Designing a Wound Dressing for Fluid Management of Skin Graft Donor Sites

A Major Qualifying Project Report submitted to the faculty of WORCESTER POLYTECHNIC INSTITUTE in partial fulfillment of the requirements for the degree of Bachelor of Science.

Keywords — Skin-graft, wound dressings, exudate management, donor sites, positive pressure

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Glossary

Exudate - Fluid that seeps out of wound or donor site due to injury and/or inflammation.

Skin Graft - Surgically removed portion of skin to be translocated onto another portion of body.

Transplant - To surgically remove one organ or tissue and attach it elsewhere.

Epidermis - Surface or outermost layer of skin.

Dermis - Layer of skin directly underneath epidermis.

Occlusive Dressing - Dressing intended to seal wound off from outside, maintain moist environment.

Nonocclusive Dressing - Nonpermeable dressing intended to prevent moisture escape or absorption, maintain dry environment.

Semipermeable - Allowing for the passage of certain substances across a barrier while preventing the passage of others.

Hydrogel - Polymer network capable of retaining water and swelling to volumes far greater than original size.

Manometer - Device used to measure differences in pressure at various heights.

Abstract

Currently, there is no adequate way to manage wound exudate from skin graft donor sites. Current therapies include occlusive and nonocclusive dressings, as well as negative pressure wound therapy. Each therapy possesses shortcomings that result in skin maceration, dressing detachment, exudate leakage, or skin irritation. This project aimed to create a safe, user-friendly, and cost-effective device to manage wound exudate. By constructing a wound model and prototype, a novel positive pressure wound dressing was designed to absorb exudate and reduce overall fluid production. The resultant wound dressing reduced wound exudate production by an average of 40.5% while allowing for the management of up to about 153.3 ± 6.1 ml of exudate compared to the current standard of care's 21.1 ± 5.9 ml. While not managing all exudate before premature failure, the dressing shows the potential for positive pressure to be a promising avenue for the future management of donor site wound exudate.

Chapter 1: Introduction

Skin grafting is a common procedure used to replace damaged or missing tissue from burns, trauma, or chronic wounds (Masella et al., 2013). Skin is often taken from the thigh to heal another part of the body. The donor site then also has to undergo the wound healing process which has specific complications. Skin graft donor sites tend to release a high volume of exudate. Wound exudate is a serous fluid that leaks out of capillaries during the inflammatory phase of wound healing as they become more permeable (Jones, 2013). It is mainly water but contains electrolytes, nutrients, growth factors, and proteins. Exudate serves to improve healing rates, reduce pain, and limit chance of infection (Jones, 2013). Due to the volume of exudate produced at skin graft donor sites, appropriate dressings for healing have been a challenge for healthcare workers for many years.

It has been determined through years of research that occlusive wound dressings better promote reepithelialization than non-occlusive dressings (Serebrakian et al., 2018). Moist dressings show faster wound healing with less pain to the patient and lower rates of infection. Due to this, there has been a move away from the former standard non-occlusive dressing of Xeroform™, towards different occlusive dressings such as Tegaderm™ (3M™ Tegaderm™ Transparent Dressing) and Opsite™ (Smith + Nephew™, OPSITE™ Film Dressings). These options are inexpensive while still maintaining a moist wound environment, but other materials are still being explored as dressings. A variety of different hydrogels and foams/sponges have been investigated in order to attempt to absorb the excess of exudate (Serebrakian et al., 2018). These products and dressings are more expensive and less commercially available.

Negative pressure wound therapy is a common technique used to treat highly exuding wound sites, but can have significant drawbacks such as pain and ischemia (Borgquist et al., 2011). There is also limited data available for its use in donor sites (Genecov et al., 1998). Positive pressure therapy has been used in the past for different wounds, primarily venous leg ulcers, but hasn't been seen in the context of skin graft donor sites. The goal of this project was to create a dressing for skin graft donor sites that is able to manage the excess exudate that is common in the wound type. The dressing should be cost-effective, easy to apply and use, and be durable for an outpatient setting. To find the best solutions, different designs were analyzed and tested based on positive pressure, hydrogels, and drainage systems.

