospitals must pay for repair of hospital-acquired pressure

ulcers, so a very minor time investment in applying our dressing could potentially save patients and surgeons many unwanted hours in surgery and recovery afterward. The net effect is reduced strain due to inpatient load and reduced litigation when compared to the existing standards of care.

Workflow: Interventions that are highly disruptive to current provider workflow are rarely integrated quickly into the standards of care. Therefore, the dressing that we are designing will integrate into the already-existing daily management of pressure ulcers. The only additional task after management of a pressure ulcer would be to cover the wound with one of our dressings, an action that would be comparable in difficulty to putting on a simple Band-Aid. Therefore, our device would satisfy the requirement of not causing a substantial change in care provider workflow.

Insurance

Major stakeholders for pressure ulcer prevention treatment, as well as any other medical intervention, are insurance companies. Both private and public insurance companies are responsible for paying for medical treatment in most cases. Insurance companies function to assist patients by covering their hospital bill as well as medical professionals in the case that the patient develops a sickness while staying in the hospital and holds the hospital liable. As of 2008, public health insurance does not reimburse hospitals for conditions developed at the hospital, including pressure ulcers.[1] To prevent this, the hospital does its best to try and prevent pressure ulcers from occurring.

Private Insurance

One of the largest private health insurance companies is Aetna. This company has criterion to define whether or not a medical intervention is necessary and deserves financial assistance. The following four paragraphs have relevant information directly taken from Aetna's website at http://www.aetna.com/cpb/medical/data/400_499/0430.html. According to Aetna's policy, pressure-relieving support surfaces (the current standard technological intervention) are considered medically necessary as durable medical equipment. There are three groups of interventions and their necessity is dependent on the patient's condition. Group 1 refers to support surfaces, group 2 refers to pressure reducing support surfaces and group 3 includes pressure reducing support surfaces.

Group 1 support surfaces include "pressure pads for mattresses, non-powered pressure reducing mattresses, and powered pressure reducing mattress overlay systems". An example of a group 1 support surface can be seen in figure 1. These are deemed medically necessary if the patient is completely immobile (meaning the patient

cannot turn or move their body themselves). If the patient has limited mobility (defined as not making enough movement to prevent pressure ulcers from occurring) or any stage of pressure ulcer on their trunk or pelvis and have either impaired nutritional status or compromised circulatory status.

Figure 1: A group 1 pressure reducing support system includes mattress overlays such as the one on the mattress above. http://www.rentittoday.com/cmsAdmin/uploads/thumb/integrity-home-medical-gel-overlay.png

Group 2 pressure reducing support surfaces include “Alternating Pressure and Low Air Loss Mattresses and Overlays”. An example of a group 2 support surface can be seen in figure 2. These can be implemented if the patient has stage 2 pressure ulcers on the trunk or pelvis and the patient has been on a pressure ulcer treatment program for about a month (and have had used the group 1 support surface) and the patient’s pressure ulcers are getting more severe or have not gotten better in a month. Another case where group 2 surfaces are medically necessary is if the patient has big or multiple stage 3 or stage 4 ulcers on their trunk or pelvis. A final precedent for group 2 surfaces are if the patient has had surgery in the past 2 months involving a skin graft for pressure ulcers and also if the patient has already used a group 2 or group 3 surface in the past 30 days.

Figure 2: A group 2 pressure reducing support system like the above device can redistribute pressure points using air bladders in the mattress. Since it is a low air loss mattress as well, it also blows air out through very tiny holes to keep the patient's skin dry. http://www.rehabmart.com/category/pressure_relief_mattress.htm

Group 3 (see figure 3) pressure reducing support surfaces include “Air-Fluidized Beds” otherwise known as “Bead Beds” can be administered only if the patient has a stage 3 or stage 4 pressure ulcer (except on the feet), the patient has severe limited mobility, hospitalization is necessary without the group 3 surface and the bed is ordered in writing by an attending physician.

Figure 3: Group 3 support systems include air fluidized beds like the one above. This device can provide microclimate management and relieves the most pressure of the three system groups.
http://www.hill-rom.com/contentassets/f51c1b48e2a54ad9958435875d568676/96.jpg

There are many details described in Aetna’s documentation that was left out above for clarity. However, they may be extremely important when it comes to getting reimbursement for a new device. The new device must meet one of these support surfaces in order to be covered by Aetna’s insurance plan. Group 1, 2 and 3 support surfaces have more detailed specifications on this website that we can refer to when trying to classify our finished device.

Public

Medicare and Medicaid have the same classification system as Aetna for describing the unique pressure ulcer prevention devices that are on the market and what necessitates their use. This is because Aetna has based their criteria off of public health insurance criteria.

Stakeholder Analysis References:

1. Bauer, Karen, Kathryn Rock, Munier Nazzal, Olivia Jones, and Weikai Qu. "Pressure Ulcers in the United States' Inpatient Population From 2008 to 2012: Results of a Retrospective Nationwide Study." *OWM*. Ostomy Wound Management, Nov. 2016. Web. 04 Dec. 2016

Market Analysis

Market Gap

As noted by our project sponsor Dr. Sadik, all pressure ulcer preventative devices on the market are either too expensive or not effective. A common device used in clinics is the Clinitron Air Fluidized Therapy Bed. This device (see figure 4) sells for around $35,000 which is very difficult for hospitals to afford. It is also very bulky and difficult for hospital staff to implement effectively.

Figure 4: The Clinitron Air Fluidized Therapy Bed.
http://www.hill-rom.com/contentassets/f51c1b48e2a54ad9958435875d568676/96.jpg

Dr. Sadik also mentioned how Mepilex foam dressing (see figure 5) is often used when therapy beds are not available. These dressings can be placed on areas where pressure ulcers have already occurred to help treat them and prevent them from getting worse. They range between $20-$70 depending on the size of the dressing but are unfortunately not very effective. They are dispensable which also drives the cost up. Other current devices on the market include the low air loss pressure mattress system (see figure 6), the alternating pressure pump and pad system (see figure 7) and pressure ulcer preventative foam mattress overlays (see figure 8).

