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A Pressure Ulcer Patch Material Study for a Wearable Sensor

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A Pressure Ulcer Patch Material Study for a Wearable Sensor

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Table of Abbreviations

ANDA……..	Abbreviated New Drug Application
ASTM……...	American Society for Testing and Materials
CAD…….....	Computer Animated Design
FDA……..	Food and Drug Administration
PCB……..	Printed Circuit Board
IRB……...	Institutional Review Board
M.A.P.™……..	Monitor Alert Project™
MQP…….	Major Qualifying Project
NR……	Normalized Results
WF……	Weighting Factor
WPI……...	Worcester Polytechnic Institute

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Abstract

A system is needed to prevent pressure ulcers and to relieve some workload that medical professionals must take on in order to care for patients susceptible to pressure ulcer formation. Currently, an electronic pressure sensor is being developed that would alert a healthcare professional that their patient is at risk of forming a pressure ulcer. Medical material studies were conducted to determine which material would best adhere this wearable sensor to the body for a maximum of seven days and not cause skin irritation, while protecting the electronic components. The final patch was comprised of Tegaderm™ Film Dressing by 3M Co. in an "I" shape. This design was able to remain adhered to the body for upwards of seven days, did not cause more than mild skin irritation, and was able to resist water penetration. Future work should further test different shapes using the sensor on different parts of the body while obtaining larger sample sizes for more robust conclusions.

Executive Summary

Pressure ulcers are localized tissue injures that are common in hospital settings and paralyzed individuals. Often they develop due to increased and prolonged pressure at bony prominences restricting blood flow and causing tissue death, but shear and frictional forces contribute to the degradation of the tissues as well. Over 1 million people develop these sores yearly and 60,000 people die due to pressure ulcer related complications, so there is a significant need to prevent them [1].

The current gold standard for preventing pressure ulcers is to have nurses turn patients every two hours, but this is time consuming and so can often not be performed effectively [2]. Additional strategies to prevent pressure ulcers include offloading that uses cushions to disperse pressure from bony prominences, pressure mapping to monitor pressures over the entire, and wearable sensors that track the motion of the patient to ensure the patient is being turned [3-5]. While all these methods have their merits, there is still not an affordable system that systematically measures various local conditions and uses that information to alert a medical professional about an impending pressure ulcer.

Currently a WPI PhD student and a separate MQP team is working on a sensor to help prevent pressure ulcers by measuring pressure, temperature, and moisture [6]. Our team was tasked with developing the adhesive packaging that would house this disposable sensor and adhere it to at risk areas of the body. Additionally, this patch needed be comfortably worn for seven days, water resistant, and biocompatible while costing less than twenty dollars.

To address this design problem, the MQP was divided into two major parts: the material selection process and the development of the patch shape. ASTM standards for assessing elastic modulus, water resistance, and adhesive shear, peel, and loop tack strengths were adapted to form the protocols that the team followed to analyze the mechanical properties of fourteen adhesive medical products [7-11]. This would determine the material to use for the patch. Elastic modulus determined if the material would bend with the body without pulling and damaging the skin. Water resistance was important for ensuring the electrical components will not be damaged or short on the person when they bathe, sweat, or soil themselves. Adhesive shear strength determined if the material would be able to remain attached to the skin throughout normal wear of the patch. Adhesive peel strength ensured that the patch would not damage skin upon removal. Adhesive loop tack determined if a recently, but incorrectly, placed patch would be able to be removed and readjusted easily and without damaging the skin.

The data from these tests were entered into a design matrix using differing weighting factors for each test based on the importance of the test on the performance of the patch material. Using the top two performing materials from this process, a duration study was performed on the team members according to an FDA guidance document for assessing transdermal patches in order to determine which material adhered the longest in practice. From this test, it was determined that Transpore^{TM} by 3M Co. adhered significantly better throughout the course of the study.

Later in the MQP, a WPI IRB approved user questionnaire was performed to determine which preliminary patch shape designs would be most intuitive to people in order for the sensor component to record accurate measurements. Using this information and additional user feedback, the team created two updated patch designs an “I” shape and a “cross” shape. With these shapes, another duration study was performed like before, but using the full patch shape and Transpore™ on the team members’ heals and elbows. This verified which shape was best and validated that the patch remained adhered for the seven days. Due to notable skin irritation, the material for this study was replaced with the next best material, Tegaderm™ by 3M Co., and the results of the test yielded that the “I” shape performed best out of the two designs.

As two final validation studies, the full “I” shaped patch using Tegaderm™ material was tested for water resistance the same way as the previous material water resistance test. This test proved that the patch could withstand being in contact with water for five hours. Finally, the team coordinated with the electronics MQP team to perform testing of the flex circuit board component integrated inside the patch. When this was done, the electronics team confirmed that the sensor was still reading pressure, temperature, and moisture measurements. When this integrated patch was put on a team member’s elbow, she noted that it was comfortable and able to stretch and bend with the arm, and she could not feel the electronic components because of the polyethylene foam padding layers.

The final patch was comprised of Tegaderm™ Film Dressing by 3M Co. in an “I” shape. The team recommends future designs using rounded corners to reduce stress concentrations at these points that could cause the patch to tear or detach from the body causing it to fail. Further testing should be conducted using different shapes on different parts of the body and obtaining a larger sample size for more robust conclusions. Additional tests should include the electronic components integrated in the patch to determine if they remain functional and accurate for the full seven days.

CHAPTER 1: Introduction

Pressure ulcers are localized injuries that form due to bony prominences causing localized tissue ischemia. This lack of blood circulation results in necrosis of these underlying tissues and open sores that can become infected, and in some severe cases, cause death. Approximately 1 million people in the United States alone are affected by pressure ulcers each year, and of this population, nearly 60,000 people die as a direct result of pressure ulcers [1]. This ends up adding up to 3.7 billion USD each year in just lawsuits and litigation and 11 billion USD for treatment [1]. Therefore, there is a significant need to find a prevention system to avoid the consequences that come with pressure ulcers.

Currently, there are a few methods to prevent pressure ulcers from occurring. The standard method in hospitals is patient turning. This involves a healthcare professional, such as a nurse, physically turning the patient every two hours to relieve pressure in certain risk areas that are known to cause pressure ulcers [2]. Although this is an effective method, it can be quite time consuming for healthcare professionals, and for this reason, it often fails since they are unable to do it efficiently [2]. Another common method is offloading, which involves padding certain risk areas to relieve excessive pressure. This can take the form of adding extra pillows under a patient or using specialized beds. However, this can often be expensive and only applies to certain areas of the body [5]. Recently, pressure mapping beds have been developed. This system monitors the patient in their hospital bed and can indicate that a pressure ulcer may form when pressures exceed a certain threshold. Unfortunately, the bed's coordinate map is according to the bed and not the patient [3]. This method would not be able to detect that the patient may be moving in their bed while still applying pressure to the same part of their body. Not only is there a need to find a prevention system, but there is a need to find a more effective and affordable prevention system.

A graduate student at Worcester Polytechnic Institute (WPI), Devdip Sen, is currently developing a sensor (Figure 1.1A) that would be able to detect pressure ulcer formation before it actually occurred [6]. The finished product will be a flexible printed circuit board that will be able to measure pressure, temperature, and moisture and alert a healthcare professional that their patient is at risk of forming a pressure ulcer. Although this is a useful, novel sensor, it will not be able to collect data if it is not properly adhered to the body. This was the problem the team sought to solve. The team was posed with the task to find a material that would be water resistant, biocompatible, and comfortable to the user that would remain adhered to the body for a maximum of seven days. In addition, the team was also posed with designing the shape of the patch that would hold the flexible printed circuit board (flex PCB) with the sensor. The patch design (Figure 1.1B) needed to be such that it would meet the goals of the project when placed on heels and elbows which are two major locations where pressure ulcers form. After conducting various verification and validation tests, the team was able to identify the most appropriate patch material and shape to meet the needs of the project.

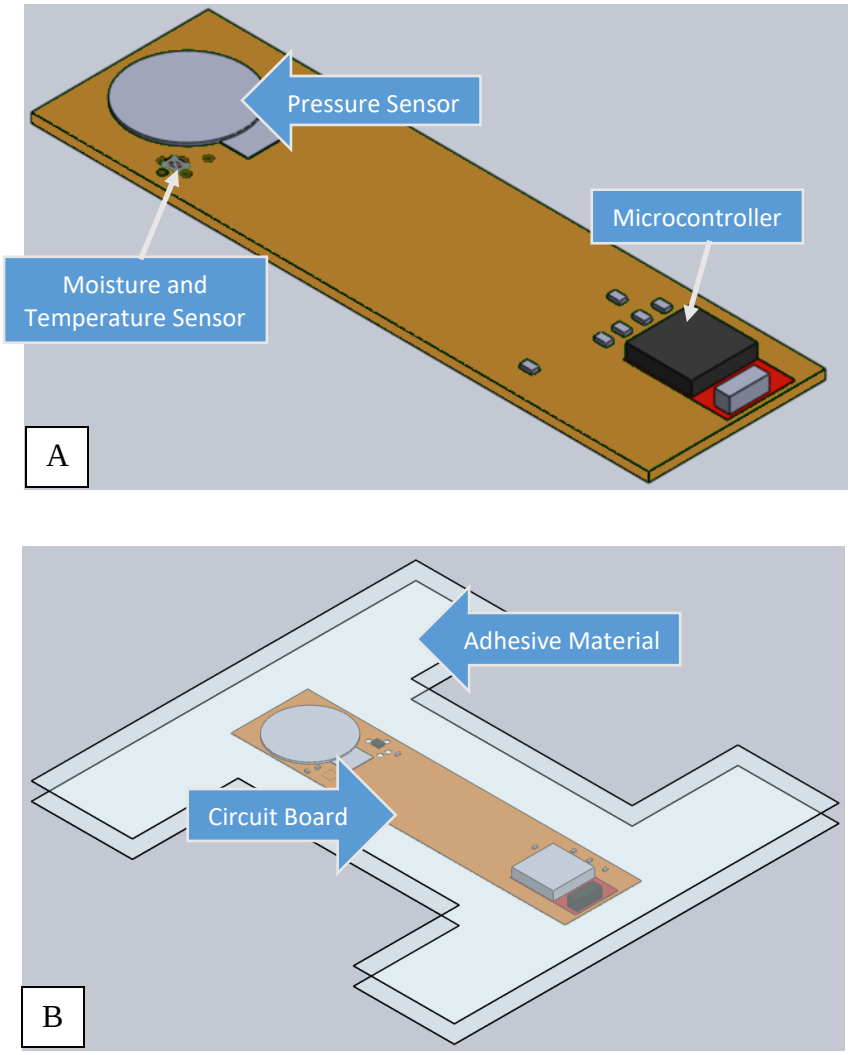


Figure 1.1: Flex PCB Developed by Electronics Team (A); PCB Encased in Adhesive Patch (B)

The team tested several adhesive medical products with different backing and adhesive material combinations. These tapes were put through a series of five different material tests which were adapted from different standards published by the American Society for Testing and Materials (ASTM). These tests were chosen based on the client statement with which the team was presented.

The first test the team conducted was an elastic modulus test. The material chosen for the final application should be as compliant as human skin, so the user's skin would not be irritated by this material. The second test focused on the shear strength of the material. Shear forces are often applied on a patient when they shift in a hospital bed, so the medical adhesive should be able to withstand these shear forces to stay in place on the patient. The third test was a peel force test that ensure that the material would not damage the skin when removed. Next, the team looked into water resistance. This was a particularly important property for this application because patients will be bathed or may soil themselves; therefore, water resistance is important to protect the electronics and the patient. Lastly, the team looked into loop tack force to ensure

the medical adhesive material was not cumbersome to use or damaging to the skin if it was placed incorrectly and needed to be repositioned.

The raw results were normalized and multiplied by the weighting factor that corresponded to the specific material test. From background research, the team assigned the weighting factors to the material tests in an order that the team believed were most important to consider when choosing the material. To ensure the weights were appropriate, these weighting factors were confirmed with the plastic surgeons also involved with the project who work with pressure ulcers daily at University of Massachusetts Memorial Medical Center.

The team conducted a duration test of the top two materials from these five tests for two reasons: 1) to decide which material was the best for our application and 2) to see if there was any difference in adhesion when using an AllKare® Protective Barrier Wipe by ConvaTec Inc.. Small samples were adhered to the team member's skin, some with the barrier wipe and some without, and observed for ten days. This duration test revealed that the material that stayed on the longest was Transpore™ surgical tape by 3M Co. and the use of the AllKare® Protective Barrier Wipe made no significant difference.

To further ensure this was the best possible material for the patch, the team wore patches made of Transpore™ tape with mock flex PCBs and observed how the patches adhered on their elbows and heels. After three days of observation, the team members concluded this material was a failure with respect to biocompatibility and comfort. The team members experienced itching, skin tearing, and skin deterioration while wearing the Transpore™ patch, which lead us to conduct the test once more with the second material, Tegaderm™ Film Dressing by 3M Co. This material was able to stay on the body for an average of 5 days while also remaining comfortable. The team concluded that Tegaderm™ Film Dressing by 3M Co. was the best material to use for this application.

In addition to material tests, the team looked into the shape and design of the patch itself. After a process of brainstorming and redesigning, the team created three major designs: a rectangle shape, an "I" shape, and a "cross" shape. The team wanted to gauge how intuitive the patch shape would be, because if the shape was not intuitive, the sensor would not be applied correctly and therefore become ineffective. Feedback from a questionnaire led the team to conclude that the "I" shaped patch was the most intuitive with the "cross" shaped patch coming in second.

Based on this data, the team tested patch shapes on themselves, comparing the "cross" shape and the "I" shape against one another. Results showed the "I" shape stayed adhered to the body longest and was the most comfortable to wear. The team concluded that the "I" shape would be the best for a sensor that would be applied to the elbow and heel. Overall, the team was able to design a patch that would encase the sensor being developed and met all the needs and most of the wants of the project.

The following chapters 2 through 8 will detail the process and rational this MQP team followed to complete this project. Chapter 2 lays out a detailed literature review on pressure ulcers themselves, the pressure ulcer industry, current methods of prevention, and medical

adhesives and patches. Chapter 3 outlines the initial client statement, the final client statement, the constraints and objectives of this project, and the regulations and standards followed in that process. Chapter 4 goes through all the preliminary testing and methods conducted. Chapter 5 and Chapter 6 address our design verification and validation respectively followed by Chapter 7 which discusses and dissects the results from the two previous chapters. Finally, in Chapter 8 there are concluding statements that sum up the entirety of the project.

CHAPTER 2: Literature Review

2.1 Background on Ulcer Formation

2.1.1 Definition

Pressure ulcers, or bedsores, are an unfortunate complication many bedridden patients and those in wheelchairs encounter. Pressure ulcers are localized injuries due to pressure and/or shear and friction against a person's skin. These forces against the body cause damage to underlying tissues [12]. Typically, the initial layers of the skin and underlying fat are damaged, but in severe cases, muscle and bone can be damaged as well.

2.1.2 Explanation of Formation

Pressure ulcers are predominantly formed due to excessive pressure. This constant pressure occurs from bone pushing against the layers of the skin and a hard surface also putting force on the other side of the body, causing a restriction of blood flow from both directions. This restriction prevents oxygen and other nutrients from reaching underlying tissues which can cause damage to the tissue, and in some cases, even necrosis.

Pressure ulcers can be complicated by shear forces against the body as well. Unlike pressure forces which act perpendicular to the skin, shear forces occur in parallel with the skin [13]. Shear forces cause skin layers to shift over one another which can cause further damage to the skin. Shear forces are not always a factor in ulcer formation, but they are a common cause.

In addition, friction forces can further complicate pressure ulcer formation. Friction is similar to shear, in the sense that these forces are in parallel with the skin. However, friction is when one surface is in motion, while another surface is stationary and the two rub against each other [14]. With shear, both surfaces are in motion, being moved in opposing directions. Both friction forces and shear forces can cause the skin to tear and further complicate the ulcer.

2.1.3 Risk Factors

A number of factors can affect the chances of ulcer formation, typically affecting the overall health and functionality of the skin. These factors include, but are not limited to: age, immobility, poor nutrition, bowel incontinence, moisture level, poor blood flow, and smoking.

Age affects the structure of the skin. As humans age the skin is not as likely to repair and regenerate as often as it once could. This causes the skin to become thinner because new skins cells are not forming as frequently. In general, as cells age, they are not as likely to produce or secrete various molecules as often as they originally could. The skin will not produce as much collagen, which is responsible for giving the skin its elasticity and strength. With skin being thinner and not as strong, an ulcer is more likely to form due to the lack of layers between a bony prominence and the outer layers of the skin [15].

Immobility can increase the risk of an individual developing an ulcer. If the patient is unable to move their body consciously, they will not be able to adequately alleviate the pressure on certain areas of the body. If this cannot occur, the chances of forming an ulcer are higher.

Nutrition is also a factor in ulcer formation. Without proper nutrition, skin will not be optimally healthy. This may cause the skin to thin and weaken, thus reducing its integrity and ability to withstand pressures from bony prominences.

Excessive moisture or dryness can increase the chances of forming an ulcer. In either condition, the skin is more likely to shear or cause friction, which can break the skin already under pressure[16].

Bowel incontinence can also contribute to excessive moisture in certain areas. This increases the negative effects of shear and friction forces against the skin, further increasing the chances of the skin breaking.

Lack of blood flow in the body can contribute to pressure ulcer formation. As the lack of blood flow decreases it starves body tissues of nutrients. This can damage and weaken the skin and the layers below the skin, making these tissues more susceptible to ulcer formation.

Smoking has a few effects that can increase the risk of ulcer formation [14]. Smoking can make the skin less elastic and weaker, cause poor blood flow, and decrease oxygen in the blood. This leaves the tissue more likely to deform under pressure and shear forces because it is weaker and not healthy.

2.1.4 Common Sites on the Body

High risk areas are those that are near or on areas where there is a bony prominence that would subject skin capillaries to high pressure forces when the patient is lying down or sitting up. Such high risk areas are highlighted in Figure 2.1.

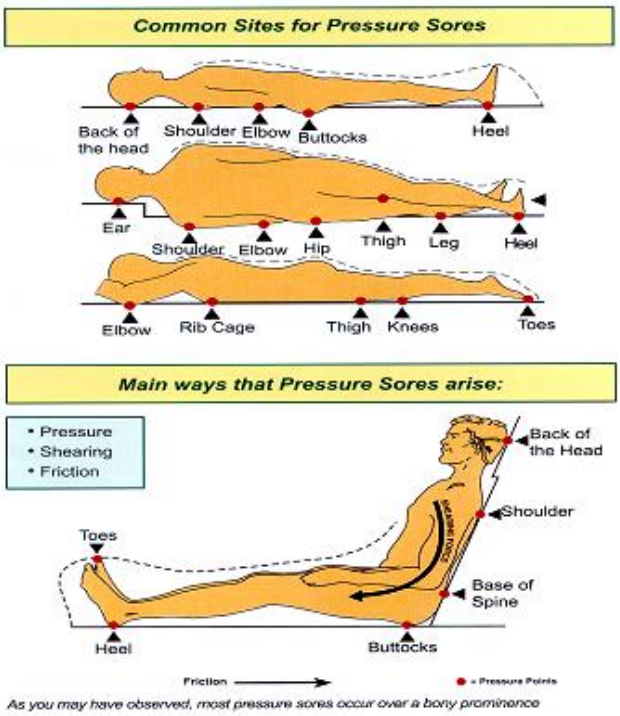


Figure 2.1: The Common Sites for Pressure Ulcer Formation.

2.1.5 Groups at Higher Risk

Typically, those who are in hospital beds, wheelchairs, or nursing homes are more likely to form ulcers because these individuals are usually in a lying down or sitting position which causes excessive pressure against capillaries. It is not guaranteed that if a person is subjected to one of the following situations that an ulcer will form, but it does increase the risk. Of these people, typically the following groups are more likely to develop ulcers: the elderly, those who recently lost weight, and those with a lack of mobility.

Elderly people are more likely to develop pressure ulcers [16]. As the skin ages, it becomes weaker. Cells are not as likely to proliferate and create collagen, a major molecule found in the skin that gives the skin strength. With this loss of cells and strength, the tissue is more likely to be damaged with added pressure forces. In addition, due to the lack of proliferation and creation of collagen, if a pressure ulcer is formed it will not heal as quickly and persist longer than usual. This could cause the ulcer to increase in depth and surface area, making it harder and more expensive to treat.

Those who have recently lost weight are also more likely to develop pressure ulcers. The weight loss results in a decrease in adipose tissue, which can certainly be beneficial for the person. However, adipose tissue protects the body by cushioning it and absorbing forces placed on the body. Without adipose tissue, there is not a layer of protection between the bone and the skin. Therefore, this lack of adipose tissue increases the risk of developing a pressure ulcer.

Those who are immobile or lack sensation have also been found to be more likely to form pressure ulcers. For those patients that cannot move on their own easily, relieving the pressure on the body can be fairly difficult. If the pressure is not relieved in time, an ulcer may form. For those with a lack of sensation, they are also not able to relieve the pressure in time but instead because they simply do not feel the pain. Although not due to immobility, this is still a group of people who suffer in a similar manner. This group of people may include those who are paralyzed, who are disabled, and who suffer from an immobilizing disease.

2.2 Diagnosis and Treatment

2.2.1 Various Stages of Ulcer Progression

Ulcers fall into different categories depending on the severity of the wound. By diagnosing which stage they fall under, health professionals can provide the appropriate treatment recommended for the specific stage. Figure 2.2 depicts the various stages of pressure ulcer formation.

Stage 1 ulcers appear similar to a blister, but the skin does not bubble as much. There is red discoloration and when touched, it will not blanch. The area is sensitive and may be significantly warmer or cooler than the surrounding skin.

Stage 2 appears much more like a blister with the skin either bubbles a bit or may even be broken. If the skin is broken, there may even be a shallow wound. The injury is not very deep, but it is common for the epidermis and dermis to be damaged.

Stage 3 ulcers are a deep wound that look almost like a crater. Skin continues to peel away and adipose tissue can be exposed. The bottom of the wound may have dead tissue.

Stage 4 is an even deeper injury, possibly exposing tissues found underneath the skin layers. This includes muscle, bones, and tendons. It is not uncommon that the bottom of the wound is permanently damaged tissue.

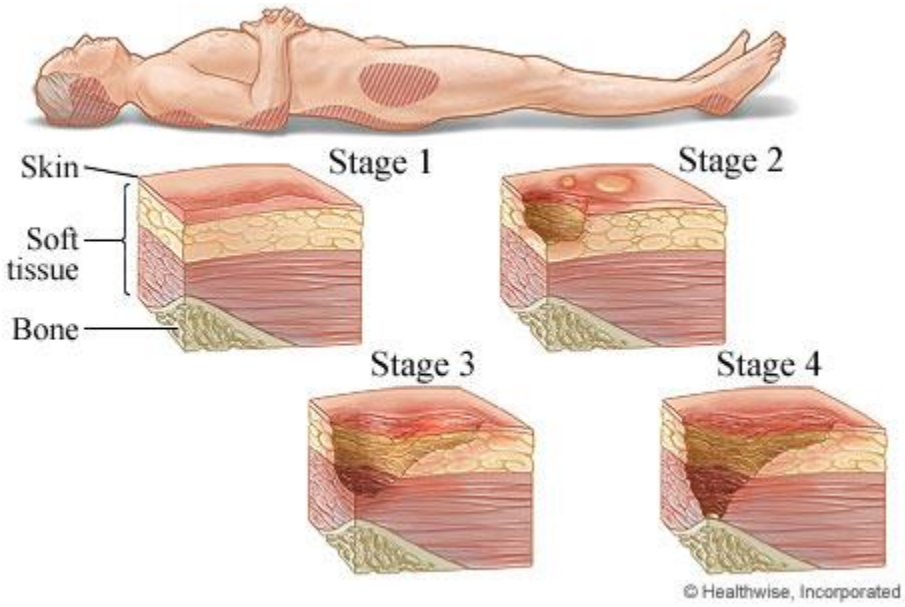


Figure 2.2: Medical Illustration of Pressure Ulcer Stages

2.2.2 Protocols for Treatment

Treatment depends on the severity of the ulcer. For Stage 1 and 2, cleaning and dressing the wound, repositioning to alleviate pressure, and choosing softer, more supportive surfaces are three effective methods. For Stage 3 and 4, due to the extensive tissue damage, those three methods are not enough. It may be necessary to remove the damaged tissue through surgery and if infected, treat it with antibiotics. In some cases, ulcers can become cancerous, in which case treatment would include chemotherapy [16].

Because of the risk factors and complications, pressure ulcers can be extremely hard to treat. These open wounds can cause a great amount of permanent damage that even surgery may not fully repair. In some cases, the blood vessels stop functioning properly which prohibits the damaged tissue from getting nutrients it needs to repair itself. This results in a long recovery time. The current prevention protocols also contribute to the length of recovery. For example, if a patient forms an ulcer on their right hip, the nurse may reposition the patient to lay on their back to alleviate the pressure from their hip. However, this new position may cause a pressure ulcer to form on another high risk area, increasing recovery time.

2.3 Ulcer Industry and Government

2.3.1 Cost of Pressure Ulcers

Pressure ulcers affect roughly 1 million people in the United States each year and 60,000 people die as a direct result of pressure ulcers annually [17]. Pressure ulcers are a preventable condition and yet 3.5% to 4.5% of all hospitalized patients in the US develop them [17]. This is a serious medical issue affecting a large number of people and has the potential to be completely avoided. Besides the burden to the patients that develop these, pressure ulcers also create a financial burden to the medical industry as a whole.

Pressure ulcer related costs are the third highest medical cost behind only cardiovascular disease and cancer [1]. In the US alone, it is estimated that treating pressure ulcers costs 11 billion dollars annually [17]. For one stage 1 ulcer, it can cost anywhere from 2,000 USD to 10,700 USD and for one stage 2 ulcer, the cost to treat it ranges from 3,000 to roughly 10,700 USD. Stage 3 and 4 pressure ulcers are even more expensive to treat ranging from 5,900 USD to 14,840 USD and 18,730 USD to 21,410 USD respectively for a single ulcer [17]. To put it in perspective, for just one hospital, Leaf healthcare estimated that l with roughly 15,000 admissions per year and an ulcer development rate of 3.5%, the hospital would save roughly 1.6 million dollars annually if the ulcer development rate dropped by just 1% [17].

2.3.2 Government and Litigation

There are also government and litigation factors to take into account when trying to understand the need for pressure ulcer reduction. As of 2008, it was decided that Medicare/Medicaid does not reimburse hospitals for costs related to pressure ulcers that are developed while under hospital care in the US [18]. This essentially means that Medicare does not cover the costs to treat the pressure ulcers if they developed while the patient was hospitalized because they are classified as a preventable condition. As of 2014, as a part of the Affordable Care Act, it was decided that hospitals that fall into the top 25% of hospitals with the highest rates of hospital acquired pressure ulcers would receive a 1% reduction of payment for all their Medicare patients [17]. In essence, the United States government is putting the pressure on the healthcare industry to find a solution in pressure ulcer prevention through financial penalties. Pressure to find a solution does not come only from the government but from the patients as well.

Pressure ulcer related lawsuits are the second leading reason for lawsuits, with over 17,000 filed annually. It is second only to wrongful death lawsuits. The average settlement for a pressure ulcer lawsuit is $250,000 USD and one study found that pressure ulcer lawsuits favor patients roughly 87% of the time [17]. With an average settlement of $250,000 USD and 14,790 lawsuits (87% of 17,000) going in the favor of the patients, this represents a financial burden of 3.7 billion USD annually in litigation alone [17]. This is just another significant financial burden on the medical industry. The medical industry would greatly benefit from a device that would lower the rate of hospital acquired pressure ulcers.

2.4 Current Methods of Prevention

There are a few current methods of pressure ulcer prevention currently in use or on the market. These methods include physically turning patients, offloading, pressure mapping, and motion sensing and they each have certain advantages and limitations.

2.4.1 Turning

Turning is the current standard procedure done for patients to prevent ulcer formation. This involves physically repositioning or turning a patient every 2-3 hours. When done on a timely schedule this can help to reduce pressure ulcer development but it puts a strain on caretakers and nurses to have to do this so frequently. This method also only works for patients that rely on caregivers, and can be disruptive to patients' sleep schedules [2].