To test these designs, a skin graft donor site model out of plastic carboys was first created. The model was constructed relying on hydrostatic pressure to mimic the pressure differential between the capillaries and the surrounding space. A model graft site was constructed at the bottom of the carboy where a 72 cm^2 hole was cut and a practice tattoo pad was placed over it to mimic skin. Small holes were poked into the practice tattoo pad to allow for the flow of model exudate. The model exudate was created using a mixture of glycerin and water to achieve a viscosity of 2.5 cP, which was estimated to model wound exudate as it is halfway between the viscosity of blood and serum. A trial run was performed before any tests of designs to determine how fast 300 mL of exudate flowed from the system. This determined how long the prototype should remain on the model system.

The designs were evaluated on this model skin graft donor site to determine if they remained effective with the excess exudate. A commonly used dressing, called Tegaderm™, was also tested on the model to allow for comparison with current treatments. Each dressing was run for three trials to determine how much exudate it could manage before failure. Various aspects of the final

prototypes were run through several validation tests to ensure that each component was functioning properly. The absorptive gel that was used was tested to determine how much of the model exudate it could absorb, as well as how much water it could absorb under pressure. The polyester fabric underwent wicking tests to determine how far the model exudate would spread from it with and without silicone adhesives sealing off the edges of it.

In order to apply the correct pressure to mimic the hydrostatic capillary pressure that is forcing exudate out, a pressure transducer was used with the Arduino™ system. A standard curve was created by testing different voltage readings compared to force. This was used for the positive pressure dressing on the model donor site to ensure that at least 15 mmHg was applied. An elastic bandage was pulled around the dressing until the system confirmed that the correct pressure was applied. The fluid management properties of this dressing were then compared to the current standard of care, Tegaderm™.

Chapter 2: Literature Review

Skin grafts are surgically removed portions of the epidermis and dermis which can be transplanted onto another location to improve the healing of challenging wound sites or reduce excessive scarring. If a wound site is too large, it may be impossible to surgically seal and reepithelialization will take far too long, greatly increasing the risk of infection. To mitigate this, the transplanted portion of skin is attached over the afflicted site, covered with a dressing, and eventually grows into the surrounding skin. Figure 2.1 shows an illustration of the procedure of skin grafting.

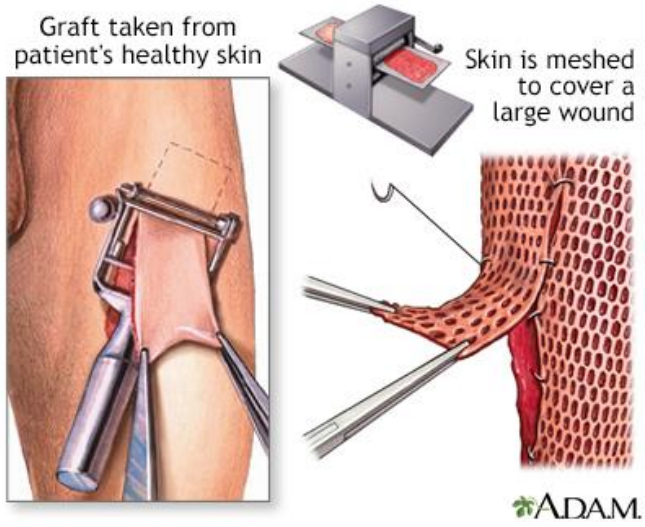

Figure 2.1 - Procedure of removing a strip of skin from a healthy portion of the patient (left), and subsequent meshing of the graft (right) Adapted from Mt. Sinai, 2021.

2.1 Wound Healing

A wound is an acute injury to the tissue of the skin, often slicing into the dermis layer. When the skin is wounded, the body must go through several processes to heal the damaged tissue. Wound healing is constituted of four main phases: the hemostasis, inflammatory, proliferative, and

maturation phase. While the phases are not entirely distinct from one another, they each work together to revitalize the tissue surrounding the wound.

As the name suggests, in the hemostasis phase the body stops the flow of blood from out of the wound site, as seen in Figure 2.2. Immediately upon wounding, the body begins to send platelets to the site, where they interact with collagen to perform their primary function: blood clotting. The platelet-collagen aggregates work through a positive feedback loop, as the aggregates secrete chemical signals which recruit more platelets to the damaged vessels. The hemostasis phase is quite short, depending on the size of the wound and certain underlying conditions of the patient. Small wounds can stop bleeding within a matter of seconds, while others may take a few minutes or a few hours (Sun et. al, 2014).