Figure 5: Mepilex foam dressing applied to the sacrum, one of the most common regions for pressure ulcer development to occur.
http://www.molnlycke.com/Global/Scaled/293x291x1/PageFiles-32642-mepilex-border-sacrum-application.jpg

Figure 6: A commonly used low air loss mattress system like the one above from 4MD Medical ranges from $350 to $4000 depending on the brand.
https://www.4mdmedical.com/index.php/catalog/product/view/id/213710/s/med-aire-alternating-pressure-mattress-replacement-system-with-low-air-loss-36-x-80-x-8/?CAWELAID=120141310000056386&utm_source=google&utm_medium=cpc&scid=scplpDRV14027&sc_intid=DRV14027&gclid=CJO2rJnP2dACFQ8vaQod0SsAHg

Figure 7: Another commonly used device is the alternating pressure pump and pad system like the one above from EVA Medical which ranges from $40 to $700 depending on the model.
https://images-na.ssl-images-amazon.com/images/I/313Z2Zz3I7L.jpg

Figure 8: Pressure ulcer preventative foam mattress overlays like the one above from Sierra Gel run from about $50 to $200.
http://www.carelinemedical.com/products/Sierra-Gel-Overlay-42-x-3/?gclid=CMSHp57R2dACFQQoaQodfzYMcQ

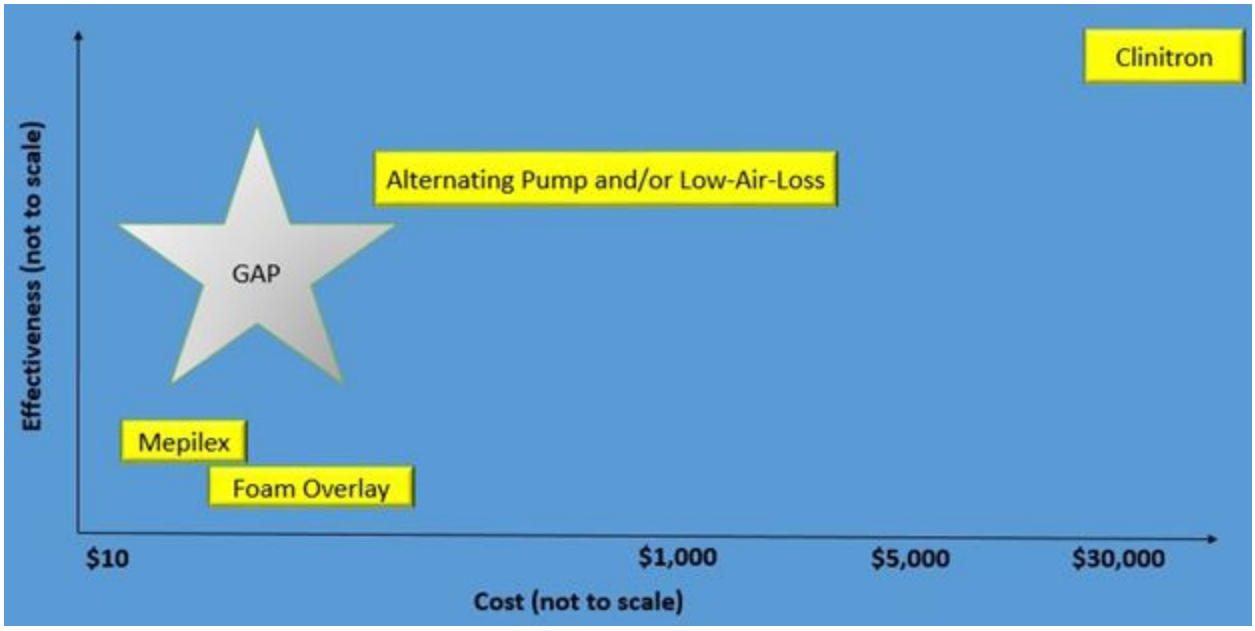


Figure 9: Gap analysis of pressure ulcer preventive and treatment devices. There is a large gap above the foam overlay and the Mepilex bandage. The alternating pump, low-air-loss mattress and the Clinitron are much too expensive while the Mepilex bandage and foam overlay are not effective enough to be practical solutions to the pressure ulcer problem.

Market Segmentation

According to Bauer et al. 2016, pressure ulcers are one of the most common medical ailments in the United States.[1] With more than 2.5 million people developing them annually, the annual cost is about $9.1-$11.6 billion. Pressure ulcer related litigation is commonplace, therefore driving this cost up another $4.25 billion on average per year. Bauer et al. 2016 conducted a study which identified key demographics and statistics related to pressure ulcer development. This study can be used to effectively segment the pressure ulcer preventative market. In figure 10(a) below, the largest demographic to receive pressure ulcers are white females who are on Medicare. However, if you are using the percentage of the total admissions that develop pressure ulcers as a metric,

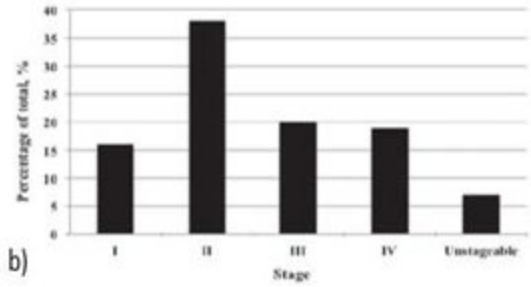
the largest demographic is African American males who are on Medicare. In both men and women of all demographics, figure 10(d) tells us that after the age of 31 the risk of developing a pressure ulcer increases exponentially with the highest risk population being those over 90 years of age. The most common stage of pressure ulcer that exists is stage 2 (figure 10(b)) and the populations of those with the existing disorder of fractures and/or incontinence have the highest risk of developing pressure ulcers (figure 10(c)).[1]

a)

	Total admissions (N)	PU cases (n)	Rate (%)	*P* value
Gender				
Male	16,366,959	325,293	2.0	<0.0001
Female	22,645,567	351,110	1.6	
Race				
White	22,621,329	407,006	1.8	<0.0001
African American	4,979,112	119,113	2.4	
Hispanic	4,160,270	48,212	1.2	
Asian/Pacific Islander	911,360	11,914	1.3	
Native American	244,062	3,467	1.4	
Other	1,221,971	17,019	1.4	
Insurance				
Medicare	14,891,815	515,233	3.5	<0.0001
Medicaid	7,860,927	65,472	0.8	
Private	12,728,058	73,878	0.6	
Self-pay	2,019,929	8,343	0.4	
No charge	192,840	914	0.5	
Other	1,307,235	11,481	0.9	

c)