2.4.2 Offloading

Offloading involves either specialized padding or pillows targeted at specific at risk body locations or things like specialized beds. They are designed to distribute the pressure on these at-risk body locations so that pressure ulcers do not form. Offloading specialized beds can be fairly expensive and a hospital or hospice facility would need to purchase many of these to be effective for their entire facility [5]. As far as the specialized padding goes this is mostly for wheelchair applications and does not extend much to other at risk areas.

2.4.3 Motion Sensing

This technique is mostly based on an electronic sensor containing an accelerometer. Leaf Healthcare has created such a product that senses motion and then predicts based on that motion data whether or not the patient is at risk of getting an ulcer [4]. This patch, shown in Figure 2.3. has shown to increase the compliance of the protocols already in place in hospitals (i.e. turning the patient) to prevent pressure ulcers [16]. The main draw-back for this type of device is that it does not actually measure pressure in the at risk areas of the body and so its predictive capabilities can only be so accurate.

Figure 2.3: Leaf Healthcare Sensor

2.4.4 Pressure Mapping and Pressure Mats

This technique utilizes a specialized mat which can measure the contact pressure between the patient and its surface. The M.A.P.^{TM} (Monitor Alert Project) system by Wellsense, Inc., shown in Figure 2.4, creates a continuous, real time heat-map-like display to show where the pressure is at a level that is likely to produce ulcers [3]. The main disadvantage of this system is that the pressure is measured based on the mat coordinate grid and not the patient themselves. This means that the patient could be moved and still be putting pressure on the same area of their body but the pressure mat wouldn't be able to distinguish this.

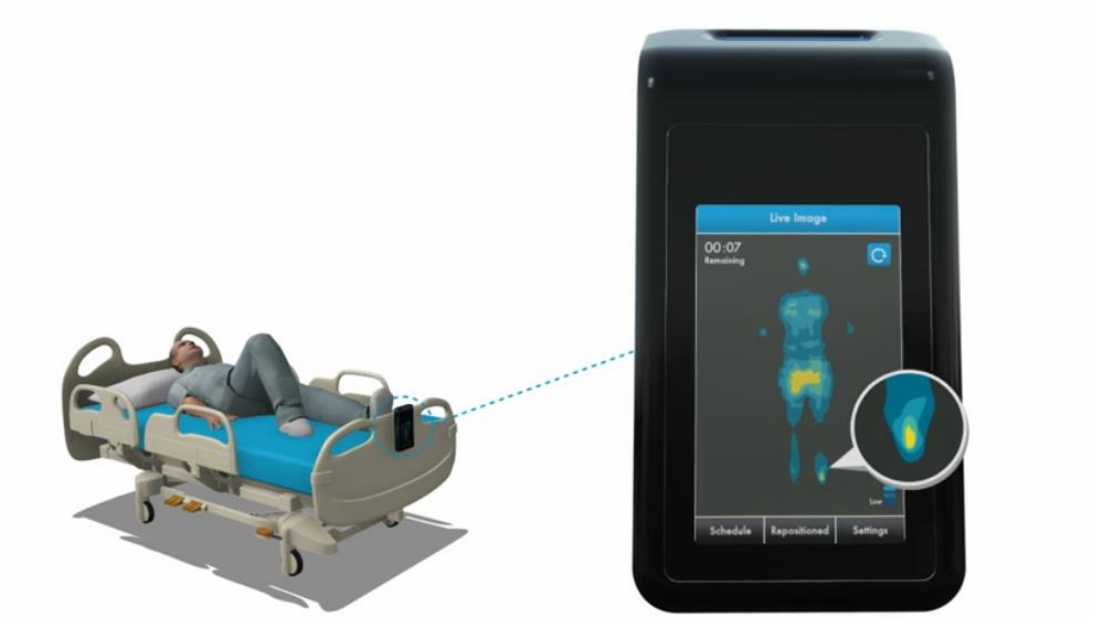


Figure 2.4: M.A.P.^{TM} System Mat and Visual Feedback

None of these current techniques is perfect, each coming with its own disadvantages. There is still a large need for a low cost pressure prevention system.

2.5 Relevant Products and Inventions

While designing a new product for market, many design considerations can be made by examining pre-existing products. Many devices have been made for the prevention of pressure ulcers, however, few use sensors that adhere to the body. A summary of the data is displayed in Table 2.1.

2.5.1 Adhesive Sensor Technologies

Leaf Patient Monitoring System

Few adhesive patch sensors exist for the prevention of pressure ulcers, however, Leaf Healthcare has developed a sensor which can be adhered to a patient's chest. This uses an accelerometer to determine if a nurse is has turned a patient who is at risk for pressure ulcer formation within the standard rotation period. If the sensor recognizes that the patient has not been turned within their rotation protocol, the system will alert the medical professional to turn the patient to prevent the onset of a pressure ulcer [19].

Electrocardiogram Electrodes

In order to visualize the electrical activity of the heart, an electrocardiogram must be tested on the patient. For this three or more electrodes, like the one shown in Figure 2.5, must be placed on the body [20]. While some applications may require the electrodes to be inserted below the patient's skin, more frequently, electrodes are applied to the surface of the skin using adhesive patches. The patches must allow for the electrical signals to be detected by the electrode and they are often kept on the body for extended periods of time [21].

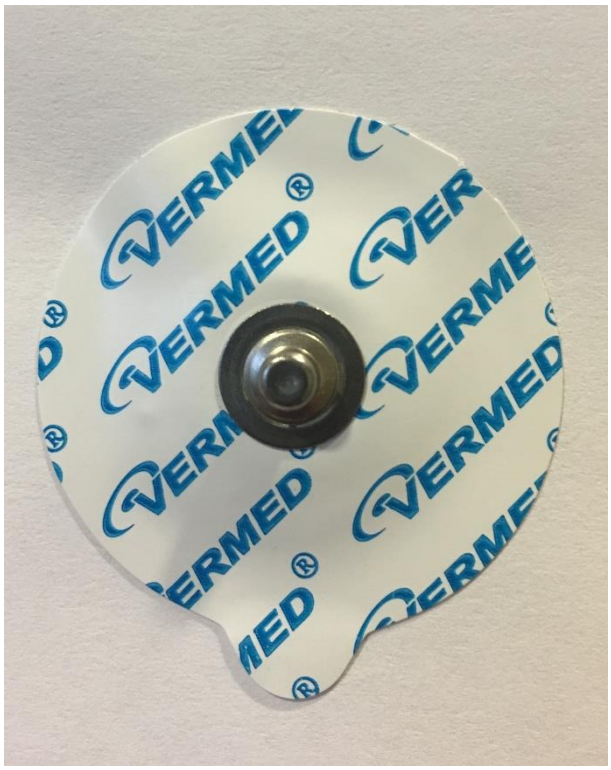


Figure 2.5: Electrocardiogram Electrode

TempTraq®

The TempTraq® patch by Blue Spark Technologies, shown in Figure 2.6, is a temperature sensor for constant body temperature monitoring for infants. The patch is adhered to the child and information is sent to a smartphone app recording a child's body temperature history. This patch is wireless, disposable, and works for 24 hours [22].

Figure 2.6: TempTraq® Patch

2.5.2 Skin and Wound Care

Adhesive Bandages

Adhesive bandages, like the one in Figure 2.7, are small dressings that are used to protect a small skin wound from external friction and contamination from debris and pathogens. An average adhesive bandage consists of an elastic layer with one side coated with adhesive, and on the adhesive side is a non-adhesive absorbent pad to adsorb excess bodily fluid from a wound to aid in healing. Adhesive bandages come in various shapes and sizes to fit different areas of the body. Also, different types are available for various needs which include but are not limited to durability, water resistance, antimicrobials, and breathability [23].

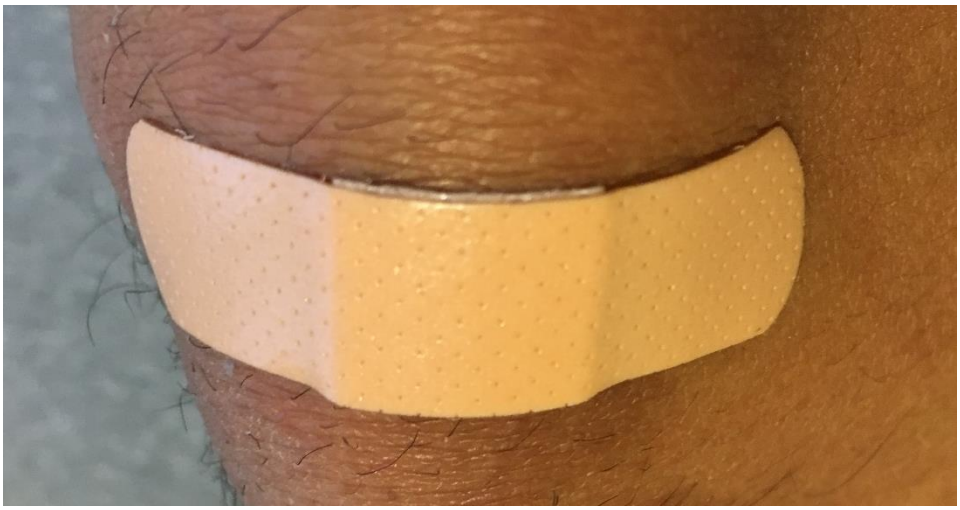


Figure 2.7: Adhesive Bandage on Knee

Dressings

A dressing is a pad of material to protect a wound from further damage. It will absorb excess fluids, reduce pressure to the wound, and will prevent contamination by debris and foreign pathogens. Many dressings are held in place using bandages or medical tape, and some now are manufactured to be self-adherent to the body [24]. Typically, dressings are made with a silicone-based adhesive. Sometimes they are porous, and other times they may be hypoallergenic. The material is dependent on the function and application.

Mölnlycke Health Care sells a sacrum foam dressing (Figure 2.8) to prevent and treat pressure ulcers. It is self-adherent, water-resistant, and has a foam pad which absorbs bodily fluids while also offloading pressure from the wound area to prevent further tissue damage [25].

Figure 2.8: Mölnlycke Health Care Sacral Dressing

Medical Tape

A wide variety of medical tapes, like the ones in Figure 2.9, are available for different needs. Fabric and cloth tapes are comfortable, breathable, and are often used for securing wound dressings and tubing [26]. They are also designed to be gentle on skin on removal. Paper tape is relatively cheap and is often used when re-taping is frequent [27]. Clear tape is used when securing tubing, stitches and other devices that require unhindered viewing [28]. Surgical tape is used to adhere to damp skin conditions [29]. For use during athletic activities, sports tape is soft and elastic and used to wrap around parts of the body providing light compression while protecting muscles from strain [30]. Elastic tape can be used wrap around a part of the body to apply compression [31]. Silicone tape is gentle on fragile skin and can be used for repeated

application [32]. All of these types of tape provide various characteristics that might serve well in the purposes of this project.

Figure 2.9: Silicone (left), Surgical (center), and Cloth (right) Tapes

Cosmetics

Many products exist on the market to perform various cosmetic purposes. Silicone gel patches, like the one in Figure 2.10 are available to help heal scars by keeping the tissue moisturized which ultimately increases the compliance of the skin. These patches are flexible and form to the skin, and they are not painful when they are removed [33]. Furthermore, corn cushions, like in Figure 2.11, are designed to adhere around a corn or callus and a soft latex foam offloads pressure from the area to reduce pain and eventually reduce the size of a corn [34].

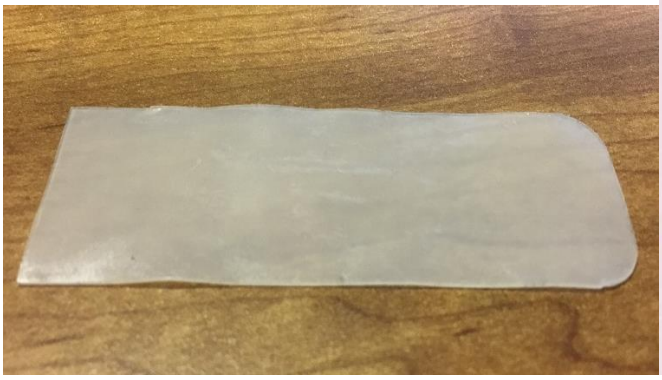


Figure 2.10: Silicone Scar Strip

Figure 2.11: Corn Cushions

2.5.3 Transdermal Patches

Transdermal patches are designed to adhere to the body and release drugs into the skin over time. Depending on the application, patches can stay on the body from several hours to a week [35]. For example, Nicoderm® CQ nicotine patches by GlaxoSmithKline Consumer Healthcare, L.P. (Figure 2.12) are designed to stay on the body for 1 day to continuously release drugs that help a person quit smoking. The patch has a low profile and is often clear and

unobtrusive [36]. While the purpose of this project does not involve the administration of drugs, the adhesive materials can be examined and future applications of the project could involve adhesives that release medications that prevent the onset of pressure ulcers.

Figure 2.12: Nicoderm® CQ Nicotine Patch

Table 2.1: Summary of Example Products

Product Name	**Purpose**	**Maximum Duration of Use**	**Waterproof**	**Device Material**	**Adhesive Material**	**Cost**
Leaf Healthcare Inc. Patient Monitoring System	Contacts medical provider when patient has not been turned within rotation period	Not accessible	Yes	Not accessible	Not accessible	$199
Medtronic Inc. ECG Monitoring Electrode	Detects heart activity	Several weeks	Yes	Not accessible	Gel adhesive	$0.32
TempTraq™ Thermometer	Monitors body temperature; relays it to smart phones	1 day	Yes	Polyethylene Foam	Silicone gel-based solution	$19.99
BAND-AID® Plastic Strips	Protects small wounds from contamination	Not accessible	Can Be	Not accessible	Not accessible	$0.03
Mepilex® Border Sacrum Dressing	Covers sacral wounds from further damage	7 days	Yes	High MVTR	Safetac® Silicone	$17.20
3M Co. Medipore™ Soft Surgical Tape	Secure wound dressings	Not accessible	Resistant	Fabric	Gentle on skin	$17.95 for 2"X10yds
Reliamed® Paper Tape	Securing for frequent re-taping	Not accessible	Not accessible	Hypoallergenic Paper	Gentle on skin	$10.95 for 2"X10yd
CURITY™ Hypoallergenic Clear Tape	Securing items with visible clarity	Not accessible	Not accessible	Transparent, hypoallergenic Plastic	Not accessible	$12.95 for 1" X 10yd
3M™ Micropore™ Surgical Tape	Holds well to damp skin	Not accessible	Not accessible	Paper Tape	Hypoallergenic adhesive	$11.95 for 2" X 10yd
Lightplast® Pro Elastic Athletic Tape	Prevent strain during sports	Not accessible	Water repellent	Cotton	Zinc-Oxide adhesive	$2.95 for 2" X 5yd
Tensoplast® Elastic Adhesive Bandage	Apply compression to edema	Not accessible	Yes	High tensile cotton cloth	Not accessible	$13.95 for 2" X 5yds
Mepitac™ Soft Silicone Waterproof Tape	Secure medical devices	Not accessible	Yes	Silicone and Polyurethane	Safetac™ Silicone	$17.08 for 1.5" X 59"
Dr. Scholl's® Corn Cushions	Removes pressure from affected area	1 day	Yes	Latex pad	Not accessible	$2.32
North Coast TopiGel® Silicone Gel Patch	Covers scars to improve compliance	6 weeks	Not accessible	Self-adhesive silicone	Self-adhesive silicone	$14.95
Nicoderm CQ®	Nicotine replacement therapy	1 day	Yes	Not accessible	Not accessible	$2.78

CHAPTER 3: Project Strategy

3.1 Initial Client Statement

Develop a wearable disposable patch that would alert a patient or caregiver to a level of tissue pressure that would potentially be harmful to tissue or that could produce a pressure ulcer. The biocompatible patch should house embedded sensors that would monitor a limited number of at risk body areas to warn caregivers preemptively of impending tissue ischemia and injury.

3.2 Technical Design Requirements

There were several constraints and objectives that we derived from our initial client statement and used to assist us in the design process. These constraints and objectives are as follows.

1. *Water resistance:* The material used for the patch must be able to protect the electronic components from water damage.
2. *Life Span:* The adhesive patch should stay adhered to the patient's skin for up to 7 days.
3. *Cost:* The non-electronic components of the material should cost no more than $100 USD to manufacture.
4. *Sensor disposability:* The patch should be designed such that the patch is completely disposable.
5. *Biocompatible:* The patch must not cause any harm or damage to the patient and must follow all relevant biocompatibility guidelines set down by the FDA.
6. *Durability:* The patch should be designed such that the electronic components will be protected from external mechanical forces.
7. *Size:* The patch should be designed such that a relatively small skin surface area will be covered by each patch, and the patch will not exceed a thickness of 3mm.
8. *Budget:* The total amount of money that can be spent on research and development of the patch not including the electronic components is $750 - $1000 USD.

3.3 Design Requirement Standards

The Food and Drug Administration (FDA) published a guidance document for "Tissue Adhesive for the Topical Approximation of Skin" [37]. Although this did not completely match the purposes of this MQP project, it did enumerate the many specifications for a product similar to an adhesive patch. The materials obtained for this project were already FDA approved for use on humans with limited potential for skin irritation.

This MQP created a product to protect electrical components from damage. The final design of the product housed the electrical components, allowing the pressure sensor to read mechanical load, while also protecting the rest of the circuitry from breaking under such stress. Furthermore, the moisture sensor of the device needed to have access to the moisture of the skin, but the rest of the electronics had to be contained in a water resistant vessel to prevent short circuiting and potential harm to the patient. The final product was designed to satisfy these conditions.

Tests were conducted to determine the water resistance of the product, such as the method prescribed by ASTM D779-16 [38]. For this standard, ASTM suggested that a moisture indicator dye be used to measure the amount of moisture that passes through a given material. Additional ASTM standard test methods for tack, peel, and shear were performed to measure the adhesive properties of the adhesive materials used for the device. The procedures for these tests are outlined in ASTM D6195-03(2011), ASTM D3330/D3330M-04, and ASTM D3654/D3654M-06(2011) respectively [39-41]. The In-Spec™ 2200 machine was used to record the tensile forces that various adhesive materials can withstand before detaching from a substrate, as per ASTM D6195-03(2011) and ASTM D3330/D3330M-04. The time it takes an adhesive material to fail when loaded in shear was measured as outlined in the method ASTM D3654/D3654M-06(2011). Elastic modulus tests were also conducted using the Instron® 5544 machine while following methods prescribed by ASTM E111-04(2010) [11].

3.4 Revised Client Statement

Develop a wearable disposable patch that alerts a patient or caregiver when unsafe conditions (such as elevated external pressure, tissue temperature and moisture) may produce a pressure ulcer. The biocompatible patch should house embedded sensors that would monitor a limited number of at risk body areas. The patch should be able to be worn for a maximum of seven days and allow for the electronics to be removed for reuse. The patch should be water resistant and materials should be sterilizable. The patch should cost no more than 20 US dollars not including the electronic components.

3.5 Management Process

After becoming more familiar with the project, the project was analyzed and broken down into tasks that were necessary to complete. The project was broken down into six main objectives and broken down further into secondary tasks. The outline of the main objectives of this project is shown in Figure 3.1.

Once the project was organized into a work breakdown structure, it was necessary to create a timeline of the objectives (Figure 3.2) to ensure objectives were completed by the end of the academic year.

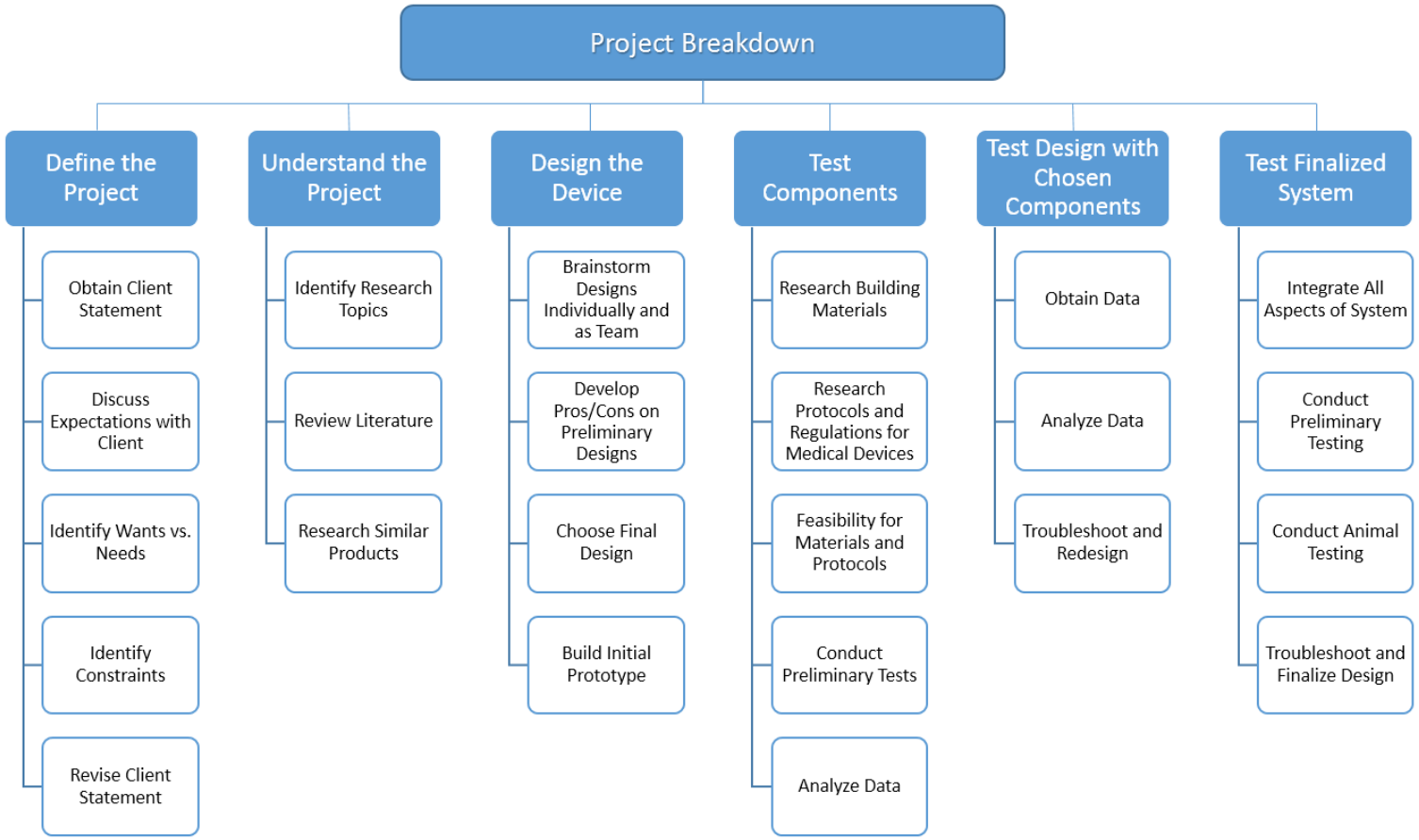


Figure 3.1: Project Breakdown

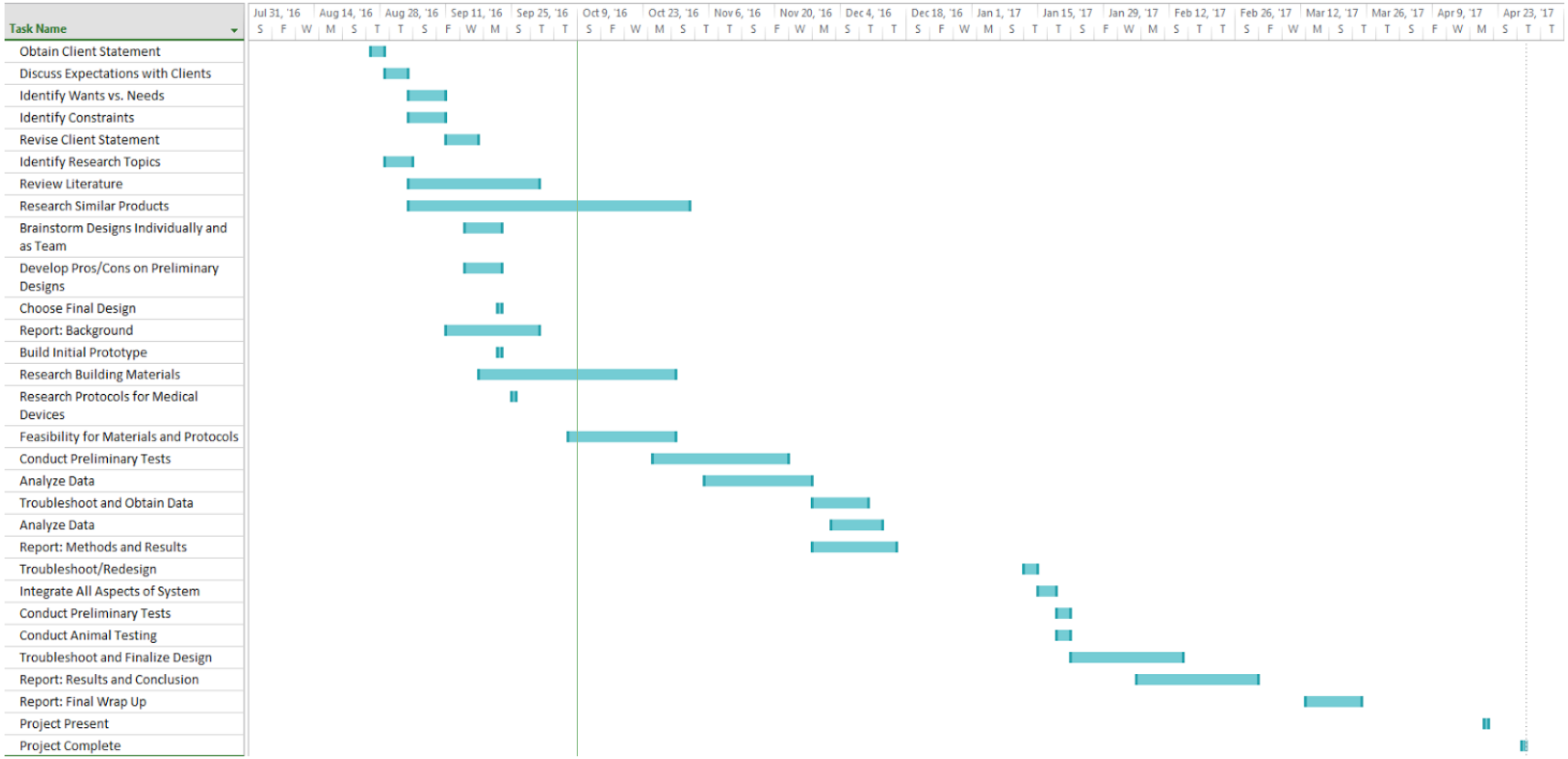


Figure 3.2: MQP Gantt Chart

CHAPTER 4: Design Process

This chapter will address how the team went about solving the challenges presented in the client statement of creating the housing for all the electrical components of a pressure ulcer prevention patch.

4.1 Needs Analysis

Based off the revised client statement, the team established the needs for the final product and the wants to have in the device. This was an important step as the wants and needs of the final product steer the design. In some of the initial designs, which will be discussed in Section 4.5.1, the team failed to correctly identify some of the needs and so the designs were not ultimately viable.

Biocompatibility was the most important need considered in the design process. If the device is not biocompatible, and if it causes harm to the patient, it cannot be used as a final product and will defeat its purpose. It follows that because of the importance of biocompatibility, the team limited the potential materials for the final product to only those materials that were already FDA approved, therefore being biocompatible and safe.

The other need that greatly influenced the design was disposability. The final product must be completely disposable for it to be actually used by professionals in the healthcare industry. After discussions with plastic surgeons at University of Massachusetts Memorial Medical Center the team realized that healthcare professionals would not use a product that took more time to prepare than a Band-Aid or ECG electrode that can quickly be applied to the body and be thrown away afterwards. Asking healthcare professionals to take the time to recover non-disposable components is not feasible. This steered the team in a direction to have both the sensor and patch as one assembled system rather than assembling the components when ready to use.