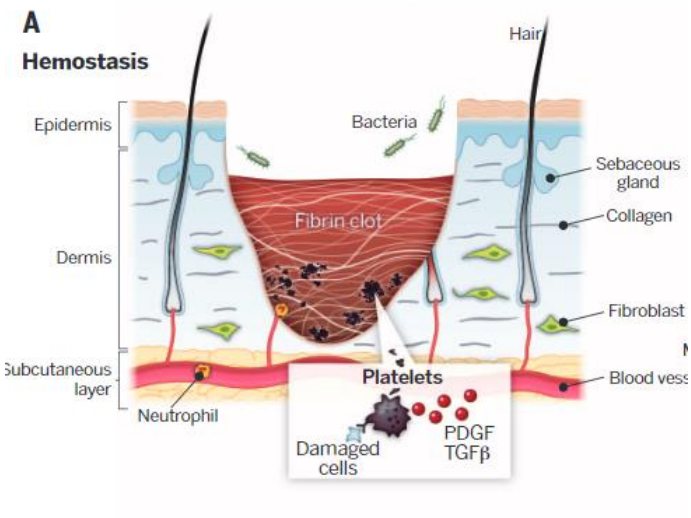

Figure 2.2 - Schematic of the hemostasis phase of wound healing. Platelets are recruited to the wound site, where they form a clot to stop bleeding. Adapted from Sun et. al, 2014.

As platelets begin to coagulate around the wound site, white blood cells jump into action. Neutrophils and macrophages are recruited to the area, as seen in Figure 2.3, where debris and bacteria are removed. This signals the beginning of the inflammation or inflammatory phase, which can last anywhere from a few days to a few weeks, again depending on the size of the wound, the wound's cleanliness, and underlying conditions of the patient. Multiple issues can arise if the inflammatory phase lasts longer than expected, sometimes being considered a chronic wound. The area around the wound may swell as fluids make their way to the open wound, setting the stage for the proliferation phase of wound healing (Sun et. al, 2014).

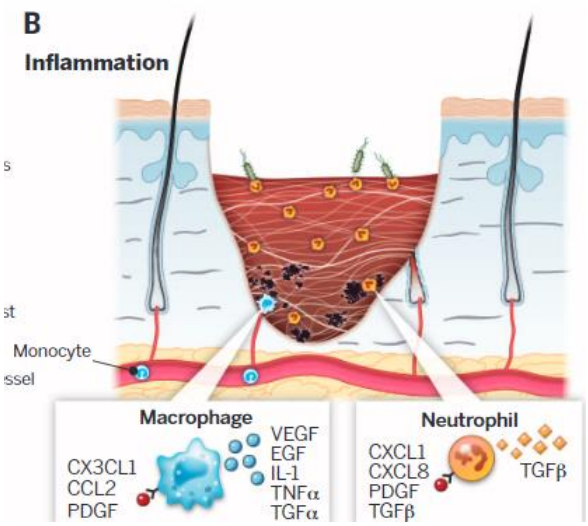

Figure 2.3 - Schematic of the inflammation phase of wound healing. Various white blood cells are recruited to help clean the wound site. Adapted from Sun et. al, 2014.

Towards the end of the inflammatory phase, the wound begins to seal itself. The inflammatory phase contains several simultaneous events that help rebuild the damaged tissue. First, the wound site undergoes angiogenesis. Platelets that arrived in the hemostasis phase release a variety of growth factors, including vascular endothelial growth factor (VEGF), TGF-β, platelet

derived growth factor (PDGF), and most importantly fibroblast growth factor (FGF). This process results in the growth of new blood vessels stemming from the remaining healthy ones.

After angiogenesis is fibroblast migration, shown in Figure 2.4. Fibroblasts recruited by the blood clot help lay the foundation for a new extracellular matrix by secreting various proteins including collagen and fibronectin. These proteins help develop the granulation tissue, which is the beginning of the new layer that will replace the damaged tissue.