	With risk factor (ICD-9 code)		Without risk factor		
	Number	Incidence rate (%)	Number	Incidence rate (%)	*P* value
Malnutrition	163,392	11.5	513,043	1.4	<0.001
Hypotension	100,887	5.5	575,548	1.5	<0.001
Peripheral vascular disease	74,579	5.1	601,856	1.6	<0.001
Incontinence	20,787	5.4	655,648	1.7	<0.001
Cerebrovascular disease	86,527	3.8	589,908	1.6	<0.001
Diabetes	251,163	3.2	425,272	1.4	<0.001
Fracture	16,799	2.7	659,636	1.7	<0.001



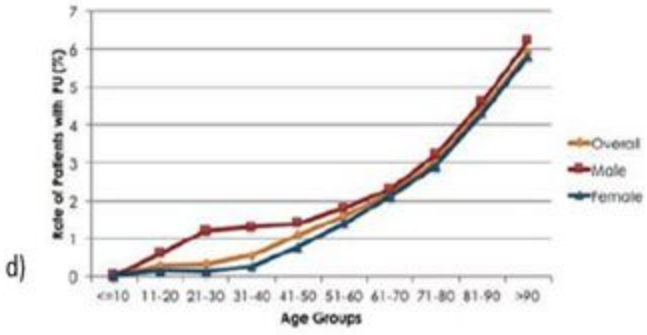


Figure 10(a): The rate of in-patients that have pressure ulcers sorted by general patient demographics such as gender, race and insurance type. (b): Percentage of total pressure ulcer patients sorted by stage of ulcer. (c): The rate of pressure ulcer development sorted by preexisting health condition. (d): The rate of pressure ulcer development in both men and women partitioned by age group.
http://www.o-wm.com/article/pressure-ulcers-united-states-inpatient-population-2008-2012-results-retrospective

Other risk factors for developing pressure ulcers are obesity, lack of sensory perception, having severe weight loss or muscle atrophy, dehydration (similar to malnutrition), excessive moisture or dryness, blood flow related disorders, smoking, lack of alertness and muscle spasms.[2]

Market Analysis References:

1. Bauer, Karen, Kathryn Rock, Munier Nazzal, Olivia Jones, and Weikai Qu. "Pressure Ulcers in the United States' Inpatient Population From 2008 to 2012: Results of a Retrospective Nationwide Study." *OWM*. Ostomy Wound Management, Nov. 2016. Web. 04 Dec. 2016

2. Mayo Clinic Staff. "Bedsores (pressure Sores)." *Bedsores (Pressure Sores) Risk Factors*. Mayo Clinic, 3 Dec. 2014. Web. 04 Dec. 2016.

3. http://www.carelinemedical.com/products/Sierra-Gel-Overlay-42-x-3/?gclid=CMSHp57R2dACFQQoaQodfzYMcQ

4. http://www.aetna.com/cpb/medical/data/400_499/0430.html

Device Design and Feedback

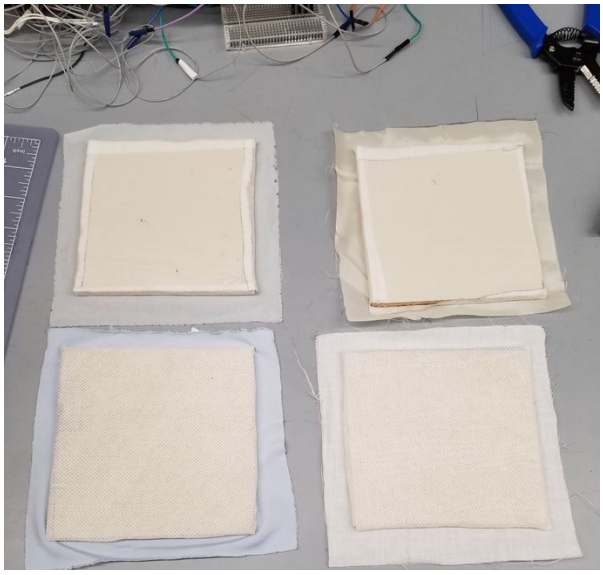


Figure 11: The four versions of the prototype dresing. Top left: White mesh fabric, top right: rayon fabric, bottom left: spandex fabric, bottom right: cotton fabric

Cost of Device:
The price of all device components at the consumer rate is as follows per dressing:
Outer layer fabric: $0.10
Akton viscoelastic polymer: $5
ReliaMed Self-Adhesive Dressing retention sheet: $0.05
Mepitel SafeTac Wound contact layer: $14
Total: $19.15.

These costs (particularly the Mepitel wound contact layer) would likely be substantially reduced when actually producing the device at a larger scale. Because the Mepilex bandage competitor is $10/dressing and performs substantially worse than our prototype bandage, our device is a cost-effective alternative. Because the decision of whether or not to put a prophylactic dressing on the patient is decided based on whether or not they are at high risk for developing pressure ulcers (Braden or Norton scales), and because our device outperforms the Mepilex bandage in preventing pressure ulcers in high-risk cases, our device would be superior as a prophylactic dressing in the market for pressure ulcer prevention.

Reimbursement:

The closest alternative to our product is the Mepilex foam dressing, which is reimbursed under HCPCS Code A6212 and A6213. While this reimbursement code is particular to foam dressings, an analogous code could be utilized for our own device that uses an alternative packing layer.

Professional Consulting:

Dr. Karim Sadik, Plastic and Reconstructive Surgeon:

Dr. Karim Sadik is the project sponsor and our primary contact for the clinician's perspective of the device and its objectives. He allowed the team to observe patients with pressure ulcers to see how they are managed and treated, and additionally allowed observation of a skin graft surgery for treatment of late-stage pressure ulcers. His advice led us to pursue preventative mechanisms of treatment and ultimately a disposable bandage instead of focussing on mattresses and larger-scale, costly devices for mitigation and treatment of existing pressure ulcers. When considering potential features of the device (e.g. providing diagnostic information, potential utilization of transdermal drug delivery, timespan of use of the device and its existing competitors) he was able to provide realistic feedback to more appropriately focus the scope and objectives of our project.

Cornell Material Scientist Dr. Meredith Silberstein:

Dr. Meredith Silberstein, a material scientist from Cornell University was pursued upon realizing that our solution would be primarily materials based. She accepted our meeting request and we spoke of our need for a material that would distribute pressure effectively. Dr. Silberstein told us that important factors to consider were stiffness, the elastic modulus of the material, elasticity, viscoelasticity, what is comfortable to the patient and the surface profile of the back. She then recommended that we conduct finite element analysis to simulate a back and the elastic moduli of a bed, human and the bandage material. Beam and plate analysis was also recommended although we needed a greater background in material science to understand what these were.