As for wants, the team used weighting factors on a scale of 0-1 with 1 being the most important as shown in Table 4.1. These wants were identified through background research that had been done by the team and as requested by the plastic surgeons on the project. Their weights were given as deemed appropriate after having conducted extensive background research. The weights were confirmed as appropriate by the surgeons. Seeing as they work with pressure ulcers constantly, their feedback was invaluable.

Elastic modulus was the most important factor and was given a weighting factor of 0.29. The elastic modulus of the material determines its ability to conform to the body and stretch easily with movement. Skin has an elastic modulus of 1.0-4.0 MPa, but for this study it was decided that the average of 2.5MPa should be used [42]. If a material use has an elastic modulus greater than this, it may create and apply shear forces to the skin that counteract when being bent. This can in turn cause the material to be uncomfortable and may even cause damage to the skin. Elastic modulus was given a high weighting to select a material that could stay adhered on the body longer while also being comfortable.

Shear force was next most important and was given a weighting factor of 0.26. It was rated below elastic modulus because the team decided that shear force resistance of the adhesive is very important in order to achieve the goal of having the final product stay on the body for seven days but slightly less important than the elastic modulus. Shear force is the force applied in parallel to the adhesive surface and can be caused by any surface rubbing against the patch. This force causes bandages to come off the body before intended. By having a high shear force resistant adhesive, the amount of time a single patch can be used will be maximized.

The next want was an adhesive with a low peel force. The peel force is the force it takes to remove an adhesive from the skin when grabbing one end of it and pulling in a perpendicular direction of the applied adhesive. Adhesives that have a peel force that is too high can lead to skin damage upon removal as the adhesive can actually pull portions of the epidermal layer of the skin off the body. Because patients who are most at risk for ulcers often have weaker and thinner skin than most, the final product should have a low peel force. This is because the final product should not cause injury to patients using it. The team weighted low peel force at a 0.21. This was rated slightly below shear since all the materials being tested are used for medical purposes on the skin already and should already cause very minimal damage.

Water resistance was the next want that was identified. The team does not anticipate the patch to be completely submerged under water but should be able to repel water and other liquids to protect the electronic components from short circuiting and to prevent the adhesive from losing its strength. The patch should be able to stay functional even after being put into bathing conditions. The electronic components will be sealed in a plastic material that will provide protection from water damage. In addition, constant contact with water could affect the quality of the skin, leaving it more prone to damage, furthering the reason for having this factor weighed so heavily. For these reasons, water resistance was given a rating of 0.15.

The final want identified was the ability to maneuver the patch if it is accidentally positioned incorrectly but not pressed down. Essentially, the patch should not be cumbersome. To determine this attribute in a quantitative way, adhesive tack force was measured which will be explained in more detail in Section 4.2.2. A low tack force indicates that the adhesive will be easier to use. This want was the least important and so rated at 0.09.

This ranking system started by normalizing the results to 1 by dividing the best result for that test by the entire data set. This made it so the best result was equal to 1 and the worst result equal to 0. After that, the data set was multiplied by the tests' respective weighting factor. For each material, the resulting number from each test was added up. The product with the sum closest to 1 was the preferable material.

Table 4.1: Design Matrix Factors

Design Parameter	Elastic Modulus is 2.5MPa	Shear Adhesion Force is High	Peel Adhesion Force is Low	Water Resistance is High	Tack Adhesion Force is Low	Total
Normalized Weighting Factor (0-1)	0.29	0.26	0.21	0.15	0.09	1
Patch Component that Affects Parameter	Backing Material & Adhesive Material	Adhesive Material	Adhesive Material	Backing Material	Backing Material & Adhesive Material	

4.2 Preliminary Material Selection Testing

4.2.1 Determining Materials to Test

Many medical dressings and adhesive patches operate in a similar way to most single sided pressure sensitive tapes. They have a non-adhesive backing layer, and the adhesive is attached to that as shown in Figure 4.1. The adhesive material is the primary determinant of how well the tape sticks to a surface, however, the backing layer often determines key features such as the compliance/rigidity, water resistance, and external texture.

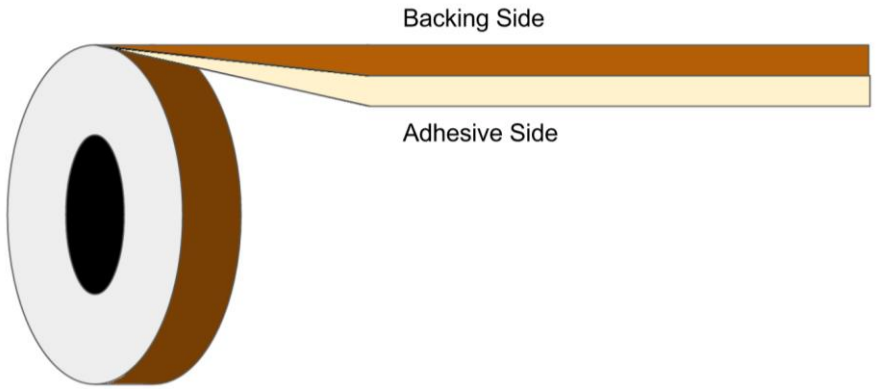


Figure 4.1: Single-sided Pressure Sensitive Tape

The medical field uses dozens of different adhesive materials and a similar number of backing materials. To fulfill testing on every adhesive-backing material combination would be costly and time consuming. Some materials, such as adhesives, require specialized manufacturing practices to create the product. Resources were not available for the team to accurately manufacture different adhesive medical tapes. Machine manufactured products are more consistent and accurate. If the team were to manufacture each combination of adhesive and

backing material by hand, there would be significant variability and heterogeneity in each sample, which would affect the results of the experiments.

Although the team could not obtain every adhesive-backing material combination, a wide assortment of medical materials were obtained to analyze as many combinations to determine the best one for the device. Products were donated by Dr. Dunn and Dr. Hickle at University of Massachusetts Memorial Medical Center, requested as free samples from medical material providers like Mediplus Ltd., or purchased from local pharmacies like CVS. Table 4.2 enumerates all the materials collected and various attributes.

Since the products collected ranged in size and had various other components such as absorbent pads, a system was created to limit the variables that would influence the tests. For all the materials, the team collected information about the adhesive material, backing material, and adhesive area. Based on the design parameters enumerated by the design matrix in Table 4.1, the patch component that held the greatest weight on the design of the patch was the type of adhesive material. This component will greatly influence the various adhesive forces that determine the patch's interaction with the skin. However, the backing material affects the patch's ability to conform to the body, the tack force of the material, and water resistance. Therefore, within each adhesive material category, the medical products were organized based on their backing material.

Additionally, in order to have enough material to create the amount of samples required for testing purposes, the adhesive area of products was evaluated. This was determined by measuring the length and width of the adhesive area. Furthermore, some products like the Curad® Bandages had a non-adhesive absorbent pad. These products were labeled with "border" indicating that they would have a significantly less adhesive material with which to work. Products that had an unobstructed adhesive area were labeled "entire". The products labeled "entire" often had more material to use, and was often easier to use to make testing samples with, so these specific products were chosen for testing. However, if the team ran out of material from these products, samples were made using the "border" products given they had the same adhesive-backing material combination. The final products chosen for testing are indicated in Table 4.2 with an asterisk.

The size of the material samples that were used for the tests was limited to the dimensions of the smallest medical tape (Steristrips®). Although they were 10 cm long, they were only 1.2 cm wide. The length of the sample adhesion area was then limited by the Curad® Bandages since the longest stretch of adhesive area of one tab was 2.3 cm before reaching the absorbent pad. Therefore, the adhesive area of the samples were limited to 2.3 cm x 1.2 cm. In order to properly load specimens for the tests, samples were cut larger than 2.3 cm. For example, the Curad® Bandage could be cut to be 3.0 cm x 1.2 cm. This would be done by including part of the absorbent pad in the sample. This did not affect the tests because only 2.3 cm x 1.2 cm areas would be adhered and the remaining length of sample would be used to clamp onto the sample.

Table 4.2: Material Information

Product Name	Adhesive Material	Backing Material	Dimensions	Adhesive Area
MediPlus™ Barrier Gel Comfort*	hydrogel	polyurethane	15.3cm x 15cm	border
MediPlus™ HC Thin*	hydrocolloid	polyurethane	10.2cm x 7.6cm	entire
MediPlus™ HC Foam Hydrocolloid Dressing	hydrocolloid	polyurethane	10cm x 10 cm	border
MediPlus™ HC Comfort Hydrocolloid Dressing with Adhesive Border	hydrocolloid	polyurethane	15cm x 2cm	border
DuoDERM® Extra Thin Dressing*	hydrocolloid	hydrocolloid	10.3cm x 10.3cm	entire
MediPlus™ PU Adhesive dressing*	hypoallergenic polyurethane	polyurethane	7cm x 6cm	entire
MediPlus™ Adhesive PU Pad	hypoallergenic polyurethane	polyurethane	5cm x 1cm	border
MediPlus™ Comfort Foam Dressing with Adhesive Barrier	polyurethane	polyurethane	2.5cm x 10cm	border
MediPlus™ Surgical Adhesive Nonwoven Dressing*	low allergy adhesive polyurethane	non-woven polyurethane cloth	10cm x 5cm	entire
Tegaderm™ Film Dressing*	acrylate/polyurethane	rayon	10cm x 10xm	entire
Nexcare™ Steri-Strip™ Skin Closure*	acrylate with "top secret" additives	polyester/rayon	10cm x 1.2cm	entire
Covidien™ Telfa™ Plus Barrier Dressing*	acrylate	woven cloth	15.2cm x 2.5cm	border
Curad® Plastic Adhesive Bandage*	acrylate	plastic	2 cm x 7 cm	border
Transpore™ Surgical Tape*	acrylate	PEVA	2.5 cm x 90 cm	border
Durapore™ Surgical Tape*	acrylate	silk/like polyester	2.5 cm x 90 cm	entire
Curad® Cloth Tape*	acrylate	cloth	2.5 cm x 120 cm	entire
Mepitac® Safetac® Medical Tape*	Safetac®	Non-woven film	4 cm x 90 cm	entire
Mepiform® Soft Silicone Gel Sheeting	Safetac®	Non-woven film	18cm x 10cm	entire
Allevyn® Sacrum Dressing	Safetac®	Non-woven film	21 cm x 21 cm	border
Mepiplex® Border Dressing	Safetac®	Non-woven film	15cm x 2 cm	border
Scar Strips*	silicone	silicone	152cm x 2.5cm	entire
MediPlus™ Silicone Comfort Border Dressing	silicone	silicone	1.2cm x 7.4cm	border

*Product chosen for testing purposes

4.2.2 Preliminary Non-human Material Testing

Adhesive Shear Strength Test: ASTM D3654 / D3654M - 06(2011) - Standard Test Methods for Shear Adhesion of Pressure-Sensitive Tapes

A 4 cm x 1.2 cm sample was cut from each medical product. The samples were marked with a permanent marker such that one end of each sample had a known area of 1.2 cm x 1.2 cm. This adherent area was placed on the edge of a steel plate (dimensions) with the excess material hanging off. A steel roller (0.90 kg) was used to roll even pressure onto this material. This was done by only guiding the roller over the tape, not by applying any additional force. This ensured that each sample was being adhered using the same amount of pressure. The steel plate was then attached to a lab bench so that the steel surface of the steel with the material was facing out from the lab bench and such that the steel was vertical with the sample hanging at the bottom of the plate. Using the overhanging extra material, a small loop of duct tape was secured and 400 g of mass was hooked onto the loop. As soon as the mass was released a stopwatch was started. The stopwatch was stopped once the mass caused the adhesive material to fall off the steel plate. This time was recorded. If the mass dropped and the adhesive material remained on the plate due to failure of the duct tape loop to remain adhered to the testing sample, then the test was restarted again using a new sample of the same material. The steel was washed with acetone between each test. The process was repeated twice for each material and the average time to failure was calculated. This preliminary data is located in Appendix A.

The team's testing methods differed slightly from ASTM D3654[8]. The standard asked for adhesion area of 6.5416 cm^2 (1 in^2). This needed to be smaller. Furthermore, due to the size change, the products could not withstand the 1000 g mass without failing immediately. The mass was therefore reduced to 400 g which was found to be the best weight during preliminary testing because the medical adhesives were able to withstand this weight for more than a second. Furthermore, the standard called for there to be enough material for the samples to form a tab by folding onto themselves. The weight would have hung from this. However, the size of the samples were too small to make these tabs, so the duct tape loop was constructed to provide a way for the mass to still put force onto the testing sample. This setup can be seen below in Figure 4.2. The goal of this test was to find the highest shear. From this test, the top two materials were Nexcare™ Steri-Strip™ Skin Closure and Curad Plastic Adhesive Bandage™.

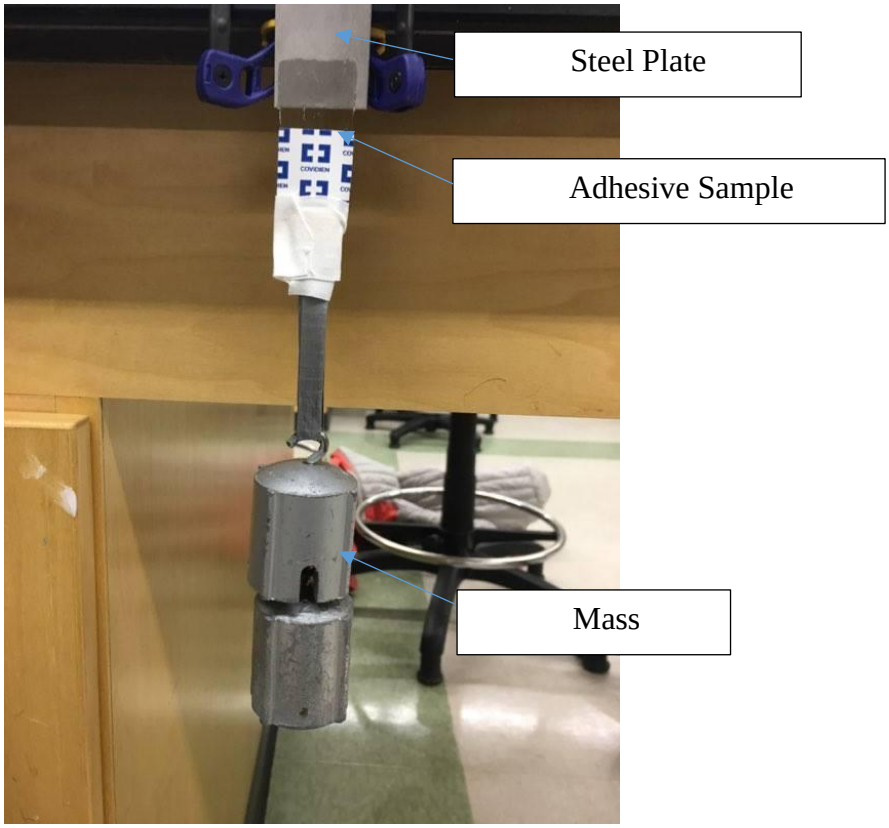


Figure 4.2: Shear Test Setup

Adhesive Peel Strength Test: ASTM D3330/D3330M-04 - Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape

In order to test the peel adhesion strength of the medical products, the team followed the protocols prescribed by ASTM D3330 [7]. This test measured the amount of force that a medical product would be exerted on a steel plate when removed using a force perpendicular to the surface to which the product is well adhered. A 10.16 cm x 5.08 cm (4 in x 2 in) steel plate was bent into the shape in Figure 4.3.

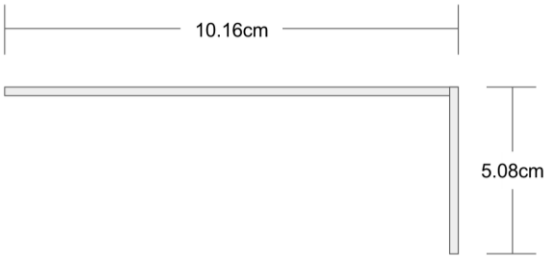


Figure 4.3: Steel L-Plate for Peel Test

A 4.0 cm x 1.2 cm sample was cut from each medical product. The samples were marked with a permanent marker such that one end of each sample had a known area of 2.3 cm x 1.2 cm. This adhesive area was placed on the long arm of the L-plate with the excess material hanging off the corner towards the short arm (Figure 4.3). A steel roller with a weight of 0.90 kg (2 lbs.)

was used to roll even pressure onto this material. This was done by guiding the roller over the tape and not applying any additional force. This ensured that each sample was being adhered using the same amount of pressure. The short arm of the L-plate was then loaded into the clamp on the base of the Instron® 5544. The upper clamp was then lowered to a height 1 cm above the L-plate and the non-adhered end of the sample was loaded into the upper clamp. The Instron® was programed to extend upwards at a constant 5mm/sec and while collecting information about load (N) over the duration of the peel. The Instron® was manually stopped once the sample became completely detached from the L-plate. The process was repeated twice for each material, and the steel was washed with acetone between each test. The maximum load was identified for each trial and the average max load was calculated between repeat trials. This preliminary data is located in Appendix A. A diagram of the test is shown in Figure 4.4 below.

The test performed had a few major differences from the testing protocol in ASTM D3330. The standard called for testing specimens to be a width of 2.54 cm and the testing length to be at least 10.16 cm. However, due to the size of the materials, the size of the specimens needed to be changed. It was decided a 4.0 cm by 1.2 cm sample was appropriate and would keep the area constant throughout both the shear and peel tests. The goal of this test was to find the lowest peel force. The two materials with the lowest peel force was the MediPlus™ Barrier Gel Comfort hydrogel dressing and Durapore™ Surgical Tape.

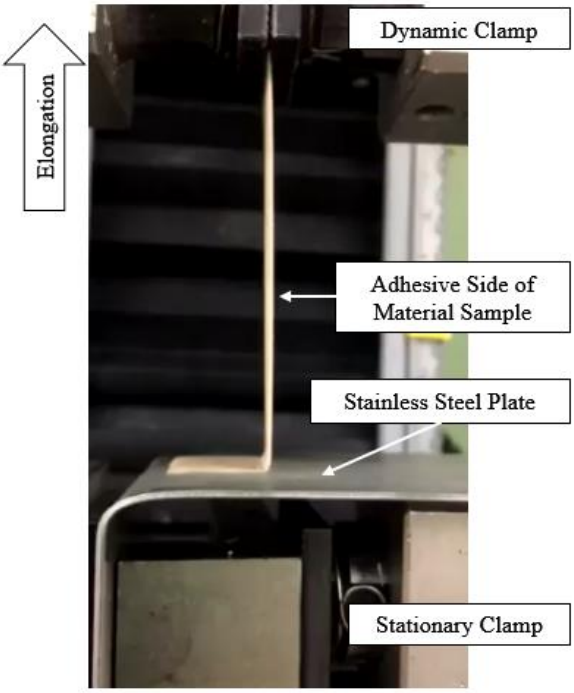


Figure 4.4: Peel Test Setup

Adhesive Loop Tack Strength Test: ASTM D6195 - 03(2011) - Standard Test Methods for Loop Tack

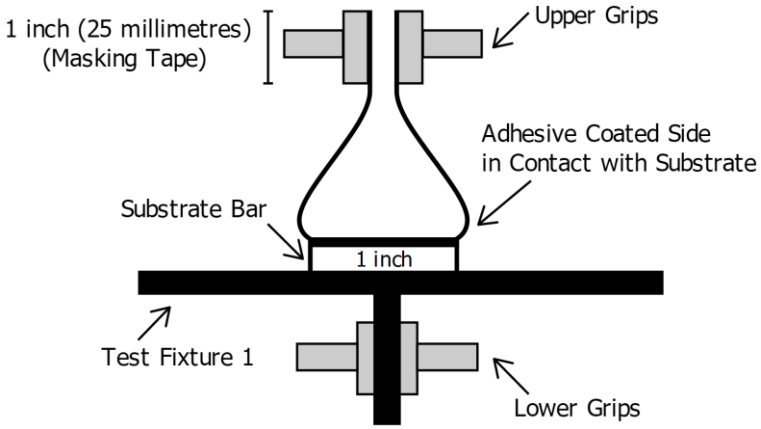


Figure 4.5: Example of Best Case Scenario for Loop Tack Testing [9]

In order to test the adhesion tack strength of the medical products, the team followed the protocols prescribed by ASTM D6195 [9]. This test measured the amount of force that a medical product would exert on a steel plate when it has just touched the steel surface. It will determine the patch's ability to be repositioned when it is accidentally adhered to the body without applying manual pressure.

A 4.0 cm x 1.2 cm sample was cut from each medical product. The samples were marked with a permanent marker such that the center of each sample had a known area of 2.0 cm x 1.2 cm. A mock piece of medical product with the same dimensions was loaded into the top clamp of the Instron® 5544 such that the 2.0 cm x 1.2 cm formed a loop below the clamp with the adhesive side facing out. The short leg of the steel L-Plate in Figure 4.2 was loaded into the lower clamp of the Instron® and the upper clamp was jogged down until the mock sample loop compressed into an inverted "T" shape on the steel plate. This setup is shown in Figure 4.5. At this position, the distance between the clamps was measured to be 0.5 cm, and the extension was zeroed on the Instron® console. The upper clamp was jogged back up and an actual testing sample was placed into the upper clamp the same way that the mock was before. The upper clamp was returned to the zero extension position, and immediately, the Instron® program was initiated, extending the upper arm upwards at a constant 5mm/sec while collecting information about load (N) over the duration of the test. The upper clamp stopped after moving 8 cm. Then the entire exposed area of the sample loop was coated with the red dye. A dye was created and composed of 30 mL clear Elmer's glue and 10 mL McCormick Culinary red food coloring. This was created to measure the area of adhesion. Exactly 6 cm of white Curad® Cloth Tape was placed on the L-plate right below the sample loop. Next the upper clamp was returned to zero again and the Instron® cycle was initiated again. This left a print of the approximate area where the sample had touched down on the steel plate previously. The tape was labeled, the area was calculated using length and width of the print (since the prints were relatively rectangular), and the tape was put aside to dry. The process was repeated twice for each material, and the steel was washed with acetone between each test. The maximum load was identified for each trial and that

was divided by its respective area. The average max force per area was calculated between repeat trials. This preliminary data is located in Appendix A.

The tack test varied greatly from the ASTM D6195 protocol. The materials used for the standard were assumed to be at least 2.54 cm wide, and the length would be sufficient to create loops using 10.16 cm of material. The loop created by this would press down onto a steel plate with an area of 6.4516 cm^2 (1 in^2) to get measurements in force per square inch. The product would press down on a known area since extra material that would bend with the loop would not have anything else to attach to. A L-plate was created for this standard that had the designated area; however, it could not be used for the purpose in the tests because the samples made were much smaller than the anticipated size from the standard. Had the tests been performed the same way, the area would have not been known to which the products adhered on the plate. For this reason, the team made the addition to the protocol to create dye imprints to measure the areas of contact. The team could not measure this area using a ruler while the sample was in the machine and touching down on the plate because the space was too confined to see measurements. The size limitations of the products greatly influenced how this test could be performed.

The goal of this test was to find the lowest tack force per adhesion area. For this test, the top materials were the Curad® Cloth Tape, DuoDERM® Extra Thin Dressing and Covidien™ Telfa™ Plus Barrier Dressing, having the lowest tack adhesion force.

Limitations with Adhesion Tests

According to the ASTM standards, it was necessary to use stainless steel to conduct the shear, peel, and loop tack tests. Though the steel worked well, it is not representative of how wound dressings adhere to human skin. The wound dressings that were tested were pressure sensitive, meaning pressure affects how much the adhesive actually adheres to the surface. Pressure forces react differently on different materials, and human dermal tissue and steel are quite different. Further testing needed to be done before concluding what materials would be the best for this application.

4.2.3 Material Testing on Porcine Skin

In order to obtain more realistic data, a more appropriate model was used to test these wound dressings. A porcine model was chosen. Porcine skin has been used in many applications before trials on human tissue because pigs have been shown to be one of the better animal-skin models due to the material properties[43]. Porcine feet were purchased at the local food store and the skin was removed with a scalpel. The standards that were used for testing did not prescribe methods for using porcine. However, ASTM F2256 Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading [7] did give this information, so the procedures for preparation were modified to meet the needs of the material testing protocols.

Adhesive Shear Strength Test

A few tests were performed using porcine skin with preparation guidelines from ASTM F2256. A 4 cm x 3 cm sample was cut from pig heels obtained from the local butcher. The samples were then cleaned with distilled water and a paper towel to remove contaminants and the piece was secured to the L-plate using clamps. The remainder of the test was the same as

when it was performed on the steel. These tests did not yield very good results because the medical products were not adhering to the sample. Results were inconclusive since the maximum time collected from a sampling of 6 different products was a partial seconds and due to the lack of adhesion to the sample itself. These materials should have adhered to the porcine skin, since it is a common model for human skin.

Adhesive Peel Strength Test

A few tests were performed using porcine skin with preparation based from ASTM F2256. For these tests, the Instron® was draped with blue chux to prevent contamination of the machine. A 4.0 cm x 3.0 cm sample was cut from pig heels. The samples were then cleaned with distilled water and a paper towel to remove contaminants and the piece was secured to the L-plate using clamps, following the same setup as in Figure 4.4. The remainder of the test was the same as when it was performed on the steel. These tests did not yield useable results because the medical products were not adhering to the porcine model and the forces that were being recorded were very low, extremely noisy and out of range of the precision of the device.

Adhesive Loop Tack Strength Test

Tack tests were not performed on the porcine model. Porcine was not used because the forces measured from testing with steel were already low. Other tests had very poor readings with the porcine model, so it was concluded the forces read for this loop tack test with the porcine model would be too low to even obtain a reading. Furthermore, the products were not adhering to the skin when performing the peel tests as evidenced by the low values. Therefore, it was predicted that testing on porcine would yield inconclusive data. The decision to not perform tests on the porcine model was also justified due to the low weighting score that was assigned to this feature, since the data would not greatly affect the results in the design matrix.

4.2.4 Preliminary Human Material Testing

Due to the lack of adhesion to the porcine skin and the noisy data obtained, it became evident that the porcine model was not an ideal model for further testing. The team decided to further investigate using a human skin model. These tests were all done via self-testing with only the members of this MQP team, since an IRB application was unable to be approved in a timely manner.

Adhesive Shear Strength Test

As mentioned previously, the porcine model was not the most appropriate model to use. The team further investigated using a human skin model to collect the final data that would determine the best medical adhesive to use for this pressure ulcer sensor. As a trial, Benjamin Parent consented to having the test performed on the underside of his forearm. More details on this will be described later. However, what is important to note is that the team realized the adhesives adhered to human skin much differently than steel. This test that had just been performed was successful, and yielded appropriate data. Therefore, the results from shear tests on a participant's forearm were going to be used as the final results for choosing the final material. The results are discussed in Section 5.2.2.

Adhesive Peel Strength Test

Because the shear test on human skin had gone so well, the team looked into using the human forearm as a replacement for the steel plate in the peel test. In an attempt to collect more usable data, Rachel Ooyama-Searls consented to allow peel tests on her arm. In order to prevent Rachel from having to put her arm in the Instron®, the team designed a way for her to be a meter away from the machine. A meter long aluminum extension bar was located and this was loaded into the upper clamp of the Instron®. The test sample was adhered to the end of the extension bar, and Rachel's arm was positioned under the sample. Her arm rested on a table that was the same height as the lower clamp of the Instron®. This setup is shown in Figure 4.6. The upper clamp was lowered to a height 1 cm above Rachel's arm, the sample adhesive are was adhered to her skin, and the sample was secured onto the skin using the steel roller. The rest of the test followed the same extension protocol as previously stated. The results of this test yielded the top two materials being the MediPlus™ Barrier Gel Comfort and Tegaderm™ Film Dressing.