After fibroblast migration is epithelialization. As epithelial cells are brought to the wound site, they are aligned along the edges of the wound and slowly migrate inwards through epithelial-mesenchymal transition. The epithelial cells are then able to attach to the underlying granulation tissue. Once fibroblasts have helped form the granulation tissue, they transition to myofibroblasts, which helps mediate wound retraction, the final stage of the inflammatory phase. Actin and myosin help pull the wound back together, attempting to fully close the wound site (Sun et al, 2014).

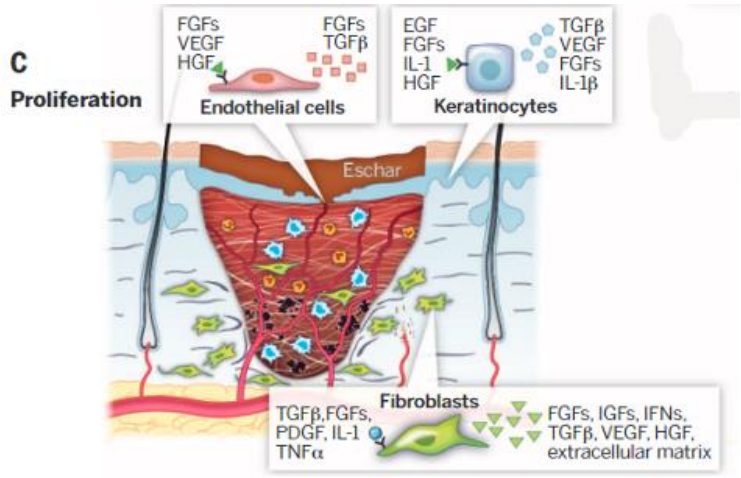

Figure 2.4 - Schematic of the proliferation phase of wound healing. Many cellular signaling molecules are used to promote angiogenesis, fibroblast migration, and endothelial cell growth. Adapted from Sun et al 2014.

The final stage of wound healing is known as the maturation phase or the remodeling phase, as seen in Figure 2.5. The remodeling phase is often the longest phase of wound healing and can last up to two years. It is during this phase where scar tissue develops. Proteins deposited at the wound site become more organized, eventually reaching around 80% tensile strength of undamaged tissue, never fully regaining their original strength.

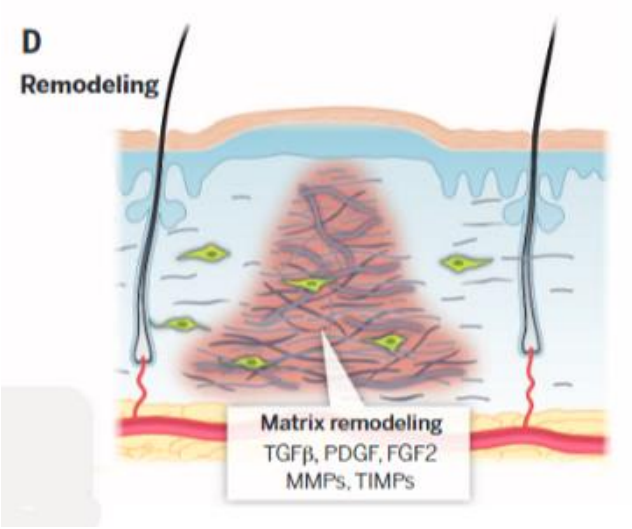

Figure 2.5- Schematic of the final phase of wound healing, the remodeling phase or maturation phase. Taking place over many years, the remodeling phase is where the newly developed matrix is rearranged to return the damaged tissue to the maximum strength possible.

2.2 Skin Graft Donor Site

When a skin graft is necessary, surgeons will place the patient under general anesthesia and use a device called a dermatome, as seen in Figure 2.6, which slices a thin strip of epidermis and dermis from the donor site. Using forceps, the surgeons can slowly remove the piece of skin to be used to cover the wound. This strip of skin is then cleaned and is sometimes run through a device known as a meshing machine, which cuts small slits into the donor skin in order to improve the

drainage of the wound as well as possibly covering a larger, more flexible area (Pope, 1990). Meshing can also be accomplished using a small scalpel.