Cornell Alumni Team:

A team of Cornell Biomedical Engineering M.Eng graduates (Gaurang Dimir, Ilya Gestin and Dae Hee Yun) were very supportive throughout the entire year of this program. They offered their assistance in any possible way and gave us advice. We conducted meetings with this group several times during the Fall Semester and every other week during the Spring Semester. During these meetings we told them our progress and they tried to help us with the process of ideation and design. They helped us come up with a pitch for our idea and Dae Hee created a 3D CAD drawing of our bandage concept. One idea they proposed was to create a hard outer shell to our bandage to potentially

distribute pressure in a novel way. We considered this idea but then discarded it after realizing that the hard material would likely dig into the patient's skin regardless of how much pressure is being taking off the area of wound generation.

Design Decision Process

While following the biodesign process, our team initially explored alternative avenues for pressure ulcer prevention and mitigation. For much of the first semester of the program, we looked at mattresses and mattress pads and tried to identify potential gaps or inefficiencies in the market. However, we found that this particular niche of the pressure ulcer prevention market was very crowded and therefore not a likely option for successful innovation by our team. On consultation with Dr. Sadik, the M.Eng. alumni team, and several other advisors, we ultimately decided to look into alternative dressings that could supplement the existing market of pressure-reducing mattresses and compete with the comparatively less-bloated dressing market.

We considered incorporating drug delivery into our project in order to tackle pressure ulcer prevention from both biomechanical and biochemical mechanisms, incorporating factors that would facilitate extracellular matrix regeneration and tissue regrowth (similar to Integra, a dressing that facilitates regeneration of burn wounds). However, once we decided to focus on prevention of pressure ulcers (rather than the mitigation thereof), a biochemical approach no longer became feasible or financially prudent. Furthermore, because the site of injury of pressure ulcers originates in deep tissues at the interface between hard and soft tissues (e.g. bone against muscle), any tissue factors that could be delivered through the skin ultimately would not have been appropriately distributed to the target area via a transdermal delivery system. For these reasons, we decided to forego drug delivery techniques in our dressing.

A common point of feedback that we received from engineering advisors was a question of whether it would be beneficial to record and report pressure readings to clinicians. However, in speaking with clinical stakeholders such as Dr. Sadik, having this additional “diagnostic” information was universally disliked. Much of the reason for this is that it would not provide useful additional information for informing patient care, and therefore the extra cost of supplying this information would be met with no practical benefit. We did utilize pressure sensing equipment for the purpose of testing our device and its ability to redistribute pressure, but otherwise no recording equipment is used in our prototype device.

As a result, our final design was a redesigned dressing that focused exclusively on providing an inexpensive, efficient, purely biomechanical advantage for preventing the formation of pressure ulcers. Once we had established this, we merely had to choose an outer layer that would mitigate frictional forces, a middle layer that would mitigate compressive forces, and a wound contact layer that would successfully adhere

without causing trauma to the skin over time or on removal. Selecting and evaluating appropriate materials for each of these purposes was instrumental to our success.

Finite element analysis attempt and considerations

As previously mentioned, the use of finite element analysis for the correct selection of our pressure distributing material was recommended by Dr. Meredith Silberstein from Cornell's Material Science Department. She recommended we use Ansys software, although we attempted to do the simulation using Autodesk Simulation Mechanical due to its much greater simplicity. The finite element analysis model we attempted only included a rectangular box with a chosen elastic modulus and a matrix of force vectors. We lost belief in the value of using finite element analysis to determine the optimal material to distribute pressure in our bandage after realizing how little we could accurately model in the allotted time. Pressure ulcer formation occurs at the interface between bone and tissue so we would have to accurately model this biological system and account for the tremendous variability in patient tissue and bone in the sacral region. We concluded that, our best course of action in determining the effectiveness of pressure distributing materials was clinical experimentation, or the next closest thing, which was experimenting on a simulated skin to bone interface using a porcine skin model.

Theoretical Design

Before we developed a bandage that more effective than general pressure ulcer preventing bandage (such like Mepilex), the functionality of pressure ulcer preventing bandage had to be clarified. Basically, pressure and shear stress are two fundamental factors that lead to pressure ulcers. However, pressure and shear stress are also dependent parameters that are difficult to independently control. For this reason, some sub-fundamental factors, such as friction between skin and cloth and skin moisture that could influence pressure and shear stress are controlled for in our experimental setup. These fundamental factors plus sub-fundamental factors are parameters that need to be tested further to improve our bandage.

Pressure Redistribution

Since the most important reason lead to pressure ulcer is high and persistent pressure at local tissue, pressure ulcer preventing bandage could also be called pressure-redistributing bandage. For the aspect of pressure, both intensity and duration

are crucial for pressure ulcer development. Since the duration of pressure is hard to be changed by doing any design of bandage, our group members decided to minimize the intensity of pressure at local tissue. After brainstorming, we identified that the shape of bandage and the pressure redistributing layer in the middle of bandage could be changed to decrease the intensity of pinpointed pressure.

Speaking about shape of pressure ulcer bandage for sacral part, almost all of the existing bandages are flat and made by stacking up different layers. Such shape design is too simple and has no attributes to decrease the intensity of pressure. For this reason, a donut shape is camed up for the sacral ulcer bandage. The donut shape bandage is the design that can avoid the contacting in the center, thus almost fully eliminates the pressure. Actually, such donut shape design is not the first time used to relieve pressure. There are couple of cushions and sofa are designed in this shape to relieve the pressure on the buttock.

Pressure-redistributing layer is the most thick layer in the bandage and it works by increasing the contacting area to decrease the peak local pressure. Because of such characteristic, pressure-redistributing layer generally elastic and shape-memorial. Our competitor, Mepilex Border Sacrum, uses a thin sheet of polyurethane foam as the pressure-redistributing layer, but the layer is too thin and not every elastic. To improve the pressure-redistributing layer, a viscoelastic polymer is decided to use. This polymer is also used as cushion to prevent pressure ulcer for patients on wheelchair.

Decreasing Shear Stress

The theory of shear stress is relative vague compared with pressure. Although both high pressure and shear stress finally lead to local tissue necrosis due to capillaries block, pressure leads to vertical tissue deformation whereas shear stress leads to horizontal tissue deformation.