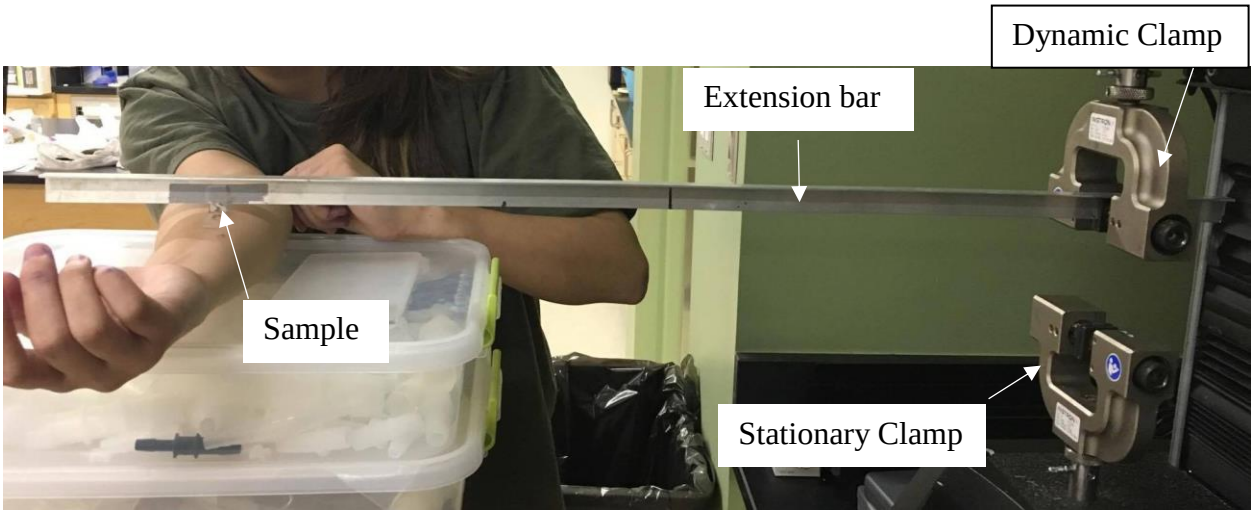


Figure 4.6: Setup for Human Peel Test using Instron® 5544

Adhesive Loop Tack Strength Test

Preliminary tack tests were not performed on human skin. It would be hazardous to place an arm or other body part into the Instron®, trusting that the program would return the clamp to the same height. There is still the risk of crushing the limb. Furthermore, performing the test away from the machine like in the peel test, would still expose the participant to potential harmful compressive forces. The decision to not perform human trials was also justified to the low weighting score that was assigned to tack, since the data would not greatly affect the results in the design matrix. The team wanted to look into using another machine that would be safer to test with the human tissue model.

Limitations with Instron® 5544

The Instron® 5544 had a 2kN load cell. Because this load cell was so high and the data obtained had such low readings, it was concluded the data may be invalid. This load cell was not sensitive enough to read such low data accurately. To fix this, the team used another Instron® with a more appropriate load cell. This Instron® E1000 was located in Gateway and had a 50 N

load cell. Unfortunately, after testing a few materials on the steel plate and porcine model, it was evident the data collected was also noisy and inconclusive just like the Instron® 5544. A different machine was needed for testing, one with a better load cell and safe to test the human tissue model.

Acquisition and Setup of Instron® In-Spec™ 2200

More conclusive tests were conducted by using an Instron® In-Spec™ 2200 Benchtop Portable with a ten pound load cell. This Instron® had a much more appropriate load cell and was quite small, decreasing the chance of any harm to any of the human subjects. In order to use the In-Spec™, grips needed to be constructed such that specimens could be connected to the load cell. Nuts were superglued together to so the screw that came out of the load cell could be connected to an eye bolt. The threads of the screw and the eye bolt were different so the assembly was secured with wire and electrical tape. In order to properly grasp the material samples, grips were made using binder clips and these were secured onto the eye bolt using wire and electrical tape as well.

The In-Spec™ 2200 differed from the Instron® 5544 in that the machine was designed to send load information to a personal digital assistant (PDA) rather than a computer. Since the machine did not come with a PDA, a new solution needed to be created to transfer the information to a computer to collect the data. Before this MQP, the output cable that would have been connected to the PDA was separated into two components: one that output displacement data and one that output load data. These components were connected to oscilloscope cables. For this MQP, the oscilloscope cable that output load data was used.

A digital multimeter was used to collect data. For this, the negative and positive terminals of the load oscilloscope cable were connected to the respective AI0+ and AI0+ ports of a National Instruments Elvis prototyping board. The data was collected using the Data Logger application of the NI ELVISmx Instrument Launcher program. The Data Logger application saved data in .lvm type files so this was converted to .xlsm type files by opening the .lvm file using WordPad and saving the file as a .txt file. This .txt file could then be converted into a .xlsm file by using the Get External Data Import Wizard in Microsoft Excel.

When the Data Logger was run, the data were collected in terms of volts so it needed to be converted to force (Newtons). This was done by collecting data for the voltage output for different masses that ranged from 0g to 1600g. 1600g was chosen because the predicted maximum load force from preliminary tests of the materials was about 3N, and 1600g was the equivalent of 15.7N. After the voltages were collected, they were input into an Excel sheet with the corresponding forces from the masses and plotted. A calibration curve was collected from the linear fit of the points and the equation of the line. This was used to convert subsequent voltages into forces. The protocol the team followed for using the In-Spec™ 2200 can be found in Appendix B, and actual testing protocols with the In-Spec™ 2200 are discussed in Section 4.3. This section describes each method actually used to determine the best material for this sensor rather than overviews of preliminary tests.

4.2.5 Water Resistance Test

In addition to the 90 degree peel, loop tack, and shear tests, the wound dressings were tested for water resistance. The original standard used was ASTM D779-16 Standard Test Method for Determining the Water Vapor Resistance of Sheet Materials in Contact with Liquid Water by the Dry Indicator Method [44]. The materials were cut into 1.2 cm by 2.0 cm samples. Weigh boats had a small 1 cm by 1 cm section cut out on the bottom. The wound dressings were adhered over the cut out section, such that the backing of the wound dressings was exposed to water. On the exposed adhesive section, an indicator powder made of powdered cane sugar, soluble starch, and methyl violet dye. The weigh boat was placed into a larger weigh boat filled with water. Water had gotten through to the adhesive when the indicator powder turned from white to purple. The standard called for timing how long it took for the rate of change in the indicator powder to increase rapidly. Seeing as how this is not a precise result, the team modified this standard by taking pictures of the sample every five minutes for a total time of forty minutes. This was determined by previous mock tests, observing that some materials exhibited some color change after five minutes, but not enough so that was deemed significant. After the forty minutes, water was poured onto the indicator powder to show what a positive control would look. The pictures would have been tested against the positive control by using an image analysis program, determining at which time point was there was a rapid increase in color change. After using this standard with five materials, it was concluded that this standard was not the correct procedure for this project's purposes. The results obtained were not conclusive and difficult to interpret.

To obtain water resistance data, a contact angle test was conducted. This test helps determine the hydrophobicity of a material. When the sensor is on the patient, it is anticipated the sensor will not be submerged in water but rather will roll off the sensor. This test will yield results of how likely water will roll off the material or adhere to it. A sample of the material was placed adhesive side down onto the bottom of the small weigh boat. Methyl violet dye was mixed with water and approximately 50 microliters of the purple solution was dropped onto the backing material of the wound dressing using a micropipette. The purple dye helped make the angle of the drop with the material easier to measure, due to the contrast of the purple against the white background. A picture was taken of the drop formed on the sample. The contact angle was found by using the image processing software ImageJ. This preliminary data is located in Appendix A.

Though this contact angle test was helpful, the sensor will be exposed to water for some time, more than just what was needed to take a picture of the 50 microliter drop. Therefore, the team later adjusted the original testing standard so that usable results could be yielded. The actual protocol used for verification purposes is discussed in Section 4.3.4.

4.2.6 Elastic Modulus Test

The final material test conducted was a test of each material's elastic modulus. It is preferable to use a material that has an elastic modulus close to or identical to that of skin. When the adhesive material has a substantially higher elastic modulus than the skin, it can end up applying shear forces, which may contribute to forming a pressure ulcer. Not only would this,

but the shear forces that would be applied make the patch extremely uncomfortable. The elastic modulus of skin ranges from 1.0-4.0 MPa but for the project's purposes the team used mean value 2.5 MPa as the elastic modulus for skin [42].

For this test, a strip of each material was cut. Sizes of the strips varied based on the amount of material the team had to work with. The initial length, width, and thickness of each sample was recorded. After recording these measurements, forces were recorded while each sample was pulled in tension using the Instron® 5544 at a rate of 60mm/sec until the sample failed. Though many values obtained were below the threshold of 20 N (which is technically the lowest value that is considered accurate for the Instron® 5544), the other Instron® machines available to the team would not be appropriate for this application. This problem was solved for other tests by using the In-Spec™ 2200; however, this machine would not be usable for calculating elastic modulus because the full extension of the machine was too small to cause a failure of the sample in tension.

MATLAB® code was written in order to calculate elastic modulus using the raw data .csv files the Instron® BlueHill® software exported. This code can be found in Appendix C. This code imported the force and extension raw data for each test. It then calculated the cross sectional area of each sample using the material width and thickness measurements imported from a separate measurements table .csv file. Next, it converted the force raw data into stress using Equation 1.

$$\text{Stress} = \text{Force} / \text{Area} \tag{1}$$

After that, it converted the extension raw data into strain using the initial length measurement from the measurement table and Equation 2.

$$\text{Strain} = \text{Extension} / \text{Initial Length} \tag{2}$$

From there, it calculated multiple elastic moduli over the course of the test using a moving slope function. The moving slope function calculated the slope of stress-strain curve, but only over an interval of 10 data points. This function is depicted by the equation below.

$$\text{Elastic Modulus} = (\text{Stress}_2 - \text{Stress}_1) / (\text{Strain}_2 - \text{Strain}_1) \tag{3}$$

These elastic moduli were then filtered to stop before a negative slope value was detected, indicating failure of the material. Finally, the elastic modulus for the material was determined by taking the maximum elastic modulus of this set. This protocol was repeated twice for each material, allowing the team to average the results and compare them with the other materials.

4.3 Methods for Final Material Verification

In Section 4.2, preliminary protocols were executed to help gain a better understanding of the tests themselves. In addition, the preliminary protocols gave the team a better sense of the material's behavior. This information helped the team formulate the most appropriate protocols to determine the best material for this sensor. The following methods yielded the actual data the team analyzed for choosing this material.

4.3.1 Elastic Modulus Test

As mentioned in the previous section, using a material with a similar elastic modulus of skin is preferable. This way, the team can ensure the patch material will not cause irritation or harm to the skin near the application site. Section 4.2 described the protocol used for mock tests, which is the protocol the team decided to use for final testing. Results of this test are described in Section 5.2.1.

4.3.2 Adhesive Shear Strength Test

Benjamin Parent consented to allow shear adhesion tests on his arm. The materials were of medical grade, and there was no risk of harm from a machine. Testing samples were cut, and the adhesive area was applied to Benjamin's skin. The remainder of the test was the same as with the steel model. This data was quite different from the data obtained using stainless steel, thus leading to the conclusion that wound dressings adhere to different surfaces in different manners and a better human skin model is required for further testing. Results are discussed in Section 5.2.2.

4.3.3 Adhesive Peel Strength Test

To test on human skin, Brittney Pachucki consented to have the Peel Test conducted on the underside of her right forearm. Essentially, the same procedure was followed as with previous tests. A 4.0 cm by 1.2 cm sample was cut from each medical product. The sample was marked with a permanent marker such that one end of each sample had a known area of 2.3 cm by 1.2 cm. The sample was attached to the top grip of the Instron® In-Spec™ 2200 and was slowly lowered down towards Brittney's arm on a spot that had been cleaned with an alcohol wipe. This adhesive area was placed on her arm and pressed down with fingers to ensure good adherence. The top grip was slowly brought up until the medical bandage was completely removed from Brittney's arm. The process was repeated twice for each material to find the average peel strength, and her arm was cleaned with an alcohol wipe between each test. Results are in Section 5.2.3.

4.3.4 Water Resistance Test

This test used samples that were cut to the dimensions of 1.2 cm by 2.3 cm and adhered to clear plastic squares that were roughly 1.5 cm^2 in area. Before being adhered to the plastic, a team member applied a spot of just the dried dye (no starch or sugar) to the center of the adhesive side of the sample. This setup can be seen in Figure 4.7 below with both a negative test result (on the left) meaning it was water proof and a positive result (on the right) meaning it was not waterproof. The team made two of these plastic square setups for each sample and placed them in a shallow bin of water. All the samples were recorded by a video camera for the first 5 hours and then checked on the hour for the next three hours. After that time period, the samples were then checked every 12 hours for the next 36 hours. Results were recorded during which hour each sample turned purple, and are discussed in Section 5.2.4.

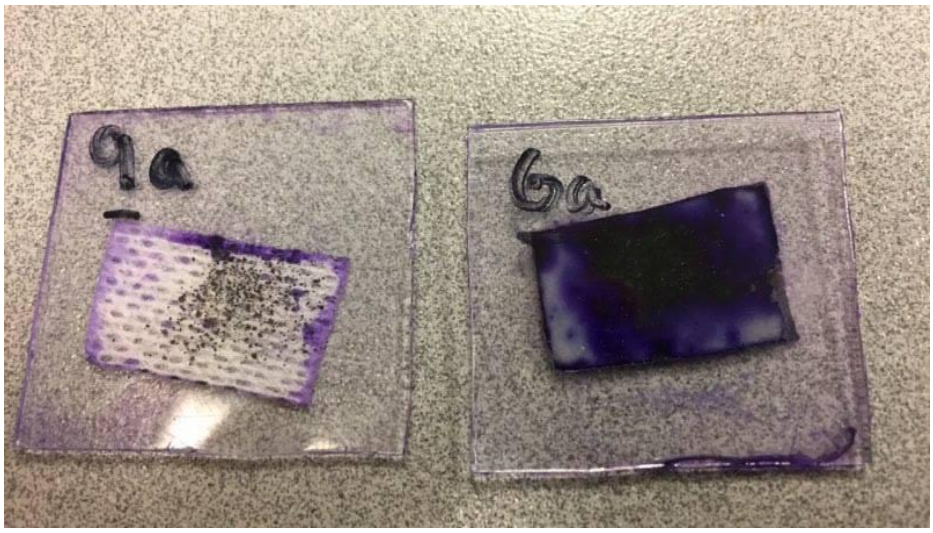


Figure 4.7: Example of Water Test Samples

4.3.5 Adhesive Loop Tack Strength Test

To test on human dermal tissue, Rachel Ooyama-Searls consented to having the Loop Tack test conducted on the underside of her right arm. Essentially, the same procedure was followed as with previous tests. A 4.0 cm by 1.2 cm sample was cut from each medical product. The samples were marked with a permanent marker such that the center of each sample had a known area of 2.0 cm by 1.2 cm. The sample was folded up, as with previous tests, and loaded into the Instron® In-Spec™ 2200. The sample was lowered down onto Rachel's arm with a predetermined height of 2 cm. Once the sample touched down, it was lifted back up. A piece of tape was placed onto Rachel's arm and the bottom of the loop was covered in dye. The sample was then lowered down again at the same height and left a print of the adhesion area. Data was calculated the same as before. Results are located in Section 5.2.5.

4.4 Pre-Patch Material Duration Study

While Shear Strength Testing was a good preliminary indicator for determining how long the product will stay on the body, the study did not actually test which material could stay on the longest. Performing such a test using all fourteen materials on the body with multiple samples would have been difficult, since this test would take up a large surface area of the body or require a great number of participants. Instead, the team concluded duration testing should be conducted on the two best performing materials from the material studies, Tegaderm™ Film Dressing and Transpore™ Surgical Tape both by 3M Co.

Originally, the team intended on conducting a human study to test these materials on a large selection of participants. In this application, the team had created testing protocols for three types of tests: a duration study to tests the patch materials, a duration study to test the patch models, and a peel discomfort study that inquired about the potential for the patch to cause pain upon removal. This application was not passed, however, since more additional applications needed to be passed through the University of Massachusetts Memorial Medical Center Institutional Review Board as well to get WPI Health Services nurses to help participants in the

case of a reaction to testing materials. Due to the time restrictions of the MQP, the IRB application with WPI was withdrawn, and the team consented to performing tests on themselves to collect some preliminary data about the materials.

The first test that the team partook in was the material duration study. The protocols from the application were adapted so that the team could complete more trials for more robust results. This test was designed to test the durability of Transpore™ versus Tegaderm™ to determine which material to use for a subsequent duration study of the actual patch shape. This material duration test also determined if the use of an AllKare® Barrier Preparation Wipe and its efficacies of prolonging the adhesive durability of medical products. This test lasted for eleven days and was repeated again at the end of the first cycle to obtain more data. The first test was conducted on the upper shoulders while the second test was conducted on the upper thigh.

Figure 4.8 depicts the placement of the materials for this test. Each skin area was cleaned with an alcohol wipe and then eight 1.5 cm^2 square adhesive samples were adhered onto each person. Sixteen samples were adhered in total, 8 on each arm, 4 of Tegaderm™ and 4 of Transpore™ on each arm. Samples were adhered in two rows of 4. The top row used an AllKare® Barrier Preparation Wipe, but the bottom row did not. Each row used 2 samples from each material. Each person in the team completed a Google Form survey every 12±1 hours for eleven days to grade the status of each material sample. Twelve hours was chosen as the time interval because it would allow respondents to record data in the morning after sleeping when the samples could have detached due to friction and shear forces experienced in bed, as well as in the evening after a day's worth of activity that could have caused the samples to detach. Eleven days was chosen as the duration period because the material needed to stay on for 7 days. If both materials were able to stay on for this 7 day time period, the team would not be able to make a conclusion. The additional four days may have been when the materials would fallen off, allowing for statistical significance to be concluded between the two materials.

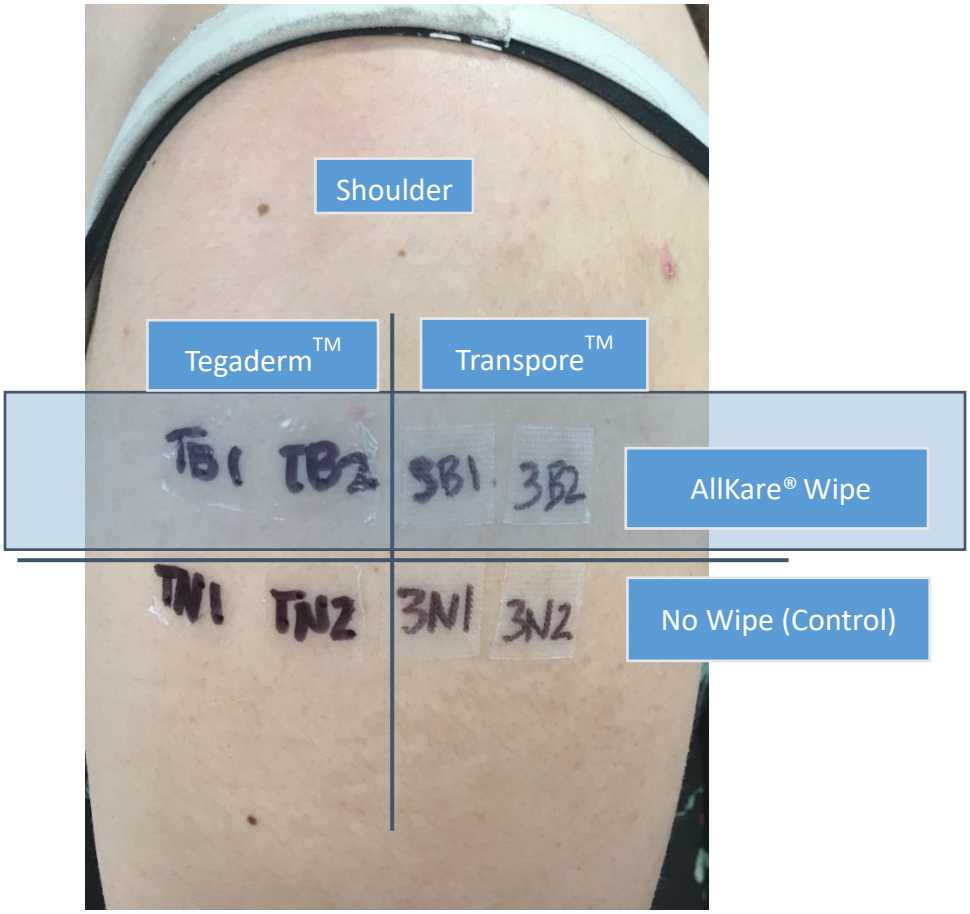


Figure 4.8: Setup of Pre-Patch Material Duration Test

The survey used for this test is in Appendix D. The grading system for this test was based off the FDA's draft guidance document for Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs. The FDA used a grading scale that ranked materials based on the criteria in Table 4.3. Essentially, for the MQP, the criteria for the scores were inverted from the FDA scores because when taking the surveys, it was more intuitive to rank a sample using a higher score if it had more material adhered to the skin. Conversely, it was more intuitive to rank a sample with a 0 if there was 0% of the material adhered to the skin. The FDA used its scores to later statistically analyze results system, so when the MQP team needed to do this, the data was converted to match the FDA grading system. Results of this study are discussed in Section 5.3.

Table 4.3: FDA Patch Adherence Grading System

Score (Multiplier for Analysis)	FDA Criteria	MQP Criteria
0	≥ 90% adhered (essentially no lift off the skin)	0% adhered (patch detached; completely off the skin).
1	≥ 75% to < 90% adhered (some edges only lifting off the skin)	> 0% to < 50% adhered (not detached, but more than half of the patch lifting off the skin without falling off)
2	≥ 50% to < 75% adhered (less than half of the patch lifting off the skin)	≥ 50% to < 75% adhered (less than half of the patch lifting off the skin)
3	> 0% to < 50% adhered (not detached, but more than half of the patch lifting off the skin without falling off)	≥ 75% to < 90% adhered (some edges only lifting off the skin)
4	0% adhered (patch detached; completely off the skin).	≥ 90% adhered (essentially no lift off the skin)

The second test the team partook in was the patch duration test. Further details of this test will be described later in this chapter. Due to time constraints and prioritizing tests, the third test, peel discomfort test, was not conducted on the team members.

4.5 Design Development

4.5.1 Preliminary Designs

In the initial brainstorming and designing process, the team considered reusability as a want which differs greatly from the direction the project was taken, as disposability was a need for the final product. Additionally during the initial designs, the team made certain assumptions about how the electrical components would look and act that were incorrect. As a result the initial designs varied drastically with the final design that was ultimately decided on.

The first step taken in the design process was to brainstorm ideas using different methods. The first method used was to think about and list all the concepts the team did not want the patch to do or to have. This was a good exercise in making a creative atmosphere as well as to get the team thinking about what the final product may need to do, not only to make it achieve certain goals but also how to design it to not have certain complications. After going through this

exercise the team brainstormed using a silent technique called a “round robin”. In this exercise, each teammate started with a sticky note and had one minute to draw and annotate a design for the final patch. After a minute was up, the design was passed to the person on the left. After looking at what was passed, the process of drawing a new design was repeated. This process was repeated five times and then as a team, all fifteen designs were looked at and discussed. This brainstorming session was useful in that it produced several different designs in roughly five minutes. From those initial fifteen designs, the team combined some together and came up with two separate ideas. Rough prototypes of these designs were made out of common materials that were readily available as shown below in Figure 4.9.

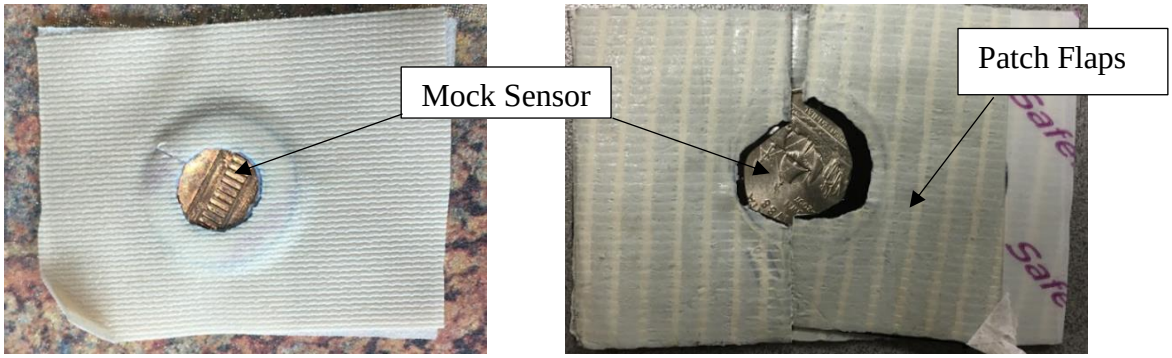


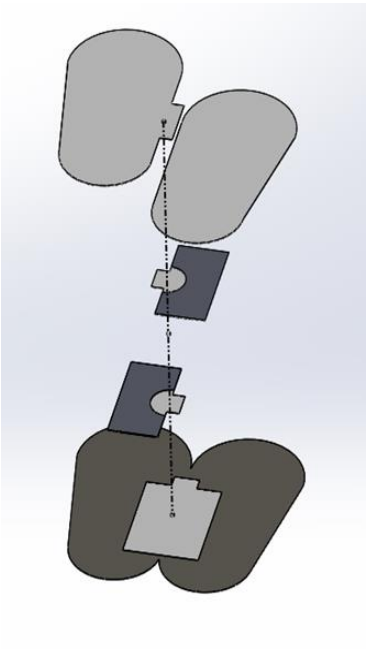
Figure 4.9: Prototype 1 (left) and Prototype 2 (right)

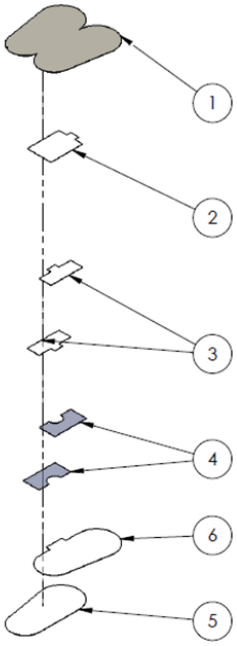
For Prototype 1, the patch component consisted of two layers of adhesive material. The bottom layer adhered to the skin and the second adhered on top of the first. The bottom layer had a small circle cut out and between these two layers was a circle of release liner that would be removed so the electronic component could be secured in that space between the two adhesive layers. This design did not allow for easy insertion of the electrical components since the adhesive layers could quickly adhere to each other after removal of the liner. This design did, however, secure the electrical components in place, protect them from water, and allowed for the reuse of the electrical component.

For the Prototype 2, a double layer approach was again used. This time the bottom layer consisted of two flaps that would fold down onto the electrical component to secure it. A hole was left at the intersection of the flaps to allow the sensor to access the skin for moisture sensing. This model also had release linings on both sides of the flaps as well as the exposed adhesive portion of the top layer to allow for easier electrical component insertion as well as to reduce contamination of the adhesive surfaces. Problems related to this prototype included water ingress at the seam of the flaps. However, this prototype did allow for easy insertion and removal of the electrical components and it secured the electrical components in place.

Moving forward from the first two prototypes, a CAD design was used for the third prototype developed as shown in Figure 4.10. This design worked similarly to the second prototype where two flaps fold down and secure the sensor into place. The flaps had a hole for the sensor component to have contact with the skin. This also had removable release liners on the flaps and top layer to reduce contamination of the adhesive parts while also improving the ease of inserting the electrical component. The difference between this and the previous prototype

was that the top layer overlapped beyond the flaps and it was cut to be a butterfly-like shape. This design has the potential to create many different shaped top layers to fit the various parts of the body where pressure ulcers form.





Part Number	Part Name	Description
1	Fabric Adhesive Top Layer	Adhesive on bottom side adheres to body
2	Release Liner	Remove to adhere sensor to top layer
3	Flap Release Liner	Remove to secure adhesive flaps onto sensor
4	Adhesive Flaps	Fold down over sensor to secure in place
5/6	Patch Release liners	Remove to adhere patch to body

Figure 4.10: Exploded Views of the Butterfly-Shaped Prototype

4.5.2 Alternative Designs

After presenting these designs to the electrical engineering team and to the project's main clients, plastic surgeons from University of Massachusetts Memorial Medical Center, it came to the team's attention that these designs were not feasible. This is due to disposability, which is needed in a hospital setting, and restrictions based on the electronic design. In creating a new design that would be feasible, the team worked closely with the ECE team designing the patch electronics and came up with three new designs shown below. The designs were based on research conducted on bandages for joints and limited by the design and size of the flexible circuit board. Having shapes with tabs allows for the stress to be distributed in such a way that the product will stay on longer.

These designs contain the sensors for the patch in one of the end of the configuration as noted by the circles in Figure 4.11, and that end will need to be adhered to the body where a pressure ulcer may occur such as a bony prominence. The other end of all three designs contain the rest of the electrical components that do not need to be directly on the potential pressure ulcer site. All three of these designs consist of 5 layers. The bottom layer is an acrylate/polyurethane (determined by verification and validation methods explained further on in chapters 5 and 6) adhesive layer that will make direct contact with the patient's skin. The middle layer or third layer consists of the flexible printed circuit board and all the electronic components. It is surrounded and encased by the second and fourth layer which are made out of a waterproof polyethylene foam designed to protect the electronics. The bottom layer of foam and adhesive will have small holes corresponding to the temperature and moisture sensors on the flexible

circuit board. The top layer is a waterproof polyester/rayon (determined by verification and validation methods explained further on in chapters 5 and 6) backing material which will seal the whole design. The geometry of each patch design was heavily influenced by the circuit board design and the surgeons supporting this project.

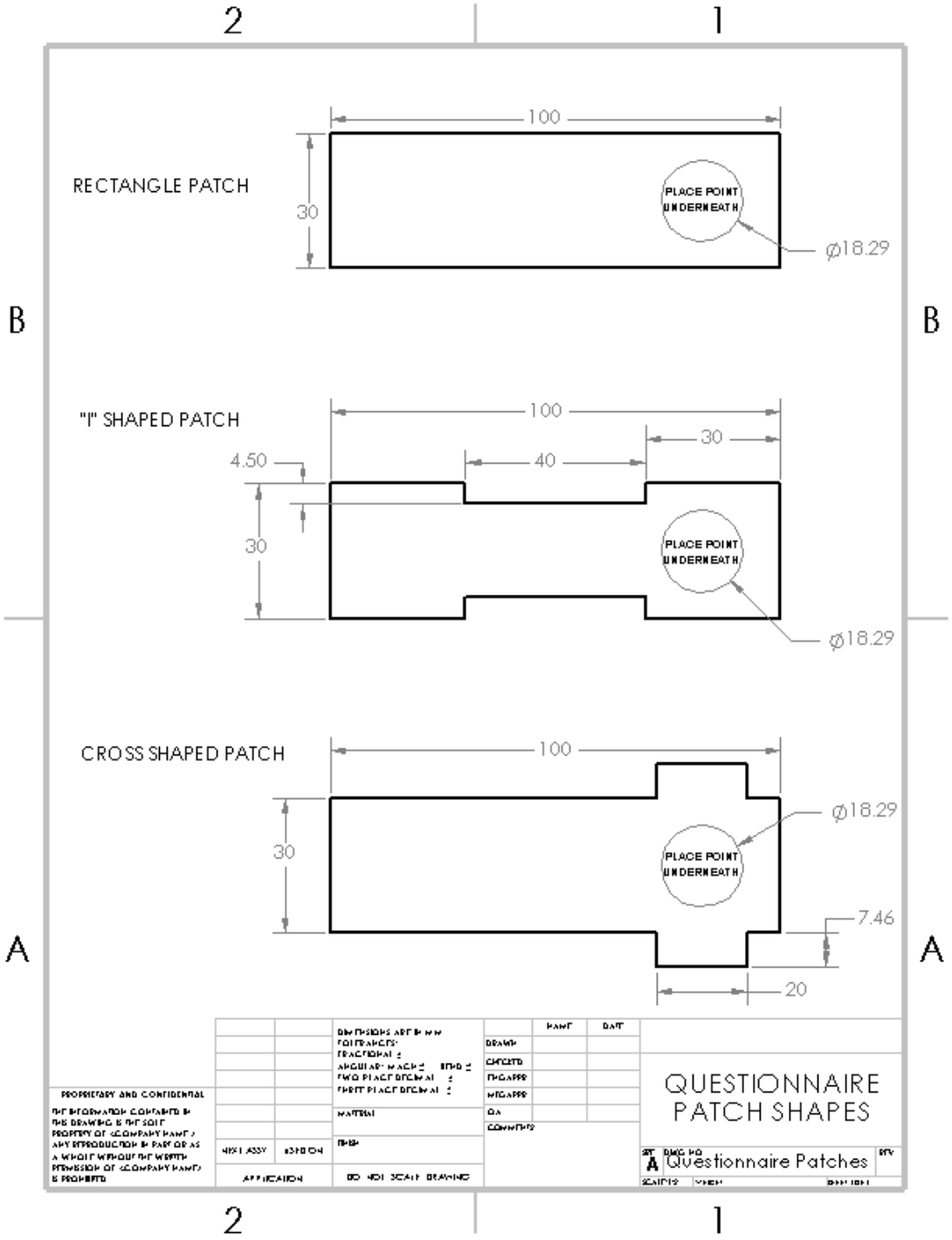


Figure 4.11: The three major designs used in the questionnaire

4.6 Final Design Selection

When choosing between the designs there were two considerations: which patch shape is most intuitive to potential consumers, and which shape works the best on skin. The first consideration is important to this project specifically because if the sensor components of the patch are placed in the wrong positions, the technology will be unable to accurately predict if a pressure ulcer will form.

4.6.1 Patch Intuitiveness User Questionnaire

To assess the first consideration, an interactive survey (shown in Table 4.4) approved by the WPI IRB was given to sixteen consenting participants. This survey started by asking participants to open mock patches, to gauge how easy it was to detach the packaging of this sensor. Occasionally, the packaging can damage the medical tapes, causing the adhesive to stick to itself. This part of the study ensured packaging was adequate for users. Then, using paper cutouts of each design one at a time, the participant was asked to demonstrate how they would place them on their heels and elbows. The participants were given no formal instructions other than to put it on their elbows and heels and a brief description of how and where pressure ulcers develop. Their responses were recorded and then the intended patch orientations were revealed to the participants. They were then asked which patch they found most intuitive and if there were improvements they felt should be made to each design. These design critiques were taken into account moving forward as the original shapes altered slightly. Both the “I” and “cross” shape patches were changed to have longer and larger tabs based on feedback from the survey (Figure 4.12 and Figure 4.13). Additional views of these designs can be found in Appendix E. From the survey responses, it was determined that the most intuitive design was the “cross” shaped patch followed closely by the “I” shaped patch. All participants were students between the ages of 18 and 22 that do not suffer from pressure ulcer complications. In the future it would be ideal to conduct this same survey with patients that are at risk of developing pressure ulcers and their caretakers. Results are further discussed in Section 5.4.

Table 4.4: Intuitiveness Questionnaire

Questionnaire for Patch Usage Study
How would you open the patch packaging before use?
How would you place this patch on your heel?
How would you place this patch on your elbow?
In what orientation would you place it on those locations?
What aspect of the design helped you decide how you were going to position the paper?
After telling the participant has demonstrated how they would put on the three example patches, we will tell them the intended placement and ask the following questions:
What change in the design would help you more to place it correctly?
How do you think the design could be improved?
How do you think the packaging could make the instructions clearer?
At the end of the study, we will ask this final question:
Which patch do you prefer and find most intuitive to use?

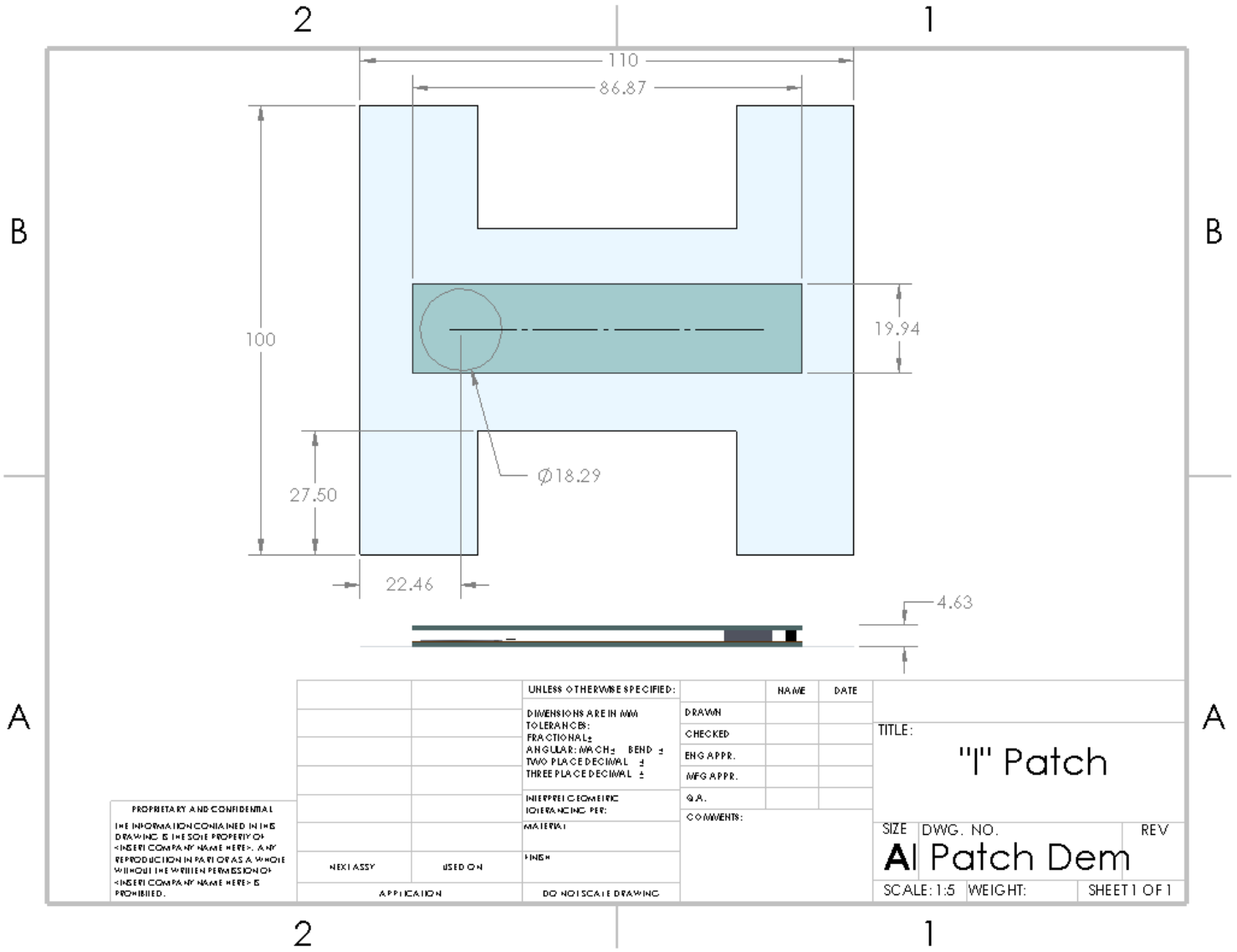


Figure 4.12: Adapted "I" Shaped Patch for Patch Duration Test

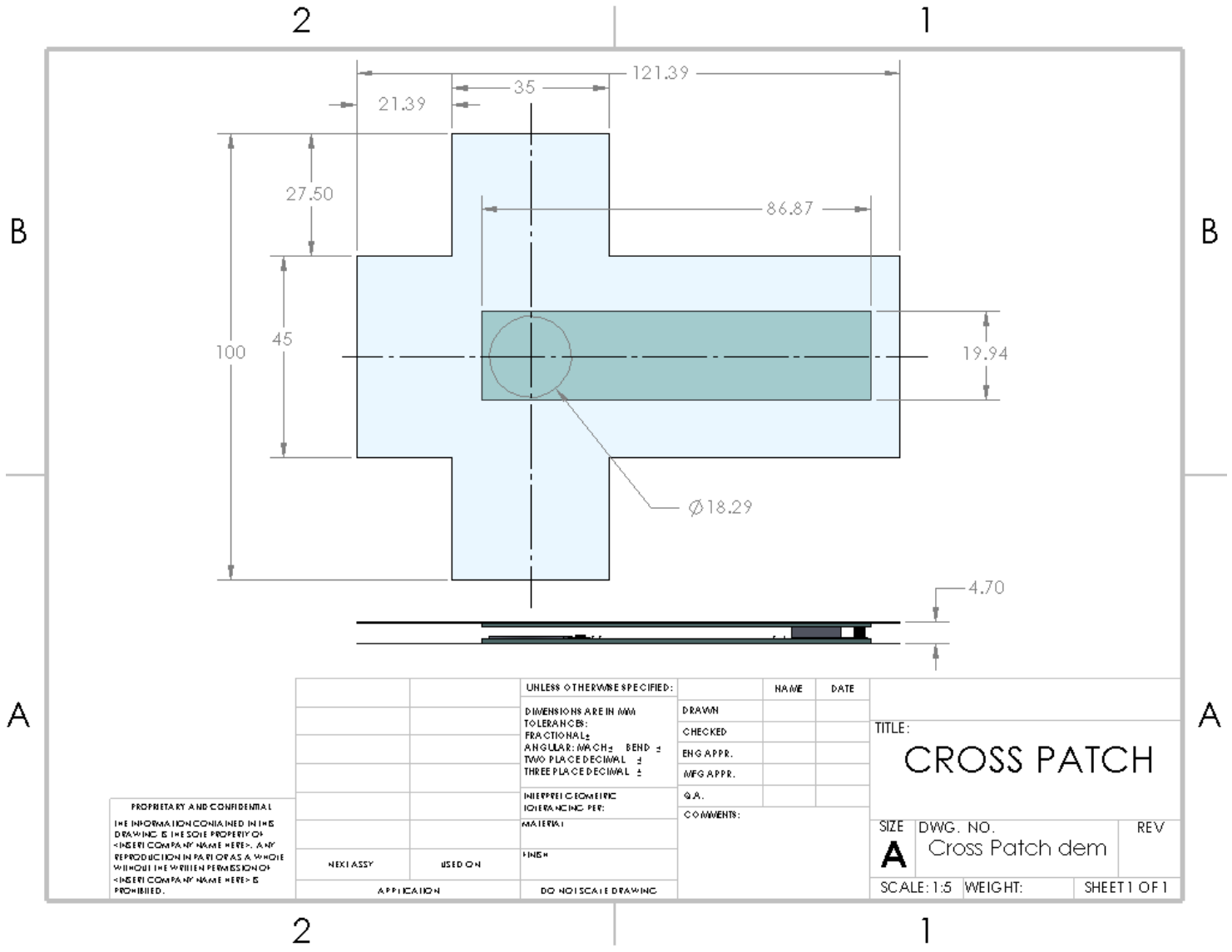


Figure 4.13: Adapted "Cross" Shaped Patch for Patch Duration

4.6.2 Patch Design Duration Validation Study

Our first consideration of the patch shape was the intuitiveness of the shape. The second consideration was which shape remained the best on the body. For the second consideration, human testing was performed on the members of the MQP team to determine which patch adhered best to elbows and heels. The team had hoped for a larger sample size rather than just the three team members, but because the IRB application was not approved in time, the team could only test on themselves.

This patch design duration validation study was performed in order to determine which patch shape performed better and to determine if it could remain functional on the body for the seven days as prescribed by the client statement. For the first round of the study each participant wore 2 adapted "I" shaped patches and 2 adapted "cross" shaped patches, one for a heel and one for an elbow each. These adapted shapes were the changed versions of the designs after the interactive survey (Figure 4.12-Figure 4.15). Each patch had two layers of the adhesive material (one top layer exposed to the air and one bottom layer adhered to the skin) and a mock flexible PCB made of 4 sheets of KODAK Inkjet Photo Transparency Film that was positioned between two layers of polyethylene foam. A coin was flipped to randomly assign an "I" or "Cross" patch to adhere to the left or right heel and then elbow. The adhesive material of these initial patches was made of Transpore™ Surgical Tape by 3M™ (Figure 4.14).

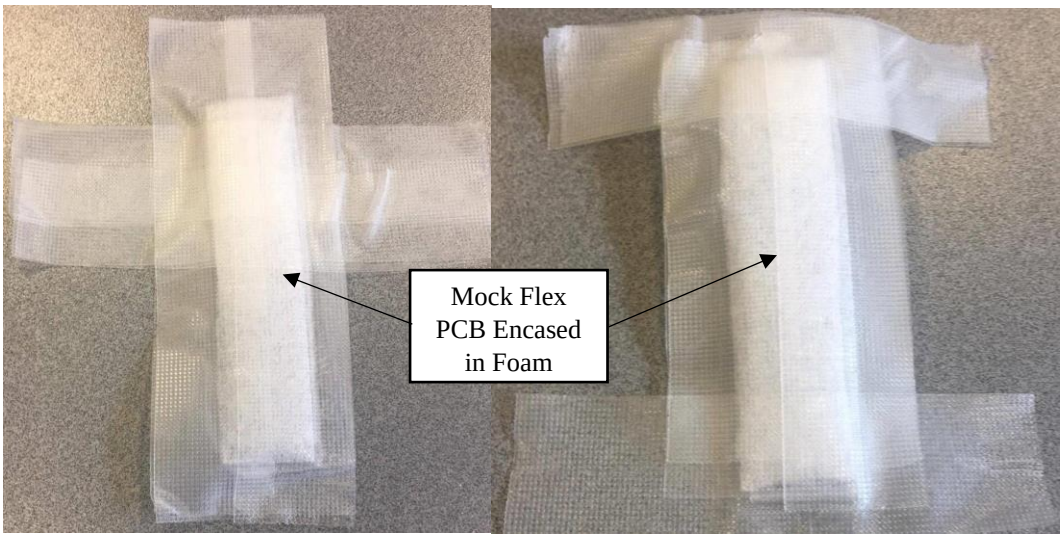


Figure 4.14: Transpore™ Patches for the Patch Duration Study

This study was intended to last for seven days. Every 12 hours each participant scored their patches on a scale of 0-4. This scoring system was the same as the one used for the Pre-Patch Material Duration Study in Chapter 4.4. Each participant also noted every 12 hours if the sensor was still functional, meaning that it was in the correct placement and adhered properly where the sensor would be. It was important that the sensor in the patches be placed on the bony prominence such that the sensor would be able to measure the appropriate data needed to detect a pressure ulcer forming. Because of this, if one side of the patch were to come off, resulting in a score of a 2, it mattered which side that was as one side contains the sensor. These responses were recorded in a digital survey (Appendix F) which stored the results in a Google spreadsheet.

Using Transpore™ Surgical Tape for the adhesive material of the patches led to significant skin irritation for all three participants, leading to the early termination of this study. This study lasted only three of the original seven days planned. Because of the irritation experienced, the patch failed in the essential biocompatibility aspect of the patch. Therefore, the study was terminated, and the next best performing material, Tegaderm™ Film Dressing by 3M Co., was used to construct and test the patches.

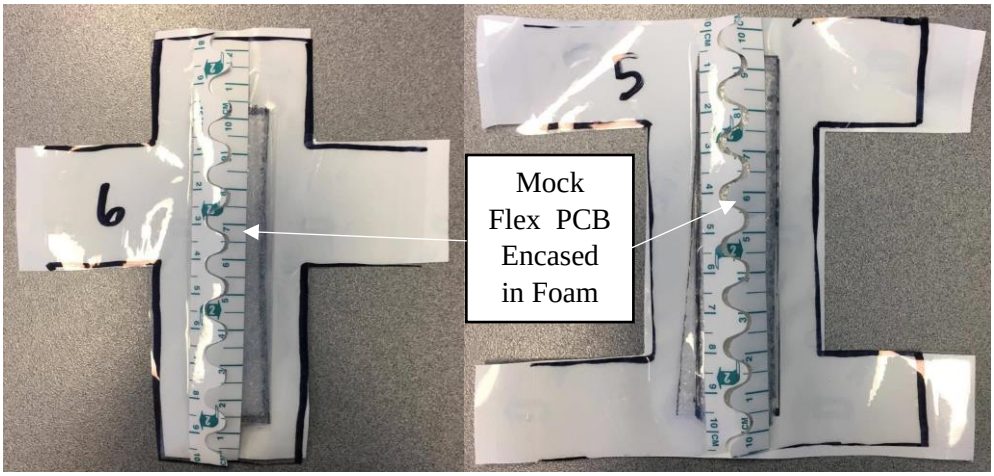


Figure 4.15: Tegaderm™ Patches for the Patch Duration Study

The same procedures were followed and the patches were adhered. After the 7 day study it was found that the "I" patch performed better than the "cross" shaped patch in that it stayed on the longest and had the sensor component of the patch adhered to the correct spot the longest.

Based on the two considerations, the final design that both adhered best to the skin and was considered intuitive was the "I" patch design with the larger tabs shown in Figure 4.12.

CHAPTER 5: Design Verification

5.1 Design Overview

In order to design an effective pressure ulcer prevention patch system, the two main factors to study were material selection and patch shape. It was necessary to select a material that would not cause harm to the user, adhere to skin for seven days, and prevent water from entering the patch. The ideal patch shape would cover a low surface area, be intuitive to the user for proper pressure sensor placement, and adhere to the skin for seven days.

5.2 Final Material Results

Unfortunately, due to the amount of testing the team had done, some materials had been completely used before being tested on the human tissue model. However, these materials had not performed well in the preliminary testing. It was concluded not testing these materials would not have made a difference on choosing the final material to use for the patch.

5.2.1 Elastic Modulus Test

Testing was performed to find a material with an elastic modulus similar to skin (3.0-4.0 MPa). This would allow the patch to put less tensile stress on the skin during everyday movements and potentially allow the patch to stay on longer. Table 5.1 displays the results of this test. Tegaderm™ film dressing by 3M Co. exhibited an elastic modulus that most matched that of skin compared to the other product samples.

The average elastic modulus was taken over the two tests for each material. Since the ideal elastic modulus was 2.5MPa, percent deviation was calculated by entering this average into a percent error equation to normalize the data as shown in Equation 4.

$$\% \text{ Deviation from Ideal} = (\text{Material E} - \text{Ideal E}) / \text{Ideal E} \quad (4)$$

In order to rank the data using the normalization method, for each material, the minimum percent deviation value of the all the results was divided by the material's percent deviation value. From this method, Tegaderm™ Film Dressing and MediPlus™ Barrier Gel Comfort were the materials with the best elastic moduli. The Tegaderm™ Film Dressing had an elastic modulus of 2.67 MPa which deviated from the ideal 2.5MPa only by 0.066% and was within the 3.0-4.0 MPa range.

Table 5.1: Final Elastic Modulus Test Results

Product Name	Average E (MPa)	% Deviation from Ideal	Normalized % Deviation
Tegaderm™ Film Dressing	2.67	0.066	1.00
MediPlus™ Barrier Gel Comfort	6.13	1.45	0.046
Scar Strips	9.43	2.77	0.024
Curad® Plastic Adhesive Bandage	13.46	4.39	0.015
MediPlus™ HC Thin	24.30	8.72	0.0076
Covidien™ Telfa™ Plus Barrier Dressing	26.52	9.61	0.0069
DuoDERM® Extra Thin Dressing	28.77	10.51	0.0063
Mepitac® Safetac® Medical Tape	36.86	13.74	0.0048
Nexcare™ Steri-Strip™ Skin Closure	51.30	19.52	0.0034
Transpore™ Surgical Tape	60.88	23.35	0.0028
Curad® Cloth Tape	119.57	46.82	0.0014
Durapore™ Surgical Tape	585.51	233.202	0.00028

5.2.2 Adhesive Shear Strength Test

The Shear Strength Test was conducted to find a material that would stay on the body the longest amount of time. To solve the problems experienced with the porcine model, Benjamin Parent consented to allow shear adhesion tests on his arm. The materials were of medical grade, and there was no risk of harm from a machine as will be discussed in later testing protocols.

To normalize the data, for each material, the maximum shear time (excluding the Curad® Plastic Adhesive Bandage outlier) of the all the results was divided by the material's shear time. The results and their normalized values are shown in Table 5.2. From this method, Curad® Plastic Adhesive Bandage and Transpore™ Surgical Tape were the top two materials for this design parameter.

Table 5.2: Shear Strength Testing Times on Human Skin

Product Name	Average Max Shear Time on Human Skin (sec)	Normalized Shear Time on Human Skin Results (sec)
Curad® Plastic Adhesive Bandage	71.48	1.00
Transpore™ Surgical Tape	35.48	1.00
Durapore™ Surgical Tape	18.94	0.53
Covidien™ Telfa™ Plus Barrier Dressing	8.59	0.24
Nexcare™ Steri-Strip™ Skin Closure	7.45	0.21
MediPlus™ HC Thin	2.66	0.07
DuoDERM® Extra Thin Dressing	2.23	0.06
Mepitac® Safetac® Medical Tape	1.62	0.05
Curad® Cloth Tape	1.48	0.04
Polyurethane adhesive	1.07	0.03
Tegaderm™ Film Dressing	0.79	0.022
Scar Strips	0.73	0.021
MediPlus™ Barrier Gel Comfort	0.61	0.017

5.2.3 Adhesive Peel Strength Test

In order to ensure that the patch does not damage underlying skin upon removal, Peel Strength Tests were conducted. The goal of this test was to find the material with the lowest peel strength.

In order to rank the data using the normalization method, for each material, the minimum peel force of the all the results was divided by the material's peel force. These results are shown in Table 5.3. From this method, MediPlus™ Barrier Gel Comfort and Covidien™ Telfa™ Plus Barrier Dressing were the top two materials for this design parameter.

Table 5.3: Peel Force on Human Skin

Product Name	Average Max Peel Force on Human Skin (N)	Normalized Peel Force On Human Skin Results
MediPlus™ Barrier Gel Comfort	1.34	1.00
Covidien™ Telfa™ Plus Barrier Dressing	1.52	0.88
Tegaderm™ Film Dressing	1.65	0.82
Nexcare™ Steri-Strip™ Skin Closure	1.82	0.74
Mepitac® Safetac® Medical Tape	1.92	0.72
Scar Strips	2.06	0.70
Curad® Cloth Tape	2.17	0.65
Polyurethane Adhesive	2.19	0.62
Transpore™ Surgical Tape	2.21	0.61
Durapore™ Surgical Tape	2.35	0.61
DuoDERM® Extra Thin Dressing	2.78	0.57
MediPlus™ HC Thin	2.89	0.48
Curad Band Aid	3.16	0.43

5.2.4 Water Resistance Test

Water was potentially hazardous to the patch for many reasons. It could short the electronics, get under the patch creating moist skin conditions conducive for pressure ulcer formation, or it could weaken the adhesive strength of the patch leading to premature detachment. Water resistance testing was performed to prevent this using an adaptation of ASTM STM D779-16 Standard Test Method for Determining the Water Vapor Resistance of Sheet Materials in Contact with Liquid Water by the Dry Indicator Method. The data for this test can be seen in Table 5.4. For this test the top tier was assigned to all the materials that did not fail after 5 hours of being submerged in water. This benchmark was established based on the assumption that patients wearing these patches would not be submerged in liquid for more than 5 hours without a medical professional noticing, and the patches need to be able to repel water for the amount of time it may take a patient to shower or bathe which was reasoned to be a maximum of an hour.

In order to rank the data using the normalization method, for each material, the material's time was divided by 5hrs. The top materials based on this water test were materials DuoDERM™ Extra Thin Dressing, Tegaderm™ Film Dressing, Scar Strips, Covidien™ Telfa™ Plus Barrier Dressing, Mepitac® Safetac® Medical Tape, and Transpore™ Surgical Tape.