According to the equation of shear stress, the first thing to do is decreasing shear stress, which also means decreasing the horizontal force between bandage and cloth. The horizontal force here is actually the friction between bandage and cloth, and friction force can be decreased by using smooth fabric with low friction coefficient such as ambince lining fabric (100% Rayon), blue brushed fabric (100% spandex) and white mesh fabric (90% Nylon, 10% Spandex). To optimize the result, three candidates were chosen for the outer layer of bandage and deformation tests will be conducted to find out the one with lowest friction coefficient.

In addition to directly decrease shear stress by controlling friction force, the whole body of bandage could be more soft, elastic and thicker to disperse the shear stress conduction from outer layer to skin. For this case, the viscoelastic polymer that used for redistributing pressure is also good at decrease shear stress. Compared with

polyurethane foam, the polymer is much more elastic which means better performance in decreasing shear stress.

Temperature, Humidity and Skin Condition [2]

Except those two fundamental factors, many risk factors that are sub-fundamental but also unignorable for pressure ulcer development. Although there are more than ten sub-fundamental factors, three of them are identified that could be applied to improve the bandage.

First of all, the risen temperature of tissue under bandage can promote pressure ulcer. As introduced, pressure ulcer is actually tissue necrosis and tissue necrosis is due to cell death. The risen temperature increases the cell metabolism which means those cells need more blood supplement and finally speed up cell death. In addition, vapor retention below bandage can also compromise the effectiveness of the bandage. Without bandage, sweat can vaporize easily to keep the skin dry. If the bandage makes the skin too moisture, the surface of skin will be more rough which means increasing the shear stress between skin and bandage, bandage and cloth. As long as the bandage is on skin, the temperature and humidity of local tissue and skin must be higher than normal condition, and the only way to minimize the accumulation of temperature and vapor is increasing the breathability of the bandage. Unfortunately, the breathability of viscoelastic polymer is very poor. For this reason, perforation on viscoelastic polymer is planned to increase its breathability. Because of the time and lack of the equipment, this feature hasn't been applied to the prototype yet.

Skin condition is another factor considered. Since our bandage is designed both for patients already have pressure ulcer and patients don’t have pressure, the damage from the adhesive layer of the bandage to patient’s skin need to be considered when the bandage is peeled off. For patients already have pressure ulcer, the cuticle of skin is more fragile. If the adhesive layer of bandage is too sticky, the cuticle will be damaged. Without the protection of cuticle, patients will be more likely to develop pressure ulcers. Mepitel® is the optimal adhesive layer used in our competitor’s bandage [1] due to its less damage to cuticle, and it is also used as the adhesive layer in our delivery.

In a sum, our new bandage should be theoretically more effective than Mepilex border sacrum for several aspects:

1), Lower peak pressure due to donut shape design and more effective pressure redistributing layer(viscoelastic polymer)

2), Lower shear stress due to more smooth outer layer(white mesh fabric) ,and thicker and more elastic layer(viscoelastic polymer)

Theoretical Design Reference:

1, SMTL Dressings Datacard. (n.d.). Retrieved May 22, 2017, from http://www.dressings.org/Dressings/mepilex-border-sacrum.html

2, International review. Pressure ulcer prevention: pressure, shear, friction and microclimate in context. A consensus document. London: Wounds International, 2010.

Experimental Design

Our experiment was modeled after a paper in the Journal of Wound Repair and Regeneration, which used a Predia pressure and shear force sensor to measure the effectiveness of wound dressings for the reduction of pressure as well as shear forces.[1] Their experimental design included porcine skin, which was used to model the pressure distributing properties of human skin during the application of a weight. The pressure and shear force sensor was placed underneath the skin to measure these two quantities simultaneously. Both interface pressure and shear forces are two commonly known factors responsible for pressure ulcer formation. Unfortunately, we could not find a distributor for the Predia sensor and the current pressure measurement systems are very expensive.

A pressure sensing mat was constructed using a matrix of force sensors about 1.26 cm in diameter. This mat was placed on a hard plastic mannequin buttocks (see Figure 11 below) which was used to simulate the shape of the sacral region. This is the region our prototype was designed to be placed upon and the most common region of pressure ulcer occurrence. A 7”x8” abdominal piece of fresh porcine skin (about a ¼” thick) was then obtained from Schrader Farms and draped over the force sensors. Weights were then placed on top of the entire setup in order to simulate the weight of the patient’s bony prominence in this region while the sensor data was recorded (see Figure 12 below). Prior to measuring the pressure data of each bandage a small weight was used to calibrate the sensors.

Figure 12: A matrix of 15 force sensors were used to approximate pressure on a sacral region of a mannequin.

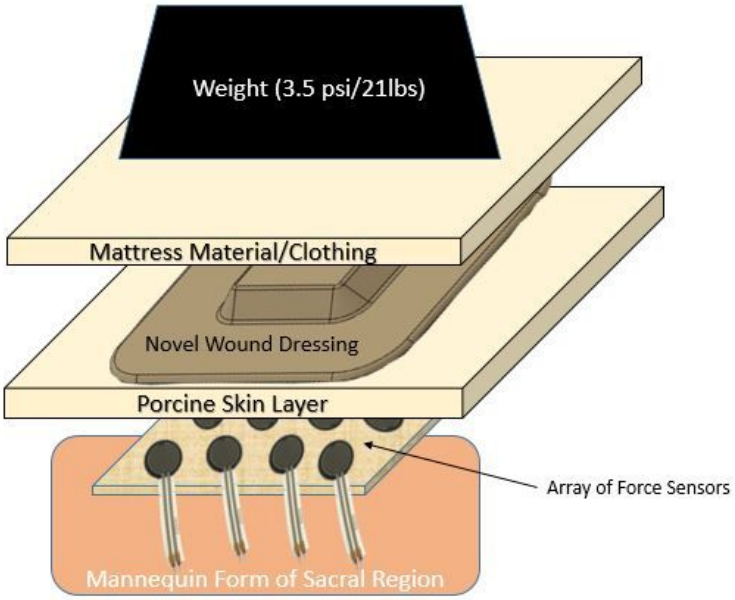


Figure 13: The experimental setup used to test the effectiveness of our bandage at distributing pressure.