Table 5.4: Final Water Resistance Test Results

Product Name	Water Time (hr.)	Normalized Water Results
Scar Strips	5+	1
DuoDERM® Extra Thin Dressing	5+	1
Covidien™ Telfa™ Plus Barrier Dressing	5+	1
Tegaderm™ Film Dressing	5+	1
Transpore™ Surgical Tape	5+	1
Mepitac® Safetac® Medical Tape	5+	1
Curad® Plastic Adhesive Bandage	4	0.8
Nexcare™ Steri-Strip™ Skin Closure	2	0.4
Durapore™ Surgical Tape	<1	0.2
MediPlus™ HC Thin	<1	0.2
MediPlus™ Barrier Gel Comfort	<1	0.2
Curad® Cloth Tape	<1	0.2
Polyurethane Adhesive	<1	0.2

5.2.5 Adhesive Loop Tack Strength Test

Medical products sometimes get placed incorrectly when first being applied to the body. Therefore it is helpful to have a product that is capable of being readjusted when not yet fully adhered to the skin and secured. In order to ensure that the patch does not damage underlying skin upon removal in this situation, Loop Tack Strength Tests were conducted. To test on human epidermal tissue, Rachel Ooyama-Searls consented to having the Loop Tack test conducted on the underside of her right arm.

In order to rank the data using the normalization method, for each material, the minimum tack force of the all the results was divided by the material's tack force. These results are displayed in Table 5.5. From this method, Curad® Cloth tape and Durapore™ Surgical Tape were the top two materials for this design parameter.

Table 5.5: Tack Force on Human Skin using In-Spec™ 2200

Product Name	Average Tack Force/Area on Human Skin (N/cm^2)	Normalized Tack Force on Human Skin Results
Curad® Cloth Tape	0.36	1.00
Durapore™ Surgical Tape	0.36	0.99
Nexcare™ Steri-Strip™ Skin Closure	0.41	0.86
DuoDERM® Extra Thin Dressing	0.43	0.83
Covidien™ Telfa™ Plus Barrier Dressing	0.44	0.82
Transpore™ Surgical Tape	0.45	0.79
MediPlus™ Barrier Gel Comfort	0.46	0.76
Polyurethane Adhesive	0.47	0.75
Mepitac® Safetac® Medical Tape	0.51	0.69
MediPlus™ HC Thin	0.52	0.68
Tegaderm™ Film Dressing	0.61	0.58
Scar Strips	0.87	0.41
Curad® Plastic Adhesive Bandage	1.25	0.28

5.2.6 Analysis of the Material Testing Data

Table 5.6 is a compilation of the data from all five material studies. The average actual results for each material and for each test are displayed as the numbers without asterisks. Weighted results which are the normalized values of each testing set multiplied by the weighting score of their respective test are displayed as the values with asterisks. The Final Design Score for each material were calculated for each product by adding up all the weighted results in the product's row. A perfect material that scored highest in all material studies would have received a Final Design Score of 1.0. The best product based on these Final Design Scores was Tegaderm™ Film Dressing by 3M Co. scoring a 0.67. Transpore™ Surgical Tape by 3M Co. was the second best material scoring a 0.61.

Table 5.6: Final Materials Selection

Product Name	Tegaderm™ Film Dressing	Transpore™ Surgical Tape	Curad® Plastic Adhesive Bandage	Covidien™ Telfa™ Plus Barrier Dressing	Durapore™ Surgical Tape	Mepitac® Safetac® Medical Tape	Nexcare™ Steri-Strip™ Skin Closure	DuoDERM® Extra Thin Dressing	Scar Strips	MediPlus™ Barrier Gel Comfort	MediPlus™ HC Thin	Curad® Cloth Tape
Manufacturer	3M Co.	3M Co.	Medline Industries, Inc.	Medtronic	3M Co.	Mölnlycke Health Care	3M Co.	ConvaTec, Inc.	CVS Pharmacy, Inc.	MediPurpose Co.	MediPurpose Co.	Medline Industries, Inc.
Elastic Modulus Avg. (MPa) (WF = 0.29)	2.67* (1.000)**	60.88 (0.003)	13.46 (0.015)	26.52 (0.007)	585.51 (0.000)	36.86 (0.005)	51.30 (0.003)	28.77 (0.006)	9.42 (0.024)	6.13 (0.046)	24.30 (0.008)	119.57 (0.001)
Shear Strength Avg. Time (Sec.) (WF = 0.26)	0.79 (0.022)	35.48 (1.000)	71.48*** (1.000)	8.59 (0.242)	18.94 (0.534)	1.62 (0.046)	7.41 (0.209)	2.23 (0.063)	0.73 (0.021)	0.61 (0.017)	2.66 (0.075)	1.48 (0.042)
Peel Strength Avg. (N) (WF = 0.21)	1.65 (0.817)	2.21 (0.608)	3.16 (0.426)	1.52 (0.883)	2.35 (0.571)	1.92 (0.699)	1.82 (0.740)	2.78 (0.483)	2.06 (0.652)	1.34 (1.000)	1.87 (0.719)	2.17 (0.619)
Water Resistance Avg. Time (hr) (WF = 0.15)	5+ (1.0)	5+ (1.0)	4 (0.8)	5+ (1.0)	<1 (0.2)	5+ (1.0)	2 (0.4)	5+ (1.0)	5+ (1.0)	<1 (0.2)	<1 (0.2)	<1 (0.2)
Loop Tack Strength Avg. (N/cm2) (WF = 0.09)	0.61 (0.579)	0.45 (0.787)	1.25 (0.283)	0.44 (0.816)	0.36 (0.987)	0.51 (0.692)	0.41 (0.863)	0.43 (0.825)	0.87 (0.408)	0.46 (0.764)	0.52 (0.681)	0.36 (1.000)
FINAL SCORE	**0.67**	0.61	0.5	0.47	0.38	0.37	0.35	0.34	0.34	0.33	0.26	0.26

* Plain vales are actual final results

** Values in parenthesis are Normalized Results (NR)

*** Outlier for this testing parameter

Only 12 materials were used due to lack of enough materials

5.3 Pre-Patch Material Duration Study Results

5.3.1 Tegaderm™ vs. Transpore™ Duration Study

At the end of the two testing periods, the data was sorted by correspondent and adjusted to make logical sense. Occasionally a correspondent ranked a sample with a higher score than at a previous time point, having gotten confused as to which score was associated with which sample. Logically, the sample should not become better adhered after having poor adhesion, so instances where samples changed like this were edited to have the previous lower score. The data was analyzed in two ways: 1) Transpore™ versus Tegaderm™ and 2) AllKare® Barrier Preparation Wipe versus no wipe (control).

First, the data from the Transpore™ versus Tegaderm™ results will be discussed. All the data was combined between the shoulder and thigh data. For each 12 hour time interval, the number of Tegaderm™ samples that scored a 4 was recorded. This was repeated for the 3, 2, 1, and 0 scores for all the 22 time intervals. This process was then repeated for the Transpore™ data.

After finding these counts, weighted averages were collected for each material for each time interval. This was calculated by adding all of the products of the number of samples that ranked a giving score, *x*, multiplied by the score's multiplier factor, *w*. Equation 4 enumerates this analysis and Table 5.7 shows all the material score counts and the respective weighted averages.

$$Weighted\ Average = \sum_i^4 w_i x_i \quad (4)$$

The total weighted average of each material was also calculated. In summary, the material with a smaller weighted average performed better, where a perfect material would have scored a weighted average of 0. From these results, Transpore™ performed best in this duration test scoring a total weighted average of 1.75 (n=48) compared to Tegaderm™'s total weighted average of 2.45 (n=48). To test the statistical significance of these results, the materials' weighted averages for the individual time intervals were input into a Two-Sample T-Test using Minitab statistical analysis software and a confidence interval of 0.05. From this, a p-value of 0.048 was obtained indicating that the results of Transpore™ were significantly different from those of Tegadem™.

Table 5.7: Tegaderm™ versus Transpore™ Data, Weighted Averages, and Average Scores

	Tegaderm™								Transpore™							
Score	4	3	2	1	0				4	3	2	1	0			
Multiplying Factor	0	1	2	3	4				0	1	2	3	4			
Time Point (hr)						Weighted Average	Average Score	ST. DEV						Weighted Average	Average Score	ST. DEV.
12	42	2	2	1	1	0.27	3.73	0.82	48	0	0	0	0	0.00	4.00	0.00
24	29	12	4	1	2	0.65	3.35	1.02	41	7	0	0	0	0.15	3.85	0.00
36	23	13	7	2	3	0.94	3.06	1.17	38	5	3	0	2	0.40	3.60	0.94
48	22	12	8	2	4	1.04	2.96	1.25	29	12	5	0	2	0.63	3.38	0.98
60	16	14	8	0	10	1.46	2.54	1.49	25	16	3	0	4	0.79	3.21	1.15
72	11	19	8	0	10	1.56	2.44	1.41	22	19	3	0	4	0.85	3.15	1.13
84	10	19	8	1	10	1.63	2.38	1.41	19	22	3	0	4	0.92	3.08	1.11
96	8	16	5	1	18	2.10	1.90	1.60	17	24	3	0	4	0.96	3.04	1.09
108	7	16	5	2	18	2.17	1.83	1.58	16	25	3	0	4	0.98	3.02	1.08
120	1	16	7	2	22	2.58	1.42	1.41	8	31	3	0	6	1.27	2.73	1.14
132	0	17	7	2	22	2.60	1.40	2.39	5	26	10	1	6	1.52	2.48	1.13
144	0	13	9	2	24	2.77	1.23	1.32	4	23	11	1	9	1.75	2.25	1.25
156	0	13	9	2	24	2.77	1.23	1.32	4	21	12	1	10	1.83	2.17	1.28
168	0	10	6	3	29	3.06	0.94	1.26	0	19	14	2	13	2.19	1.81	1.23
180	0	8	7	3	30	3.15	0.85	1.20	0	19	13	3	13	2.21	1.79	1.24
192	0	7	6	3	32	3.25	0.75	1.16	0	15	9	7	17	2.54	1.46	1.27
204	0	4	4	3	37	3.52	0.48	0.97	0	8	10	9	21	2.90	1.10	1.15
216	0	4	4	2	38	3.54	0.46	0.97	0	8	7	8	25	3.04	0.96	1.17
228	0	4	4	2	38	3.54	0.46	0.97	0	8	5	5	30	3.19	0.81	1.18
240	0	3	2	4	39	3.65	0.35	0.84	0	5	3	4	36	3.48	0.52	1.01
252	0	1	3	3	41	3.75	0.25	0.67	0	5	3	4	36	3.48	0.52	1.01
264	0	0	2	5	41	3.81	0.19	0.49	0	5	2	3	38	3.54	0.46	0.99
ALL	169	223	125	46	493	2.45	1.55	1.65	276	323	125	48	284	1.75	2.25	1.55

In order to visualize the difference between the two materials, Figure 5.1 shows the unweighted average score of each material for each time point. The average score was calculated using Equation 5, where *S* was the score, *x* was the number of samples that ranked the score, and n was the total number of samples for the given material in the given time interval. The vertical line indicates the 168hr (7 day) time point that the patch must remain adhered until. The horizontal line indicates where the material reaches 50% detachment. Since the linear fit line for Transpore™ had a smaller slope that indicates that, on average, its material samples remained better adhered to the body over the course of the study compared to Tegaderm™.

$$Average\ Score = \frac{\sum_i^4 s_i x_i}{n} \quad (5)$$

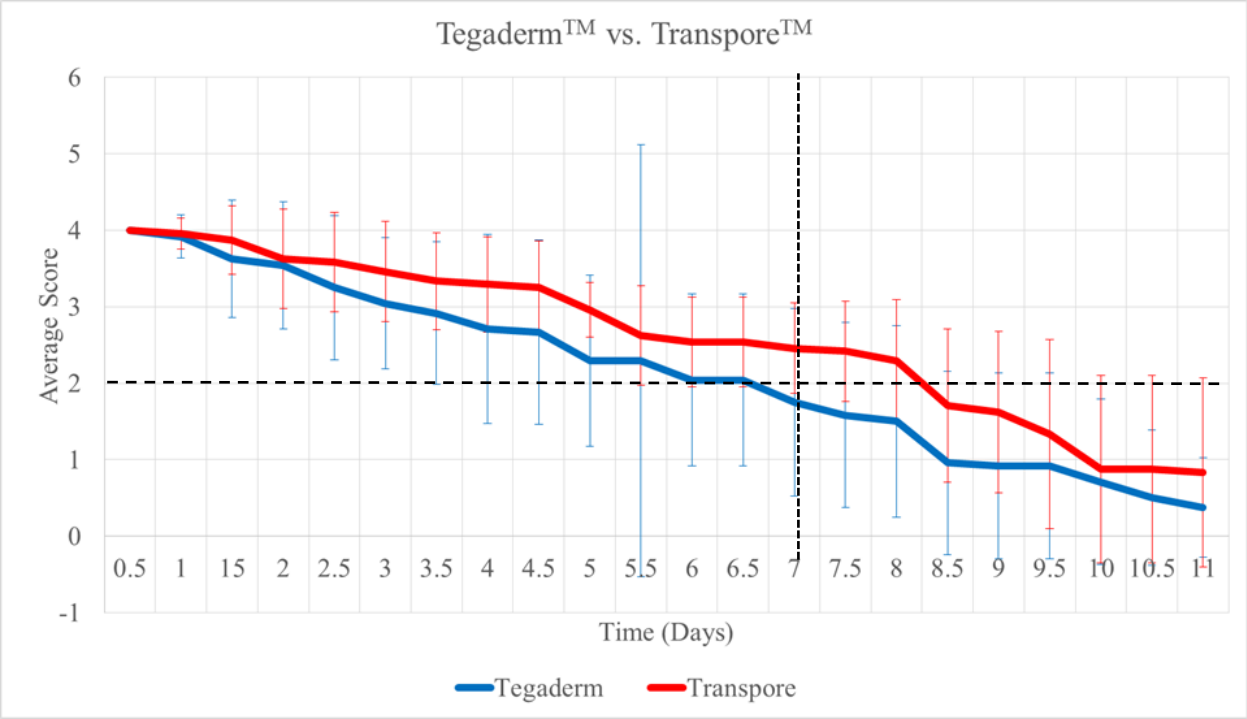


Figure 5.1: Tegaderm™ versus Transpore™ Average Score over Time

5.3.2 AllKare® Protective Barrier Wipe Duration Study

The same analysis procedures were followed to analyze the material duration studies to determine a difference in using the AllKare® Protective Barrier Wipe. However, instead of separating the data based on material used, the separation was determined based on if the wipe was used or not. Table 5.8 shows all the material score counts and the respective weighted averages. From these results, both the AllKare® Protective Barrier Wipe and the control scored a total weighted average of 2.10 (n=48). To test the statistical significance of these results, the materials' weighted averages for the individual time intervals were input into a Paired T-Test using Minitab® statistical analysis software and a confidence interval of 0.05. From this, a p-value of 1.0 was obtained indicating that the results of the AllKare® Protective Barrier Wipe and

the control were statistically the same. This means that the AllKare® Protective Barrier Wipe does not improve the adhesive endurance of the material.

In order to visualize the difference between the two materials Figure 5.2 shows the unweighted average score of each material for each time point. The vertical dashed line indicates the 168hr (7 day) time point that the patch must remain adhered until. Both testing conditions were able to remain adhered beyond this time point. Above the horizontal dashed line indicates the sample was more than or equal to 50% adhered.

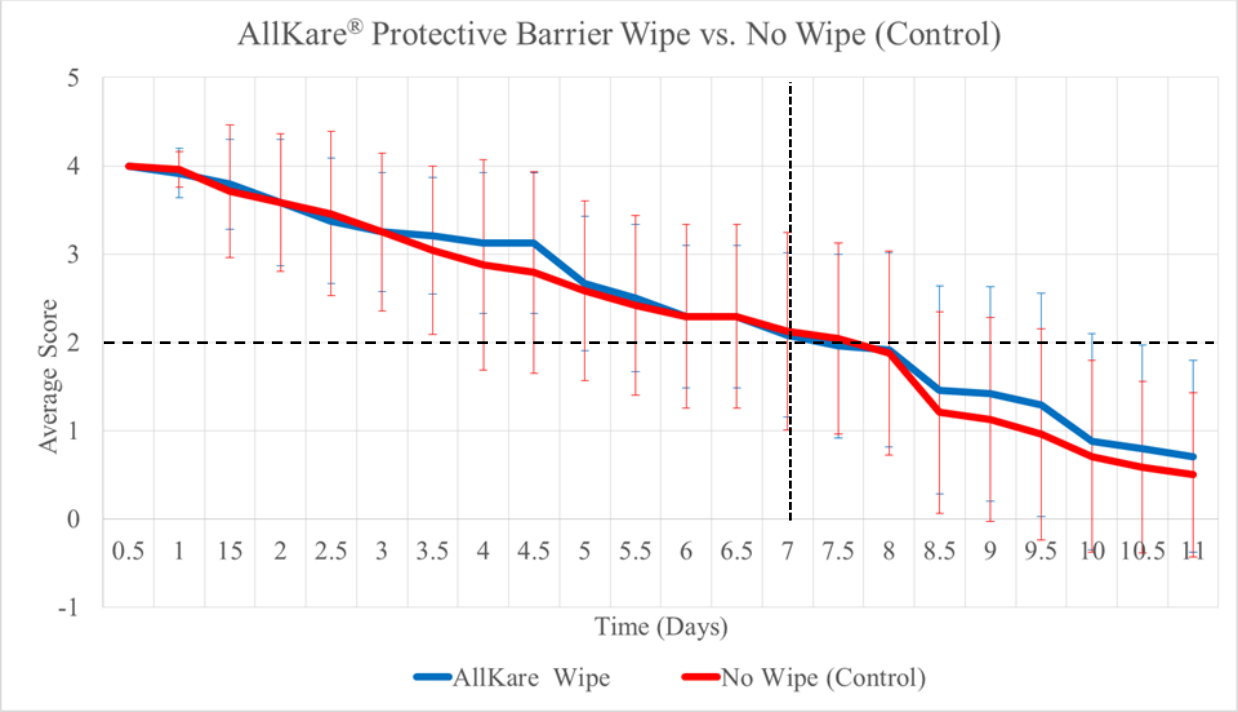


Figure 5.2: Effect of Barrier Prep Wipe on Material Adhesion over Time

Table 5.8: Barrier Wipe versus Control Data, Weighted Averages, and Average Scores

	AllKare® Barrier Preparation Wipe								Control (No Wipe)							
Score	4	3	2	1	0				4	3	2	1	0			
Multiplying Factor	0	1	2	3	4				0	1	2	3	4			
Time Point (hr)						Weighted Average	Average Score	ST. DEV						Weighted Average	Average Score	ST. DEV.
12	48	0	0	0	0	0.00	4.00	0.00	42	2	2	1	1	0.27	3.73	0.82
24	36	10	2	0	0	0.29	3.71	0.54	34	9	2	1	2	0.50	3.50	0.82
36	30	10	5	0	3	0.67	3.33	1.10	31	8	5	2	2	0.67	3.33	1.10
48	25	13	6	0	4	0.85	3.15	1.18	26	11	7	2	2	0.81	3.19	1.10
60	20	15	6	0	7	1.15	2.85	1.37	21	15	5	0	7	1.10	2.90	1.37
72	17	18	6	0	7	1.21	2.79	1.34	16	20	5	0	7	1.21	2.79	1.32
84	16	19	6	0	7	1.23	2.77	1.32	13	22	5	1	7	1.31	2.69	1.31
96	14	18	5	1	10	1.48	2.52	1.47	11	22	3	0	12	1.58	2.42	1.50
108	14	17	5	2	10	1.52	2.48	1.49	9	24	3	0	12	1.63	2.38	1.47
120	5	20	8	0	15	2.00	2.00	1.46	4	27	2	2	13	1.85	2.15	1.43
132	3	18	11	1	15	2.15	1.85	1.38	2	25	6	2	13	1.98	2.02	1.36
144	2	16	13	2	15	2.25	1.75	1.33	2	20	7	1	18	2.27	1.73	1.44
156	2	14	14	2	16	2.33	1.67	1.33	2	20	7	1	18	2.27	1.73	1.44
168	0	12	11	3	22	2.73	1.27	1.28	0	17	9	2	20	2.52	1.48	1.35
180	0	12	9	4	23	2.79	1.21	1.29	0	15	11	2	20	2.56	1.44	1.32
192	0	10	9	4	25	2.92	1.08	1.25	0	12	6	6	24	2.88	1.13	1.28
204	0	6	8	5	29	3.19	0.81	1.12	0	6	6	7	29	3.23	0.77	1.10
216	0	6	6	4	32	3.29	0.71	1.11	0	6	5	6	31	3.29	0.71	1.09
228	0	6	5	3	34	3.35	0.65	1.10	0	6	4	4	34	3.38	0.63	1.08
240	0	5	1	4	38	3.56	0.44	0.97	0	3	4	4	37	3.56	0.44	0.90
252	0	4	2	3	39	3.60	0.40	0.92	0	2	4	4	38	3.63	0.38	0.82
264	0	3	2	4	39	3.65	0.35	0.84	0	2	2	4	40	3.71	0.29	0.74
ALL	232	252	140	42	390	2.10	1.90	1.62	213	294	110	52	387	2.10	1.90	1.61

5.4 Patch Intuitiveness User Questionnaire

As described previously, the Patch Intuitiveness User Questionnaire was used to determine which patch shape of the major three was the most intuitive and user friendly. The results of the survey were coded for key concepts and tabulated (Table 5.9) and counts were taken of how many people placed the patch correctly (Table 5.10). This data was used to determine which two patch shapes would be used moving forward for the patch duration study and also to make shape adjustments before testing them. To determine which two patches to test moving forward, the team looked primarily at a combination of the counts of correct placement and also which patch participants said they preferred and thought was most intuitive. For the counts of correctness all the patch shapes scored relatively in the same range (Table 5.10). This range was between 25% and 31 % correct placement. Due to the closeness in results of counts, the team then turned to the participants' responses about which patch they preferred and thought was best suited for our application. The results for this were more distinct with 10 participants choosing the "cross" patch, 5 participants choosing the "I" patch, and only 1 participant choosing the rectangle shaped patch. From these results both the "cross" and "I" patches were chosen to move forward with some adjustments. It was noted that 31% of participants suggested adding additional length to the tabs on the "I" and "cross" patches, which the team took into consideration. These adjustments were made (as seen in Figure 4.12 and Figure 4.13) for the patch duration study.

Table 5.9: Coding Analysis of Questionnaire

Codes	Participant count (out of 16)	Participant percent
Suggested Diagram or Instructions	13	81.25%
Preferred "I" Shape	5	62.50%
Preferred Rectangle Shape	1	6.25%
Preferred "Cross" shape	10	31.25%
Suggested Moving Sensor	3	18.75%
Suggested Extension of Tabs	5	31.25%
Suggested Changing the Peel-off Backing Shapes	6	37.50%

Table 5.10: Correct Placement Analysis

Shapes	Correct Placement on Heel	Correct Placement on Elbow	Total Correct Placements	Percentage out of Possible Correct Placements
"I" Shape	0	9	9	28.13%
"Cross" Shape	0	8	8	25.00%
Rectangle Shape	1	9	10	31.25%

CHAPTER 6: Design Validation

6.1 Design Process

Several studies were performed in order to develop the patch component of the pressure ulcer prevention patch system that adhered to the body. The MQP team began with researching the definition and causes of pressure ulcers as well as elements that make up other related adhesive medical devices. It was determined that the adhesive patch component consists of two key elements: the material and the shape. First, various materials were tested for key properties of elastic modulus, shear force resistance, peel force, water resistance, and tack force. These properties were analyzed using a feasibility matrix with weights supported by plastic surgeons who would be using the final product. Tegaderm™ Film Dressing by 3M Co. was determined to be the best material to use for the patch mainly due to its elastic modulus, and water resistance. This material needed to be verified, however, to determine if it would be able to remain adhered to the body for the seven day period required by the client statement. This material and the second best performing material Transpore™ Surgical Tape by 3M Co. underwent a 10 day verifying duration study to determine if they met this criteria. From this test, however, Transpore™ performed significantly better than Tegaderm™. For this reason, the prior was chosen to test the various shapes of the patch design.

From discussion with stakeholders, it was determined that another key property of the patch system was its ability to be placed correctly on the body. If the user places the patch incorrectly, the sensors will not read the correct data and may not alert a healthcare professional of an impending pressure ulcer. This would be detrimental to the patient and may also harm the healthcare professional due to malpractice litigation. For these reasons, the MQP team performed a Patch Intuitiveness Questionnaire with everyday people to determine which of the final designs of the patch were most intuitive for proper use and characteristics for improvement. With these results, the top two patch designs were improved and chosen for the validation study.

6.1.1 Validation Study Methodology

The validation study was performed in order to determine if the model of the pressure ulcer prevention patch met the design criteria, while also testing the shape of the design. The patch would ideally be biocompatible, comfortable, water resistant, and stay on the body for seven days while still being functional.

From all the material testing Transpore™ was chosen to perform this study, however, it failed in biocompatibility and water resistance. At day three, all three participants noted pain on both of their elbow patches. Two participants also experience skin tearing and deterioration. Since the purpose of the patch is to prevent pain from pressure ulcer formation, this model failed its biocompatibility test.

Tegaderm™ scored the highest from the design matrix, but did not perform as well as Transpore™ in the Pre-Patch Material Duration Verification study. The latter is why it was not chosen as the initial material for the validation study. However, since Transpore™ failed Tegaderm™ was used as the backup material.

6.1.2 Validation Study Results

While performing the validation study conducted with Tegaderm™, it was quickly apparent that the lifestyle of the participants greatly affected the condition of the patches. Patients at risk of developing pressure ulcers would likely not have similar lifestyles to those who tested the product. The MQP team is active, putting on and taking off shoes on a regular basis and showering every day. Because of this the heel patches became detached/nonfunctional within a few days of the start of the study. However, some elbow patches remained attached and functional until the end of the study showing that the design worked in this model. The data from the validation study surveys were analyzed using the same system used for analyzing the Pre-Patch Material Duration Study discussed in Chapter 5.3, however, instead of comparing two materials used, it compared the "I" shaped patch to the "cross" shaped patch. The table displaying the combination of both elbow and heel data and results is located in Table 6.1. Using this analysis, the "I" shape patch received a total weighted average of 1.56 and the "cross" shaped patch received a 1.99, thus indicating that the "I" shape performed best. However, after performing a two sample T-Test of the two weighted average sets yielded a p-value of 0.121. Using a confidence interval of 0.05, this indicates that the choice of shape does not significantly affect the performance.

Table 6.1: "I" Shape versus "Cross" Shape Data, Weighted Averages, and Average Scores

	"I" Shape								"Cross" Shape							
Score	4	3	2	1	0				4	3	2	1	0			
Multiplying Factor	0	1	2	3	4				0	1	2	3	4			
Time Point (hr.)						Weighted Average	Average Score	ST. DEV						Weighted Average	Average Score	ST. DEV.
12	3	2	1	0	0	0.67	3.33	0.82	2	4	0	0	0	0.67	3.33	0.52
24	3	2	1	0	0	0.67	3.33	0.82	2	3	1	0	0	0.83	3.17	0.75
36	3	2	1	0	0	0.67	3.33	0.82	2	3	0	0	1	1.17	2.83	1.47
48	2	2	2	0	0	1.00	3.00	0.89	1	2	1	1	1	1.83	2.17	1.47
60	2	1	3	0	0	1.17	2.83	0.98	1	2	1	0	2	2.00	2.00	1.67
72	2	1	3	0	0	1.17	2.83	0.98	1	2	1	0	2	2.00	2.00	1.67
84	2	1	2	0	1	1.50	2.50	1.52	1	2	1	0	2	2.00	2.00	1.67
96	2	1	2	0	1	1.50	2.50	1.52	1	2	1	0	2	2.00	2.00	1.67
108	2	0	2	1	1	1.83	2.17	1.60	1	1	1	0	3	2.50	1.50	1.76
120	2	0	2	0	2	2.00	2.00	1.79	1	1	1	0	3	2.50	1.50	1.76
132	2	0	1	0	3	2.33	1.67	1.97	1	1	1	0	3	2.50	1.50	1.76
144	1	1	1	0	3	2.50	1.50	1.76	1	1	1	0	3	2.50	1.50	1.76
156	1	1	1	0	3	2.50	1.50	1.76	1	0	2	0	3	2.67	1.33	1.63
168	1	1	1	0	3	2.50	1.50	1.76	1	0	2	0	3	2.67	1.33	1.63
ALL	28	15	23	1	17	1.57	2.43	1.57	17	24	14	1	28	1.99	2.01	1.58

In order to account for the poor data obtained from the heel study, the analysis was performed again using only the elbow data. In this analysis, the “I” shaped patch received a total weight average of 0.48 whereas the “cross” shaped patch received a 1.07. Inputting these data sets into the two sample T-Test yielded a p-value of 0.008 indicating that the “I” shaped patch was significantly better. As depicted in Figure 6.1, the “I” shape patch had an average score above 2 throughout the entire testing period, performing better than the “cross” shape. While these conclusions maybe be a good start, more testing on more people should be performed to obtain more robust results.