Attempting to purchase a strain sensor was next to impossible. Therefore, a tissue deformation experiment was constructed in lieu, in order to measure the deformation of porcine skin, another major cause of pressure ulcer formation. Deformation testing was conducted with four stretch sensors (see Figure 13 below) that were placed in the same location as the force sensors mentioned above. In order to test deformation of the skin due to a horizontal force, the mannequin setup was placed at a 20 degree angle while the weights were being administered. Therefore, if the weight was 45 N, the horizontal force applied to the pig skin was about $45cos(20)$ N or about 42 N. Each stretch sensor was stitched into the pig skin to ensure that the sensor would stretch in tandem with the pig skin. The stretch sensors were calibrated by noting the voltage corresponding to a 5, 10,15 and 20 mm stretch of the sensor. The correspondence between mm stretched and voltage output were noticeably exponential.

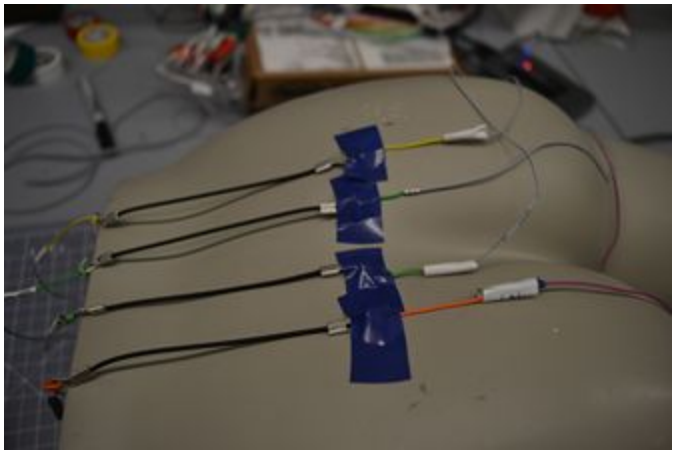


Figure 14: Four stretch sensors fixed to the sacral region of a plastic mannequin.

Data was acquired with special thanks to Dr. Newton de Faria for generously setting up a MyRIO with a multiplexer to channel all 15 analog force sensors into a PC simultaneously. He also connected the stretch sensors to the MyRIO and wrote a LabView program to demux the signals in the PC. The data was obtained directly from this program during experimentation and then analyzed using Microsoft Excel.

Experimental Design Reference

1. Ohura T, Takahshi M, Ohura N. Influence of external forces (pressure and shear force) on superficial layer and subcutis of porcine skin and effects of dressing materials: Are dressing materials beneficial for reducing pressure and shear force in tissues? Wound Repair Regen. 2008; 16(1):102-107.

Experimental Protocol

A total of 5 unique bandages were tested, 4 of them included our designed bandage, each with a different fabric comprising their outer layer and the 5th was our main competitor, the Mepilex sacral bandage. The different fabrics tested, as previously mentioned, were rayon, spandex a white mesh made of 90% nylon and 10% spandex and a 100% cotton fabric. These tests were compared with a control test that involved the experiment with no bandage.

To test the effectiveness of the bandages at distributing pressure, the following protocol was followed:

1. Calibrate force sensors using small weight.
2. Place the pig skin over the sensors
3. Wait for data output to stabilize.

4. Place the bandage that is being tested (or no bandage in the case of the control) on top of the skin layer and over the mannequin's sacral region.
5. Wait for data output to stabilize to record pressure with no weight added.
6. Apply a 10 pound weight vertically positioned over the mannequin sacral region and pig skin.
7. Wait for data output to stabilize, then remove weight.
8. Apply a 10 pound weight horizontally positioned (flat) over the same region.
9. Wait again for output to stabilize, then remove weight.
10. Apply a 20 pound weight vertically positioned over the same region.
11. Wait for output to stabilize, then remove weight.
12. Repeat steps 1-11 while exchanging the bandage.

The experimental protocol to test the deformation of the pig skin under a horizontal force was as follows:

1. Calibrate stretch sensors by measuring their outputs while stretched at 5, 10, 15 and 22 mm.
2. Tilt the mannequin at a 20 degree angle.
3. Place the pig skin over the sensors.
4. Wait for data output to stabilize.
5. Place the bandage that is being tested (or no bandage in the case of the control) on top of the skin layer and over the mannequin's sacral region.
6. Wait for data output to stabilize to record pressure with no weight added.
7. Apply a 10 pound weight horizontally positioned (flat) over the mannequin sacral region and pig skin.
8. Wait for data output to stabilize, then remove weight.
9. Apply a 20 pound weight horizontally positioned over the same region.
10. Wait for output to stabilize, then remove weight.
11. Repeat steps 1-10 while exchanging the bandage.

Results Analysis

The peak pressure results from compression testing are depicted below:

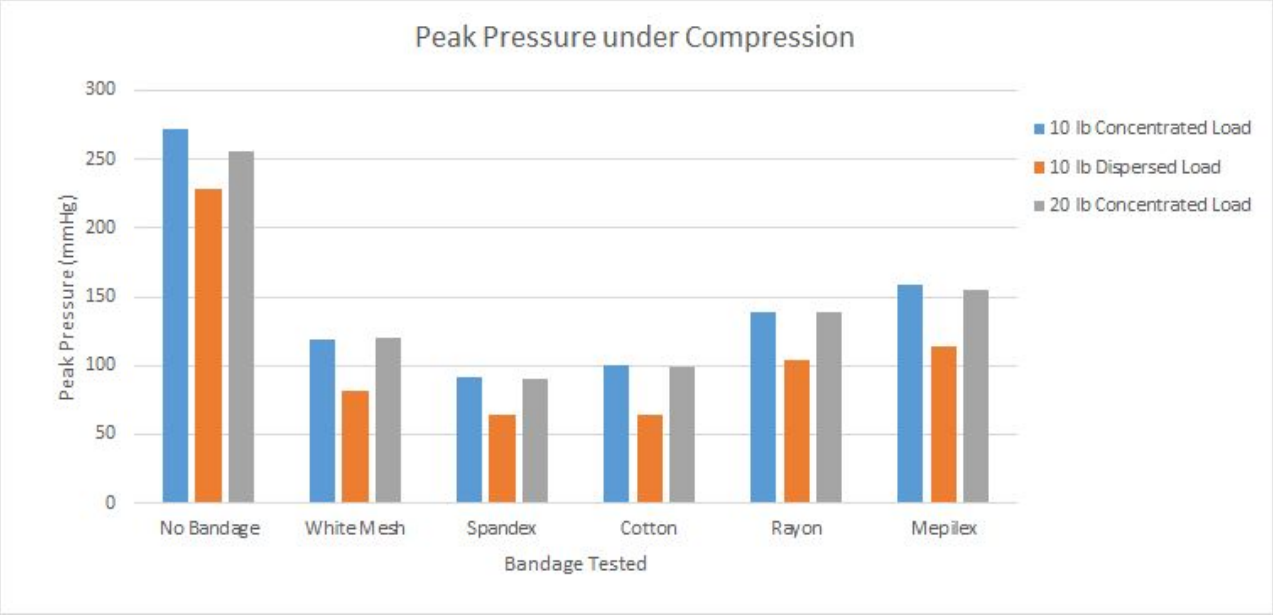


Figure 15: Results of compressive load tests, comparing “No bandage,” the prototype bandages, and the Mepilex bandage.