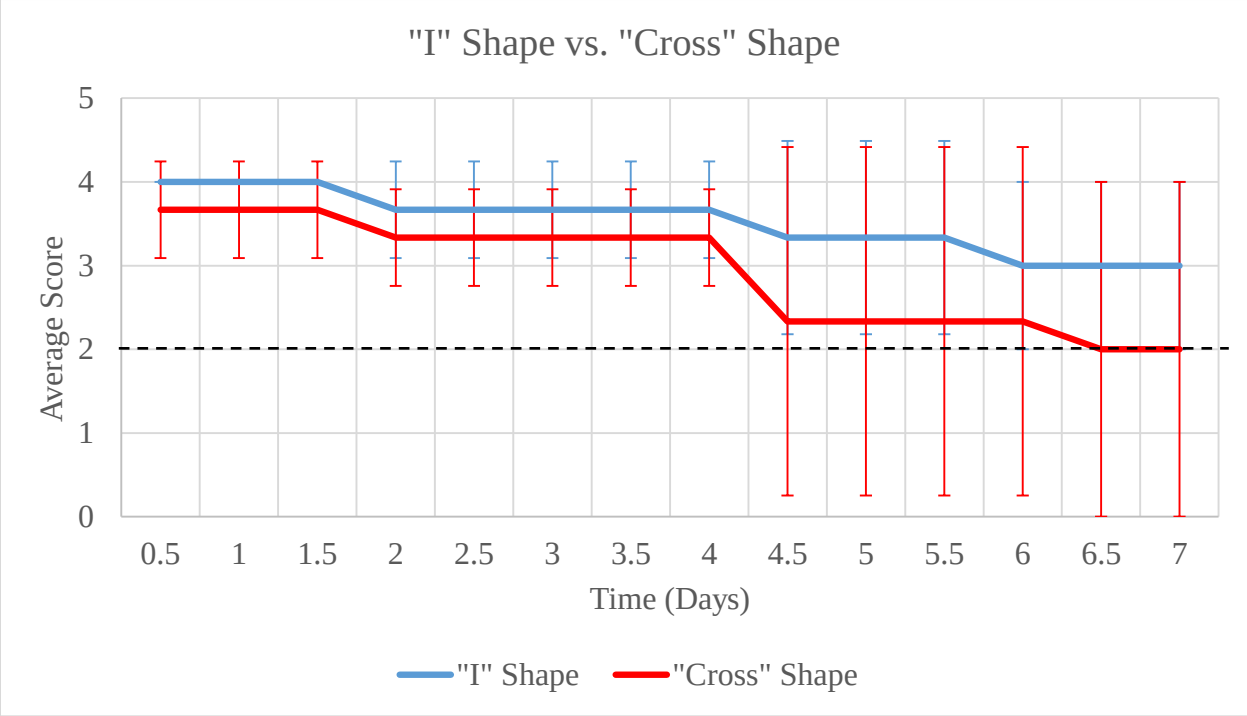


Figure 6.1: "I" Shape versus "Cross" Adhesion over Time

The data from this study were also analyzed for functionality. This is because a patch can be half off the body and receive a score a 2 but depending on which half of the patch is no longer adhered the body changes whether or not the patch is still functional. This happens as the result of the pressure sensor being on one side of the patch. On average the “I” shaped patches stayed functional for approximately 5 days whereas the “cross” shaped patches stayed functional for approximately 3.5 days. This data can be seen in Table 6.2.

At the end of the Tegaderm™ study, it was noted that the patches seemed to dry out the underlying skin mainly in the center of the patch where there is less gas exchange with environmental air. Additionally, the patches could at times be itchy. This study was more successful than the Transpore™ study because patches were able to remain on the body for the full study period without inducing pain. It is possible that the size of the patch may have caused some of the biocompatibility issues, so efforts should be taken to reduce these dimensions. Additionally, for the elbows, minimal to no moisture was detected on the skin underneath the

patch indicating that the design was water resistant in practice. Using the "I" shaped patch with Tegaderm™ allowed the patch design to fulfill the needs of the design criteria.

Table 6.2: Patch Duration Test Functionality Analysis

	Hours Until Patches were Non-Functional			
	"I" Elbow	"I" Heel	"Cross" Elbow	"Cross" Heel
Participant 1	168	72	144	96
Participant 2	168	108	144	36
Participant 3	84	84	60	48
Individual Average	140	88	116	60
Combined Average	114 (5 Days)		88 (3.5 Days)	

6.2 Impact

6.2.1 Economics

Our device could economically impact both hospitals and patients that are at risk/suffer from pressure ulcers and pressure ulcer related issues. Because Medicaid and Medicare do not fund hospital acquired pressure ulcer treatment, the brunt of this 11 billion dollars annually used to treat pressure ulcers falls on hospitals and patients [1]. Part of the reason these ulcers are so costly to treat is because they are very difficult to treat [13]. The lack of blood flow greatly increases the amount of time needed for healing. By preventing the ulcers from forming in the first place the bulk of the costs related to pressure ulcers would be eliminated. In comparison to the average cost of treating pressure ulcers these patches will be relatively low cost. There is also the alleviation of costs to hospitals in the form of reduction in lawsuits. Currently 3.7 billion dollars are spent annually on litigation over pressure ulcer related cases and are the second leading reason for lawsuits, with over 17,000 filed annually [1]. It is second only to wrongful death lawsuits. By reducing the number of pressure ulcers that develop, the number of lawsuits and the money going towards those lawsuits will also greatly decrease.

6.2.2 Environmental Impact

In the original concepts for this design, our team had intended on making our device reusable discarding only the adhesive and foam components. The conceived design was to have a reusable flexible circuit board with a rechargeable battery. The circuit board and battery would have been able to be removed from a used patch and then reused in a new patch so that the amount of waste could be reduced. However, due to client concerns about ease of use and the need for the entire patch to be disposable, the design changed to be completely disposable. This means that there may be a negative impact on the environment from the device if it becomes the new standard in pressure ulcer prevention as it would most likely be disposed via landfill. However, our product also has the potential to positively impact the environment as it will reduce the waste associated with pressure ulcer wound care. Wound dressings are constantly changed in attempt to keep the ulcer clean to promote healing. All this medical waste would be significantly reduced because our product would prevent ulcers from forming in the first place.

6.2.3 Societal Influence

This device has the potential to not only improve the quality of life for the 1 million people in the United States with pressure ulcers but also to greatly reduce the amount of time spent by nurses and caretakers on preventing these pressure ulcers. By freeing up some of that time, nurses and caretakers are more able to spend their time caring for others rather than spending a significant amount of time caring for pressure ulcer sores. In addition, since the device has the potential to save hospitals in the US billions of dollars, collectively that money could be spent on new diagnostic equipment, funding for research, etc. that could help many more people now and in the future. Essentially this device has the potential to make a major impact not only for those afflicted by pressure ulcer but also for the medical community at large and anyone affected by a medical issue.

6.2.4 Political Ramifications

This technology to prevent bedsores could potentially affect communities that hold strong religious beliefs against the use of technology. Traditionally the condition of pressure ulcers is prevented by routine monitoring by nurses without the use of electronics (though this method often fails to prevent pressure ulcers). If this device changes the standard practice for preventing pressure ulcers, hospitals may no longer continue with the traditional methods which would be more accessible to certain communities.

This technology also has the potential to impact federal laws in the United States and how they deal with funding allotted to hospitals. Under the current system, the 25% of hospitals that have the highest incidence rate of pressure ulcers lose one percent in funding from the federal government each year. If this device is successful at reducing pressure ulcers and can be distributed equally to hospitals across the nation, then legislation that we currently have now could be removed.

6.2.5 Ethical Concerns

The pressure ulcer prevention patch would in theory reduce the number of man hours spent by nurses caring for and manually preventing pressure ulcers. While this MQP views this as net positive by relieving overworked nurses, there does exist the possibility that some nursing positions may no longer be needed. This falls in line with any ethical concerns that arise as technology improves and can replace the manual work of humans. This team believes, however, that the net ethical benefits to patients' quality of life outweighs the chance that there may be less need for nurses in certain areas.

6.2.6 Health and Safety Issues

This device is designed specifically to prevent pressure ulcers, and in doing so, vastly improve patient quality of life. By preventing pressure ulcers this device has the potential to prevent approximately 60,000 deaths every year in the United States alone and the pain and suffering of over 1 million people [1]. As a medical device it is paramount that the device is biocompatible and safe for all potential users. To achieve this our team used only FDA approved materials currently on the market as medical adhesives and conducted extensive material tests including self-studies to make sure the patches were comfortable and did not harm the skin. The final material chosen for our device has an elastic modulus comparable to that of human skin

meaning that the material does not tug or pull on the skin while the patient is wearing it. The foam in the device is also designed to cushion those sensitive areas of the body and protect them from the electronics which or uneven heights on the flexible circuit board. The patch is also designed in such a way that there is no chance for electrocution as the electronics never come into direct contact with the skin and the board is also electronically insulated by the foam.

6.2.7 Manufacturability

The potential for this device to be manufactured and produced is very high. All of the electronic components of this device and the material components can be purchased in bulk. Specifically, polyethylene foam is highly inexpensive and easy to manufacture and 3M Co. already manufactures high volumes of Tegaderm™ Film Dressing. Assembly would be similar to the TempTraq™ by Blue Spark Technologies which is a device that measures infant temperatures using a flex circuit board and foam encasement already on the market. If eventually this device is bought by 3M Co. then manufacturability only goes up as they have supply lines already in place. Ultimately, this device has great potential to be manufactured in bulk.

6.2.8 Sustainability

There is no effect in terms of renewable energy for this project.

CHAPTER 7: Discussion

7.1 Final Product

The aim of this project was to create a device that would be able to secure a flexible printed circuit board to the skin for seven days while being biocompatible, comfortable, water resistant for up to five hours, and disposable.

This validation study confirmed that the patch would remain functional for approximately five days. The “I” shaped patches outperformed the “cross” shaped patches in the duration validation study and the “I” shaped patches averaged about five days, just two days short of the seven day goal. While this is a shorter time span than ideal, the patch stayed on and was functional for multiple days which is the main intent of this wearable patch.

Biocompatibility was achieved in the sense that only FDA approved materials currently on the market as medical tapes and adhesives were used in this project. As medical supplies already on the market, they are sterilizable and safe for use. For disposability, no toxic or highly expensive components were used in the making of the device. To confirm the water resistance of the final patch a water resistance validation test was done. The result from this test showed that the patch was water tight for over 5 hours

The comfort of the patches was confirmed from the elastic modulus testing and validation testing. If the elastic modulus of a material significantly differs from skin, it will cause either the material to pull on the skin or the skin to pull on the material, which in turn causes discomfort. This idea was shown in the first failed validation test conducted by the team with Transpore™ Surgical Tape. The measured elastic modulus of this tape from the material tests conducted was 60.88MPa which varies greatly from the 2.5MPa elastic modulus of skin. This test, which lasted only three days, caused notable reactions including skin irritation and pain on multiple participants. This round of validation tests was stopped immediately as the team noticed these adverse effects. The second round of validation tests used Tegaderm™ Film Dressing which has a measured elastic modulus much closer to that of skin at 2.1MPa. This test was able to be conducted for all seven days on some participants and there were no notable side effects. Participants also noted that the Tegaderm™ Film Dressing felt comfortable, often noting they had forgotten the patch was still on them.

The team conducted a final very preliminary test with the flexible PCB board inside the patch. The goal of this test was to see if the sensors on the PCB could still read pressure temperature and moisture values. This test was done working with the electronics team that developed the PCB. The integrated patch sensor system can be seen in Figure 7.1. The wearer in this very preliminary test noted that the patch was able to comfortably bend with the body. More testing needs to be conducted in the future.

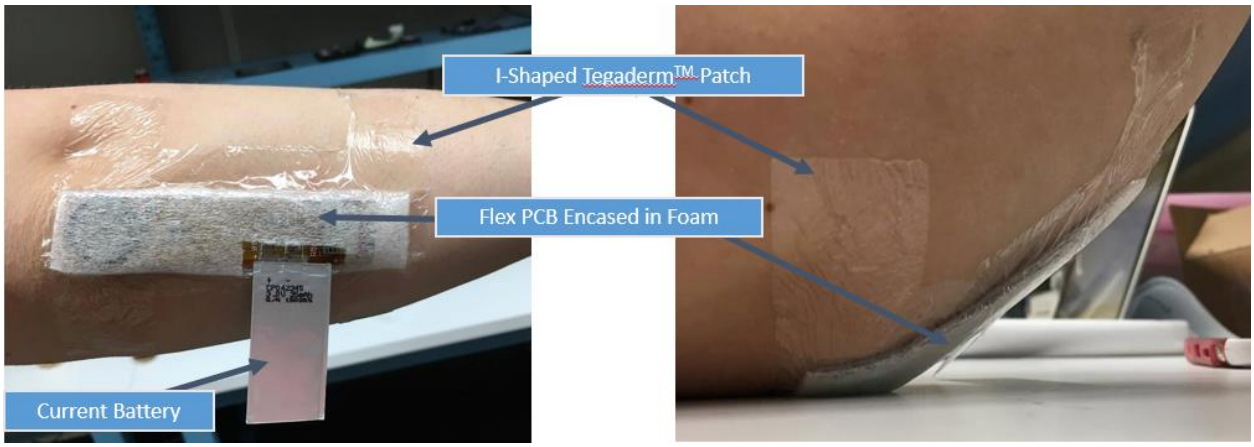


Figure 7.1: Preliminary Integration of Flex PCB in Adhesive Patch

Additionally the final patch is more user friendly when compared to other prevention devices on the market. Offloading boots are both cumbersome and only help prevent pressure ulcers on the feet. When compared to a thin wearable patch, the patch system is much more practical for a wider variety of patients on a wider variety of potential ulcer locations. When comparing the patch system to pressure mapping and motion sensing the potential for prevention is much higher with the patch system. This is because the patch system gets to the root of the issue which is detecting pressure ulcer conditions on different body areas. One might argue that pressure mapping also does this however, if a person shifts on the map the map cannot tell that pressure is still accumulating on the same body part. Finally, this patch system not including the electronics is extremely cost effective, potentially costing less than a dollar to create each patch. The electronics when manufactured in bulk would also be able to be quite cost effective.

7.2 Caveats and Future Considerations

One issue in this project was the small sample sizes for some of our preliminary material testing and verification testing. For the material tests supplies of each material were limited, leading to only two tests being done on each Instron® per material. For the validation tests, the low sample size came from not having IRB approval; therefore, the only the MQP team could test on themselves. Because of the small sample sizes the statistical significance may not be completely valid. The team suggests more robust testing in the future to gain a larger sample size. Another issue in this project is that all testing and questionnaires were conducted on healthy, active participants not at risk of developing pressure ulcers. To achieve a more accurate understanding of how the final device would stay adhered to the body of a patient at risk for pressure ulcers, studies need to be done with that population of people.

In addition, the team suggests developing a diagram or instruction booklet for putting on the patches. This is based on the questionnaire results where 81% of participants suggested having instructions or a diagram in conjunction with the final patch for users. The team also suggests investigating further into the benefits of having rounded corners in the patch design (Figure 7.2) which would alleviate stress concentrations at the sharp corners of the current design. Finally, the last suggestion moving forward is that testing be done combining the real

flexible printed circuit board into the patch adhesive (instead of the plastic model used in these tests) and test duration and functionality of the device as a whole.

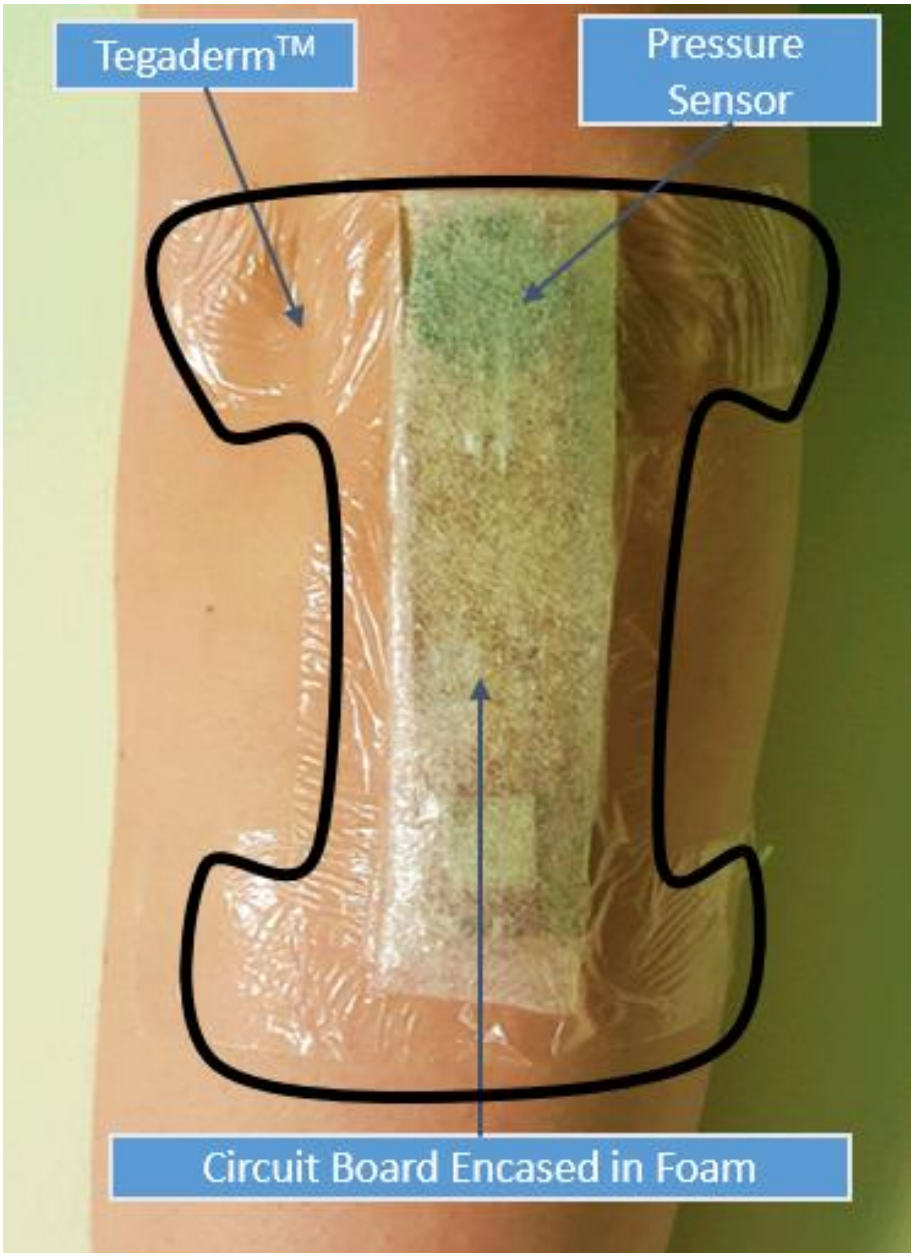


Figure 7.2: Ideal Rounded Corner Integrated Patch Design

CHAPTER 8: Conclusions & Recommendations

The intended product of this project was to create a housing component for a pressure ulcer prevention sensor. This housing component should be an adhesive patch that would adhere to an area of the body that would be at risk of forming a pressure ulcer. Ideally, this patch design should remain on the body for at least seven days, should be water resistant, and should be biocompatible. The final design was able to achieve most of these goals.

Through various ASTM Standards and human testing, the team was able to determine the best material to use for this application, as well as the best shape the patch should be. Based on preliminary verification testing, the team was able to determine Transpore™ Surgical Tape by 3M Co. was the most appropriate material to use. However, after validation testing, it became clear this material was not adequate for this purpose. Although this material performed the best in verification testing, in validation testing it proved to be uncomfortable, irritating skin and causing rashes and harm to the skin on all three human participants. The team deemed this as a design failure, and continued testing with the second best material, which proved to be quite the success. The material, Tegaderm™ Film Dressing by 3M Co., was comfortable, flexible, and biocompatible. It remained on the participants for an average of 5 days, was water resistant past 5 hours, and caused no skin damage leading the team to choose this medical bandage as the final material to be used. To further ensure the electrical components would be protected, the team also decided to use polyethylene foam to encase the circuit board and protect against water. Also, the team recommends using rounded corners on the patch shape to alleviate any stress concentrations that may form due to corners of the patch shape.

In addition to material testing, the team looked into the size and shape of the electrical sensor housing. This shape needed to be able to move with the joints of the body in a comfortable manner and not become detached. The team conducted a questionnaire to gauge the intuitiveness of different patch shapes. This data lead the team to further test the “I” shape and “cross” shape. After testing each shape on the three team members, it became evident that the best shape was the “I” shape.

Further testing should be done to test other shapes of patches. Through this research, it became clear a different shape may be required for different joints and areas of the body. For example, the patches on the heels fell off much sooner than the patches on the elbows. Further testing should include looking into a more appropriate shape for the heel and shapes for other common risk areas. Different parts of the body are exposed to different forces and move in different manners than the elbow. Therefore, different shapes should be looked into in the future. In addition, it would be extremely valuable to test the patch on more than just three people. A sample size of three is not large enough to make a valid conclusion.

The team's major recommendation is to construct the patch in an "I" shape using Tegaderm™ film dressing (with a backing material made of rayon and an adhesive layer made of urethane and acrylate polymers) to house and adhere the flexible PCB board to patients.

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Appendix A: Data from Preliminary Material Selection Testing

Product Name	Shear Strength Avg. on Steel (Sec.)	Peel Strength Avg. on Steel Using In-Spec™ (N)	Loop Tack Strength Avg. On Steel Using In-Spec™ (N/cm2)	Contact Angle (Degrees)
MediPlus™ Barrier Gel Comfort	0.375	0.590265	0.3999114583	51.0
MediPlus™ HC Thin	13	2.012385	0.4982636218	69.4575
Polyurethane adhesive	21.03	1.491695	1.12235	75.717
MediPlus™ Surgical Adhesive Nonwoven dressing	101.805	1.400815	0.6614337662	127.4905
Nexcare™ Steri-Strip™ Skin Closure	1173.51	1.23992	1.43662617	61.1285
DuoDERM® Extra Thin Dressing	24.635	1.400205	0.3411844729	102.0695
Tegaderm™ Film Dressing	0.765	0.728335	0.9138086111	75.9855
Scar Strips	0.49	1.29827	0.8982091751	97.562
Covidien™ Telfa™ Plus Barrier Dressing	1.91	0.833015	0.3387135943	123.599
Mepitac® Safetac® Medical Tape	3.27	1.768895	1.281391204	93.127
Curad® Plastic Adhesive Bandage	975.84	1.020025	1.274719907	72.9315
Transpore™ Surgical Tape	340.685	0.74725	1.088230208	73.2405
Durapore™ Surgical Tape	194.66	0.649155	1.567225463	96.8055
Curad® Cloth Tape	35.42	1.10244	0.211890625	100.4475

Appendix B: Protocol for In-Spec™ 2200 Use

1. Prepare Hardware
    a. Plug in In-Spec™ 2200 and NI Elvis board into power socket
    b. Screw grip assembly onto the load cell
    c. Take **red** lead from alligator clip connected to center oscilloscope pin and insert into **AI0 +** on Elvis board
    d. Take **black** lead from alligator clip connected to center oscilloscope pin and insert into **AI0 -** on Elvis board
    e. Turn on both the In-Spec™ 2200 and NI Elvis board
2. Prepare Computer Interface
    a. Open NI ELVISmx Instrument Launcher computer program if it does not automatically initiate
        i. Open Data Logger application
            1. Settings
                a. ai0 is chosen for data channel
                b. Sampling rate is 20 Samples/sec
                c. Choose file path for where to save the data by clicking on the folder to the right of the log button (make sure the file will save as an .lvm)
3. Collect Data
    a. Click start button in Data Logger
    b. Click log button (this collects the data) in Data Logger
    c. Choose direction on the In-Spec™ 2200 (up or down)
    d. Press Start/Stop button on the In-Spec™ 2200 to make In-Spec™ move and begin testing
    e. Press Start/Stop Button on the In-Spec™ 2200 when done with test
    f. Press end in Data Logger
4. Converting Data Type (.lvm to .xlsm)
    a. Open data file (.lvm) using Notepad
        i. Save as .txt file
    b. Open Microsoft Excel

i. Click Data tab>Get External Data>From text>choose .txt data file

ii. Import Wizard

1. Select “Delimited”> Next
2. Delimiters are “Tab” and “Space”>Next
3. General>Finish
4. Choose New Spreadsheet>OK

iii. The data is now in .xlsm (or other .csv type file)

5. Convert output voltage to load (Max load of load cell is 50N)
    a. Collect data when 0g, 100g, 200g, 700g, 1200g, and 1600g are attached to the grips
    b. Plot the voltage output versus the corresponding weight (N)
    c. Use equation of linear fit line to convert output voltages of new data into loads

Appendix C: MATLAB® Code for Elastic Modulus Test Analysis

```
function data = readMyData(fileName);

fileID = fopen(fileName);
formatData = '"%f""%f""%f"';

n = 1;

while(1)
    string = fscanf(fileID,'%s%[^\r]%');
    string = strrep(string,',','');

    if(isempty(string))
        break
    end

    vector = sscanf(string,formatData)';

    if(~isempty(vector))
        data(n,:) = vector;
        n = n + 1;
    end

end

fclose(fileID);
```

```
function [uW_s, slope]=movingSlope(u,F,W,N)

% u=xdata; F=ydata
%
% N= Moving increment
% W= Window size

for i=1:floor((length(u)-W)/N)-1
    uW=u((i-1)*N+1:(i-1)*N+1+W);
    FW=F((i-1)*N+1:(i-1)*N+1+W);

    % polyfit is faster than fit
    p=polyfit(uW,FW,1);
    slope(i)=p(1);
    uW_s(i)=mean(uW);
end
```

```
function dimensions = readDimensionData(fileName)

fileID = fopen(fileName);
formatData = '"%f""%f""%f""%f""%f"';

n = 1;

while(1)
    string = fscanf(fileID,'%s%');
    string = strrep(string,',','');

    if(isempty(string))
        break
    end

    vector = sscanf(string,formatData)';

    if(~isempty(vector))
        dimensions(n,:) = vector;
        n = n + 1;
    end

end

fclose(fileID);
```

```
clear; clc; close all;
i = 2;

names = {'Specimen_RawData_1.csv','Specimen_RawData_2.csv'};
fileName=names{i};
dimensionsTable='Elastic Modulus Dimensions for Retry 221.csv';
```

Read Data

```
data=readMyData(fileName);
% readMyData is a function which reads my dataset:
% format: "0.00000","0.00000","3.63201"
% if your dataSet does not contain "" you may need to use dlmread or
% xlsread or change readMyData

%dimensions = readDimensionData(dimensionsTable)
%width = dimensions(:,3);
%thickness = dimensions(:,4);
%L = dimensions(:,5);
%dataSet=1; % optional
%A=width(i)*thickness(i)/1000000;  % dimensions of specimen in m^2 and mm
%disp(['*** Data Set =', num2str(dataSet)])
```

Used the above code for a full table of dimensions, but used code below to measure 1 or 2 samples

```
width = 12.31; %mm
thick = .63;
A = width * thick / 1000000;
L = 23.05;
%lastCycle=9; % breaking=10; is unneccesary % cycles we are interested in, pls rename
```

define variables of interest

```
t=data(:,1); ext=data(:,2); F=data(:,3); %changed u to ext
```

Convert the F-d data to stress-strain

```
S=F/A; % stress
e=ext/L;%(i); % strain, e = strain


%fig2=figure;
%plot(e, S); hold on;
%xlabel('Strain');ylabel('Stress(Pa)')
```

Calculate the slope

```
W=20; N=1; % you may need to change the value of W
% for reference plot the first moving window

%figure(fig2)
%hold on
% line(e1([1, W, W,1]), S1([1, 1, W, W]),'Color','m')

%fig4=figure;
[eW, Slope]=movingSlope(e,S,W,N);% use interpolated data
%subplot(2,1,2)
%plot(eW, Slope); grid;
%xlabel('e');ylabel('Slope(units)');
% use this too look at the data so you dont get an unwanted slope
% may need to remove unreal data - be sure to give reasoning!
```

Identify where material fails so do not select

```
break_stop = find(Slope<=0,1);
break_Slope = Slope(:,break_stop);
maxE = max(Slope)
```

Appendix D: Google Survey for Pre-Patch Material Duration Study

Preparation Wipe Survey - Tegaderm Transpore

Thank you for participating in our study. Please complete this survey, so we can collect data about your samples. If you have questions or concerns, please contact us at patchmqp@wpi.edu.