As you can see, our bandages, specifically the ones with spandex and cotton outer layers, appeared to reduce interface pressure almost twice as much as our competitor, the Mepilex bandage and below the pressure threshold generally known to cause pressure ulcers (~200 mmHg). These results are consistent with different weights and pressure, as noted in the legend. Concentrated load refers to a weight placed “pin point” in the sacral region, while dispersed load refers to the weight laid flat over the region.

Contour maps displaying the pressure distribution in the sacral region were generated from each of the sensors during each experiment. They are depicted below:

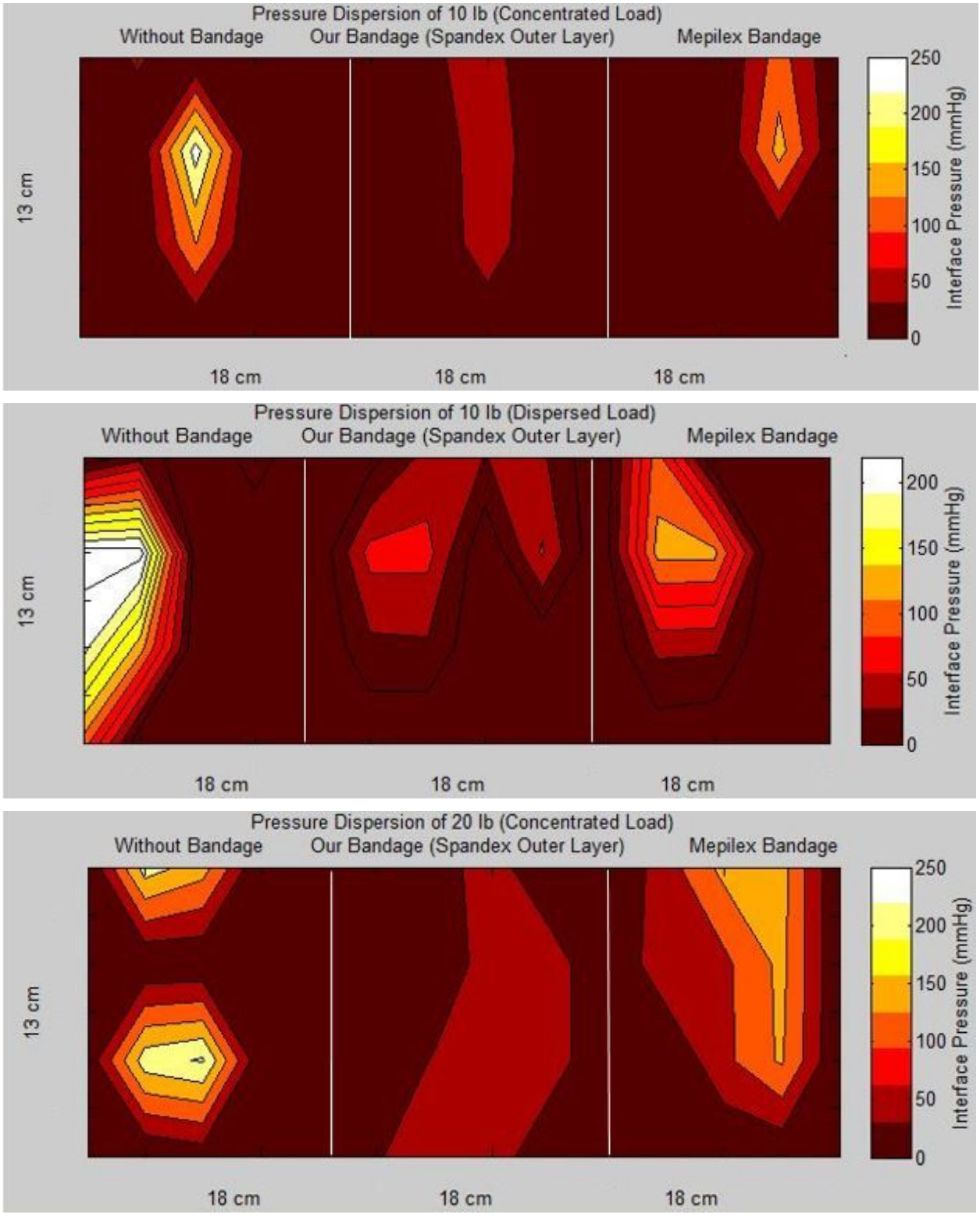


Figure 16: Contour diagrams of pressure distribution in 10lb concentrated load (top), 10lb dispersed load (middle), and 20lb concentrated load (bottom) test cases. 200 mmHg indicates high risk of pressure ulcer formation.

As you can tell, our bandage, specifically the one with the spandex outer layer, dispersed pressure much greater than no bandage at all and our competitor, the Mepilex.

The results from our porcine skin deformation tests are as follows:

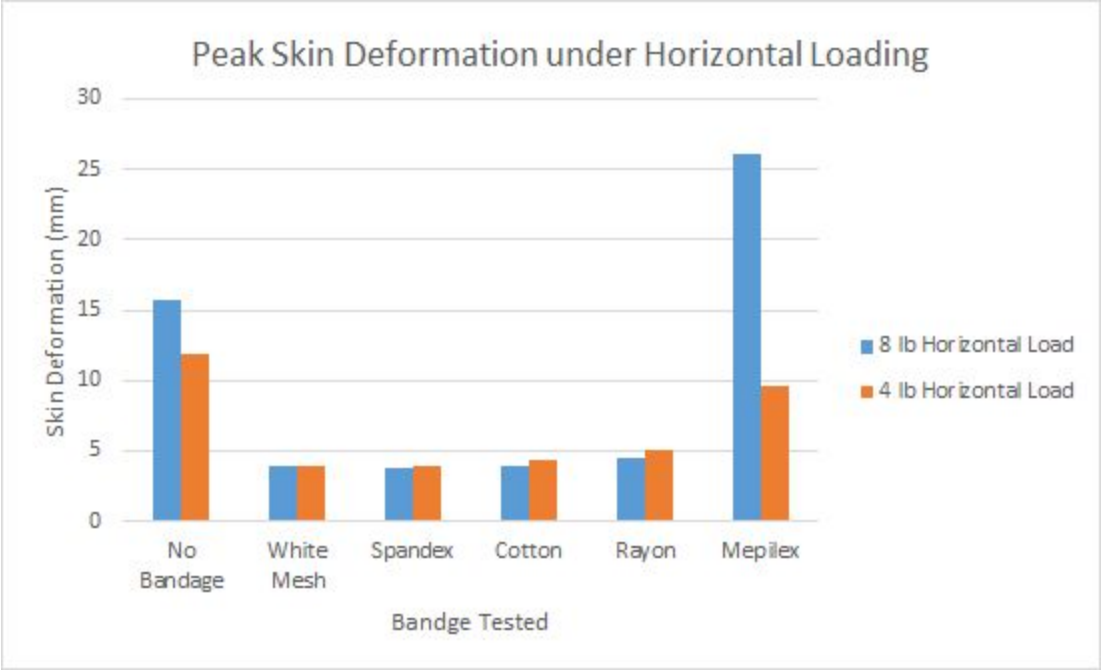


Figure 17: Effect of shear force on peak skin deformation in no bandage, test bandage, and Mepilex cases.

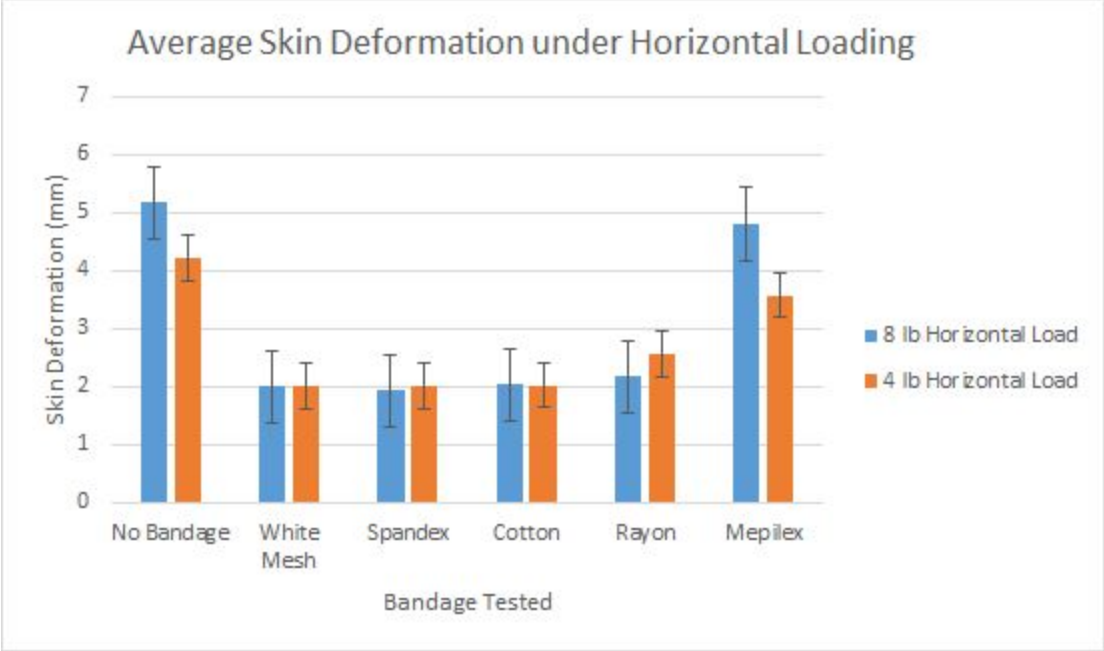


Figure 18: Effect of shear force on average skin deformation in no bandage, test bandage, and Mepilex cases.

As you may be able to determine from the graphs above, our bandages all seemed to reduce peak and average skin deformation under horizontal forces by about twice as much as our competitor, the Mepilex. There seems to have been an error in measuring the skin deformation under the 8 lb horizontal force with the Mepilex bandage. Perhaps a more robust experimental setup for skin deformation would have prevented this.

In conclusion, our bandages proves to be a much better alternative to the Mepilex bandage when considering three major contributing factors to pressure ulcer formation: peak interface pressure, pressure distribution and skin deformation. In addition to these optimistic results, clinical trials or animal testing would be able to empirically demonstrate that our bandage would actually reduce the incidence of pressure ulcers.

Future Objectives

Shape design and materials considerations

Currently, the shape of our prototype is a simple rectangle. This was done to simplify manufacturing procedures while designing the prototype for bench testing, but through finite element analysis we could identify potentially more optimal shapes of dressings for distribution of pressure in the sacral region. Performing this simulation would allow us to empirically test a few optimized shapes, and therefore determined what design would be the best for our purposes.

As for materials, due to the high cost of silicone adhesives and the growing market for low-cost alternatives to silicone adhesive dressings, it would also be best to wait for development and commercialization of these dressings before bringing our product to market. Inclusion of a low-cost but non-traumatic adhesive would cause our dressing to be even more competitive in the prophylactic pressure dressing market. Consideration of other viscoelastic packing materials may also be beneficial if more inexpensive options are available, but the Akton polymer has proven both inexpensive and effective at pressure distribution, and so this may not be necessarily substituted in future product designs.

Microenvironment test

An additional factor in determining the effects on pressure ulcer formation is the moisture and potential maceration of skin - that is, “waterlogged” skin is more fragile and more likely to tear and ultimately form lesions such as pressure ulcers. Dressings of all types potentially cause moisture buildup and maceration of the skin, so it is important to conduct microenvironment moisture and humidity testing to ensure that this isn’t a concern with our relatively bulky dressing. Given that this issue was not observed with the Mepilex bandage, which uses the same wound contact layer as our own prototype, this is unlikely to cause a concern upon testing.

FDA

As a non-invasive dressing with a wound contact layer that is already used and well-established in other medical devices, our device would easily be considered a Class I device by the FDA, posing minimal risk to the user. As a Class I device with many substantially equivalent devices on the market, we could pursue a 510(k) to receive clearance by the FDA without costly clinical testing. Predicate devices would include the Akton polymer overlay and the Mepilex foam dressing for pressure ulcers.