* Required

1. **What participant number are you? Please use Arabic numerals (1,2,3) for your answer.** *

2. **Please select today's date.** *

   Example: December 15, 2012

3. **Please select the current time** *

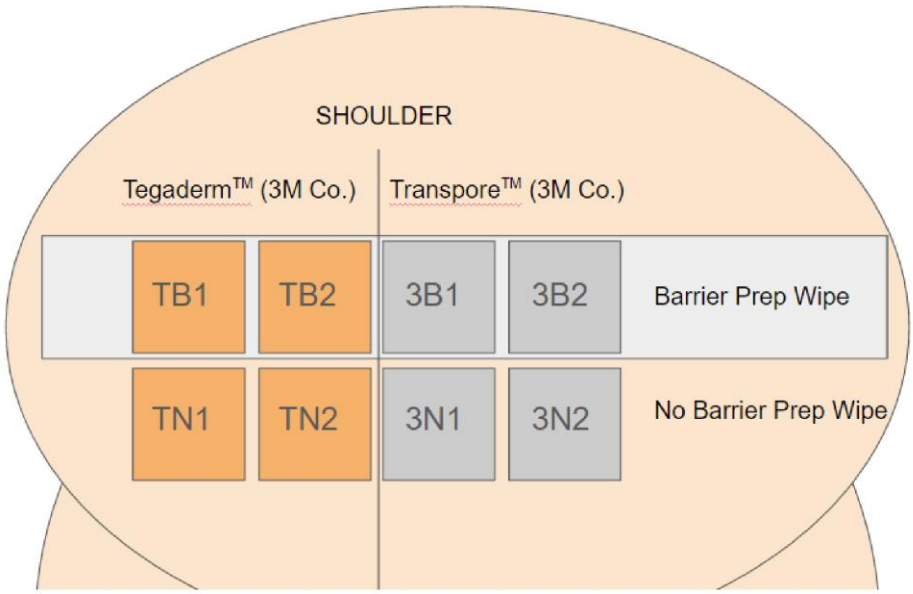
   Example: 8:30 AM

Sample Data Recording Left Shoulder Mepitac

Please record your measurements using:
4 = ≥ 90% adhered (essentially no lift off the skin)
3 = ≥ 75% to < 90% adhered (some edges only lifting off the skin)
2 = ≥ 50% to < 75% adhered (less than half of the sample lifting off the skin)
1 = > 0% to < 50% adhered (not detached, but more than half of the sample lifting off the skin without falling off)
0 = 0% adhered (sample detached; completely off the skin).

Scores for common material detachment (shaded is area that has lifted off the skin)

Patch Placement



4. **What is the score for sample TB1 on your left shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

5. **What is the score for sample TB2 on your left shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

6. **What is the score for sample TN1 on your left shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

7. **What is the score for sample TN2 on your left shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

Sample Data Recording Left Shoulder 3M Transpore

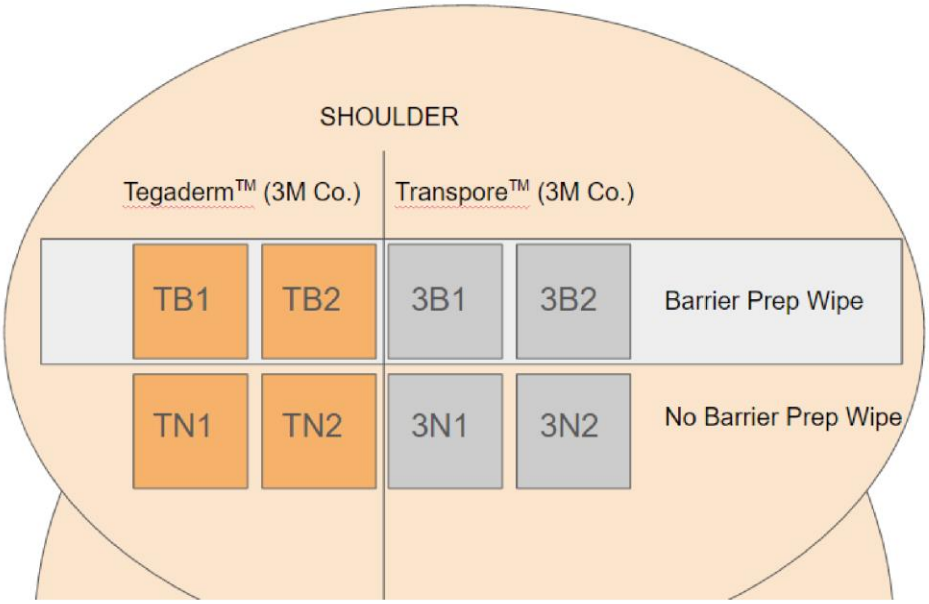
Please record your measurements using:
4 = ≥ 90% adhered (essentially no lift off the skin)
3 = ≥ 75% to < 90% adhered (some edges only lifting off the skin)
2 = ≥ 50% to < 75% adhered (less than half of the sample lifting off the skin)

1 = > 0% to < 50% adhered (not detached, but more than half of the sample lifting off the skin without falling off)
0 = 0% adhered (sample detached; completely off the skin).

Scores for common material detachment (shaded is area that has lifted off the skin)

Score = 0 Score = 1 Score = 2 Score = 3 Score = 4

Patch Placement



8. **What is the score for sample 3B1 on your left shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

9. **What is the score for sample 3B2 on your left shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

10. **What is the score for sample 3N1 on your left shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

11. **What is the score for sample 3N2 on your left shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

Sample Data Recording Right Shoulder Tegaderm

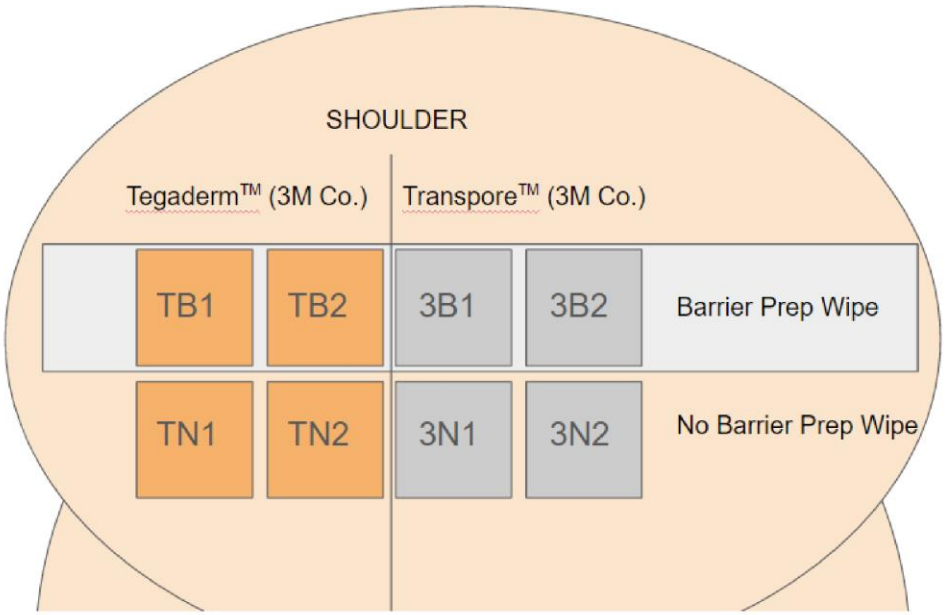
Please record your measurements using:
4 = ≥ 90% adhered (essentially no lift off the skin)
3 = ≥ 75% to < 90% adhered (some edges only lifting off the skin)
2 = ≥ 50% to < 75% adhered (less than half of the sample lifting off the skin)

1 = > 0% to < 50% adhered (not detached, but more than half of the sample lifting off the skin without falling off)
0 = 0% adhered (sample detached; completely off the skin).

Scores for common material detachment (shaded is area that has lifted off the skin)

Score = 0 Score = 1 Score = 2 Score = 3 Score = 4

Patch Placement



12. **What is the score for sample TB1 on your right shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

13. **What is the score for sample TB2 on your right shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

14. **What is the score for sample TN1 on your right shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

15. **What is the score for sample TN2 on your right shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

Sample Data Recording Right Shoulder 3M Transpore

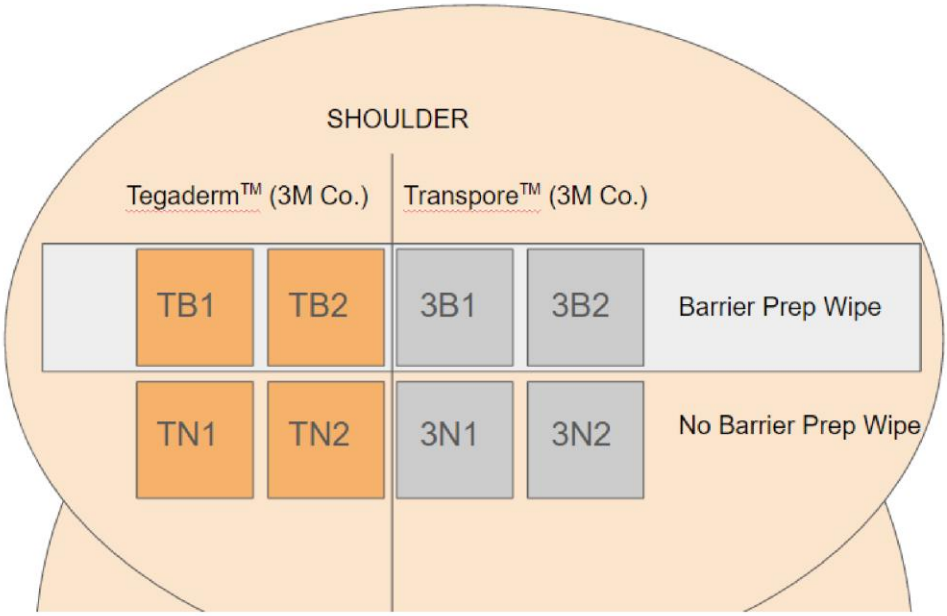
Please record your measurements using:
4 = ≥ 90% adhered (essentially no lift off the skin)
3 = ≥ 75% to < 90% adhered (some edges only lifting off the skin)
2 = ≥ 50% to < 75% adhered (less than half of the sample lifting off the skin)

1 = > 0% to < 50% adhered (not detached, but more than half of the sample lifting off the skin without falling off)
0 = 0% adhered (sample detached; completely off the skin).

Scores for common material detachment (shaded is area that has lifted off the skin)

Score = 0 Score = 1 Score = 2 Score = 3 Score = 4

Patch Placement



https://docs.google.com/forms/d/13pP6TMUvJci_6ZDayU4iedry_NxvN4Llu85rJ51Wa5Y/edit

16. **What is the score for sample 3B1 on your right shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

17. **What is the score for sample 3B2 on your right shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

18. **What is the score for sample 3N1 on your right shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

19. **What is the score for sample 3N2 on your right shoulder?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

Water Exposure

20. **Were any of the sample adhesion sites exposed to water for greater than 3 minutes?** *
Mark only one oval.

- ◯ Yes *Skip to question 21.*
- ◯ No *Skip to question 22.*

Water Exposure Continued

21. **In this recording period, what was the total time (in minutes) that the sample adhesion sites were exposed to water? Please use Arabic numerals (1,2,3) for your answer.** *

_____

Final Comments

22. **If you have any comments or suggestions, please let us know. Thank you!**

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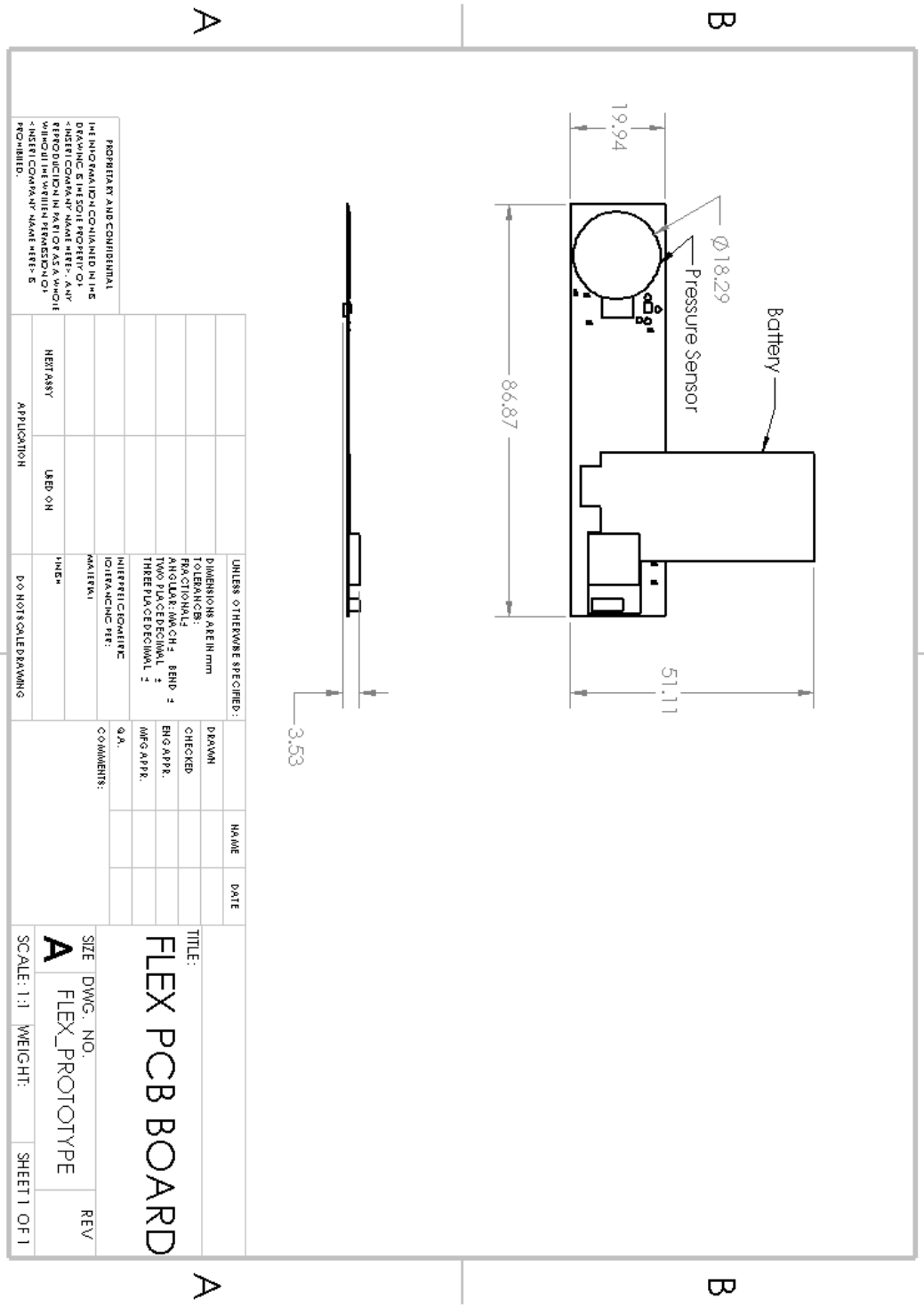
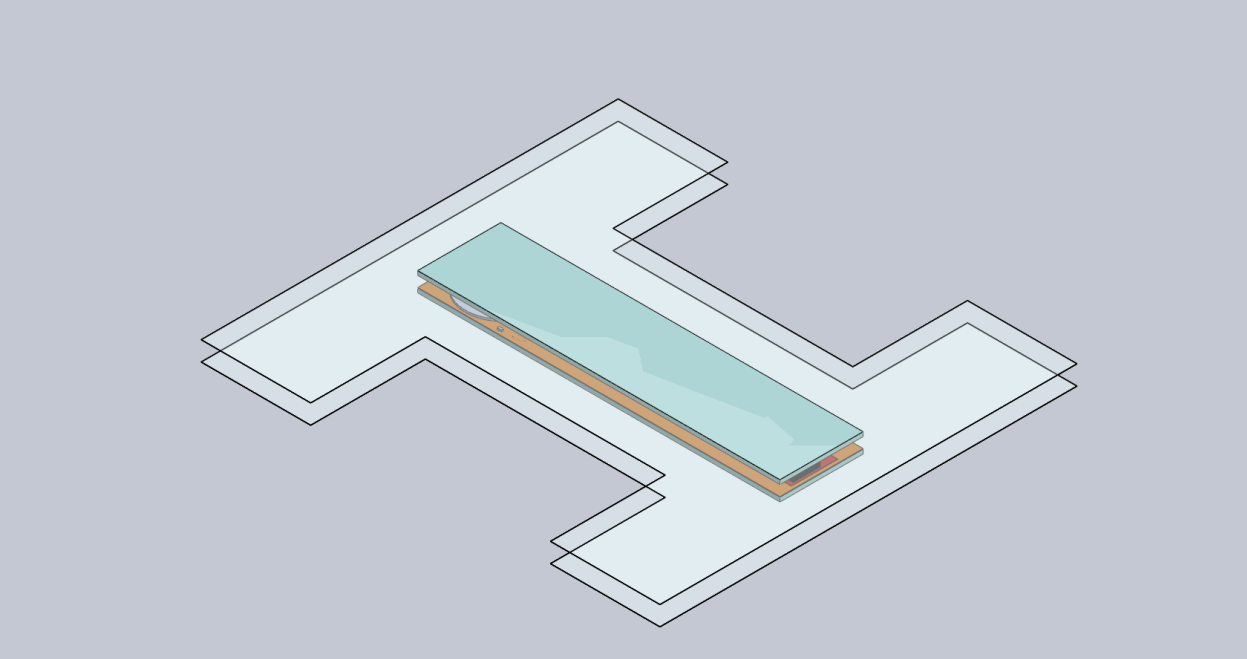
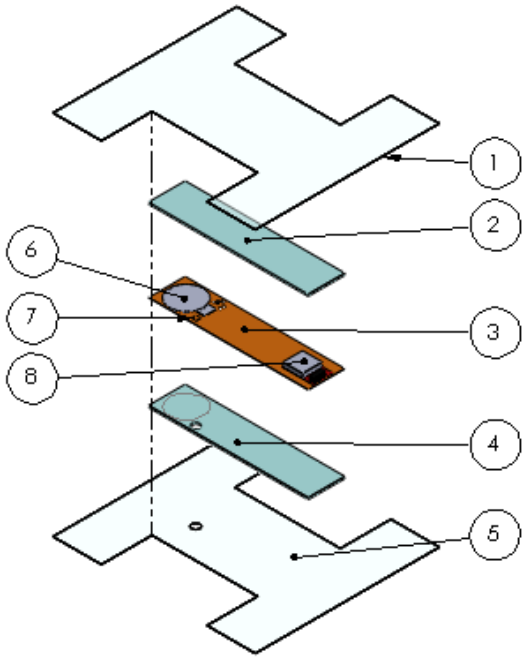
Appendix E: Adapted Patch Designs CAD Models





Final “I” Shape Patch

PART NO.	PART NAME
1	Backing Layer
2	Polyethylene Foam
3	Flex PCB
4	Polyethylene Foam
5	Adhesive Layer
6	Pressure Sensor
7	Moisture/Temperature Sensor
8	Microcontroller



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DIMENSIONS ARE IN MM
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL

FINISH

NEXT ASSY | USED ON

APPLICATION

DO NOT SCALE DRAWING

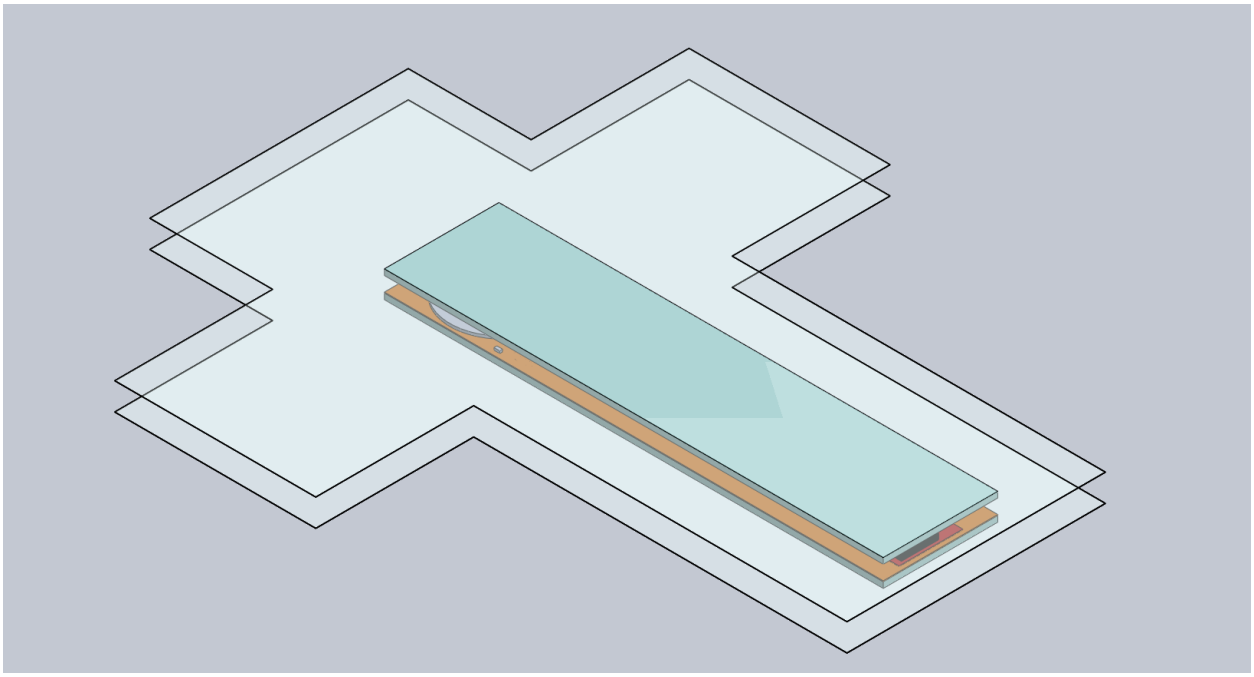
	NAME	DATE
DRAWN		
CHECKED		
ENG APPR		
MFG APPR		
QA		

COMMENTS:

"I" PATCH
EXPLODED VIEW

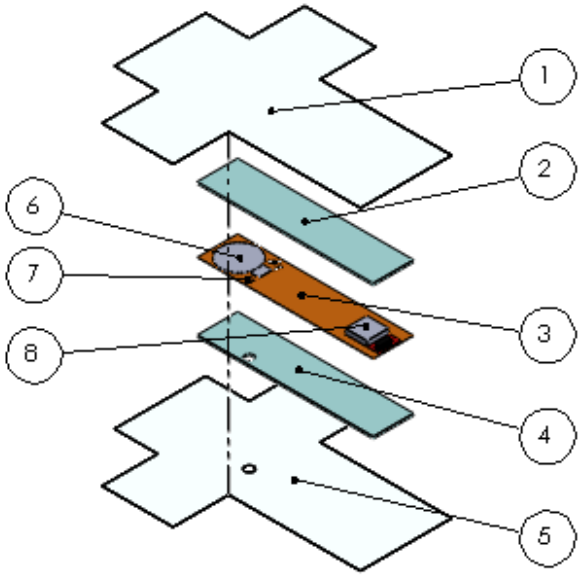
SIZE A | DWG NO I Patch | REV

SCALE: | WEIGHT: | SHEET



Final “Cross” Shape Patch

PART NO.	PART NAME
1	Backing Layer
2	Polyethylene Foam
3	Flex PCB
4	Polyethylene Foam
5	Adhesive Layer
6	Pressure Sensor
7	Moisture/Temperature Sensor
8	Microcontroller



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DRAWN
CHECKED
ENG APPR.
MFG APPR.
QA
COMMENTS:

CROSS PATCH EXPLODED VIEW

SIZE A | DWG NO. Cross Patch EXPLODE | REV

Appendix F: Google Survey for Patch Duration Validation Study

Adhesive Patch Duration Survey

Thank you for participating in our study. Please complete this survey, so we can collect data about your samples. If you have questions or concerns, please contact us at patchmqp@wpi.edu.

* Required

1. **What participant number are you? Please use Arabic numerals (1,2,3) for your answer.** *

2. **Please select today's date.** *

   Example: December 15, 2012

3. **Is this the AM or PM time point?** *

   Mark only one oval.

   - ◯ AM
   - ◯ PM

Patch Data Recording "I"

Please record your measurements using:
4 = ≥ 90% adhered (essentially no lift off the skin)
3 = ≥ 75% to < 90% adhered (some edges only lifting off the skin)
2 = ≥ 50% to < 75% adhered (less than half of the patch lifting off the skin)
1 = > 0% to < 50% adhered (not detached, but more than half of the patch lifting off the skin without falling off)
0 = 0% adhered (patch detached; completely off the skin).

Scores for common material detachment (shaded is area that has lifted off the skin)

Score = 0 Score = 1 Score = 2 Score = 3 Score = 4

4. **What is the score for your "I" ELBOW patch?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

5. **Is the sensor still functional for your "I" ELBOW patch?** *
Mark only one oval.

- ◯ Yes
- ◯ No
- ◯ Maybe

6. **What is the score for your "I" HEEL patch?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

7. **Is the sensor still functional for your "I" HEEL patch?** *

Mark only one oval.

- Yes
- No
- Maybe

Patch Data Recording CROSS

Please record your measurements using:
4 = ≥ 90% adhered (essentially no lift off the skin)
3 = ≥ 75% to < 90% adhered (some edges only lifting off the skin)
2 = ≥ 50% to < 75% adhered (less than half of the patch lifting off the skin)
1 = > 0% to < 50% adhered (not detached, but more than half of the patch lifting off the skin without falling off)
0 = 0% adhered (patch detached; completely off the skin).

Scores for common material detachment (shaded is area that has lifted off the skin)

8. **What is the score for your cross ELBOW patch?** *

Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

9. **Is the sensor still functional for your cross ELBOW patch?** *
Mark only one oval.

- ◯ Yes
- ◯ No
- ◯ Maybe

10. **What is the score for your cross HEEL patch?** *
Mark only one oval.

	0	1	2	3	4	
0% adhered (completely detached from skin)	◯	◯	◯	◯	◯	≥ 90% adhered (essentially no lift off the skin)

11. **Is the sensor still functional for your cross HEEL patch?** *
Mark only one oval.

- ◯ Yes
- ◯ No
- ◯ Maybe

12. **Have you experienced any itching, pain, or other symptoms?** *
Check all that apply.

- ☐ None
- ☐ Itching
- ☐ Pain
- ☐ Other: _____

Water Exposure

13. **Were any of the patch adhesion sites exposed to water for greater than 3 minutes?** *
Mark only one oval.

- ◯ Yes *Skip to question 14.*
- ◯ No *Skip to question 15.*

Water Exposure Continued

14. **In this recording period, what was the total time (in minutes) that the patch adhesion sites were exposed to water? Please use Arabic numerals (1,2,3) for your answer.** *

_____

Final Comments

15. **If you have any comments or suggestions, please let us know. Thank you!**

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