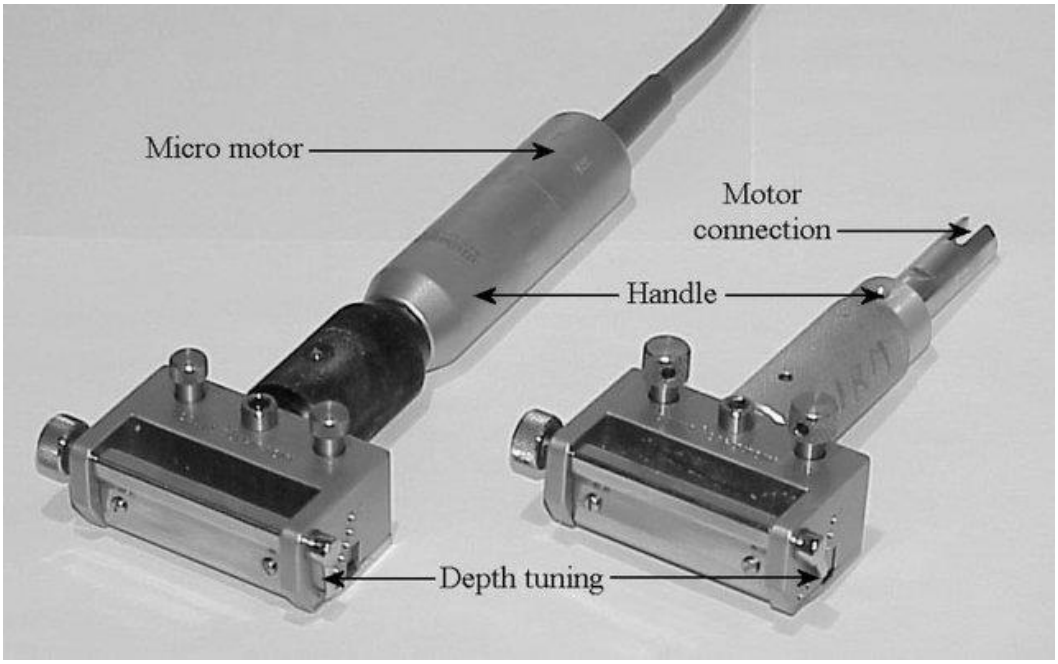

Figure 2.6 - Example of a dermatome, which is used to remove a graft of skin, often the epidermis and dermis, from a patient. Adapted from Dombre, 2003.

Skin grafts may be necessary after a variety of instances, including plastic surgery, burn wounds, cancer removal, or other traumatic wounds. Skin grafting is a procedure known to date as far back as 2,000 years ago in India, where documents suggest skin grafts were used to perform rhinoplasties (Davis, 1941). Most of the time, skin grafts are called “autografts,” as the patient receives a graft from another portion of their own body. The most popular donor sites include the thigh, back, and upper arm.

After surgery, many patients have reported that the site where skin was taken from to cover the wound, the donor site, was more painful than the wound site itself (Romanelli, 2019). This is likely due to many nerve endings being exposed in the procedure coming in contact with the

dressings during reepithelialization. Because of this, management of the donor site in addition to the wound site is a critical factor in post-surgical healing. Most donor sites are healed within three weeks of the operation, but some may last longer due to certain pre-existing conditions or comorbidities such as diabetes, renal insufficiencies, or history of smoking (Mathes, 2006). One of the main concerns with skin graft donor sites is the production of exudate in the early periods of reepithelialization. In attempts to manage the high production of exudate, a number of different dressings have been used to cover the donor site post-operation.

2.3 Wound Exudate

Wound exudate is a serous fluid that leaks out of capillaries during the inflammatory phase of wound healing as they become more permeable (Jones, 2013). The driving force that causes exudate out of the capillaries is known as hydrostatic capillary pressure (Vowden, 2003). Exudate is mainly water but contains electrolytes, nutrients, growth factors, and proteins. Exudate serves to improve healing rates, reduce pain, and limit chance of infection (Jones, 2013). It's growth factors include platelet-derived growth factors (PDGF), fibroblast growth factors (FGF), and epithelial growth factors (EGD) in order to promote the growth of fibroblasts, keratinocytes, and endothelial cells (Okan et. al, 2007) Fibrin protein is also commonly found in exudate to promote clotting along with platelets (Cutting, 2003). Matrix metalloproteins (MMPs) and fibrinolytic agents contribute to the breakdown of dead tissue and cytokines help to build up new tissue (Jones, 2013).

For acute wounds exudate can be very beneficial, but for chronic wounds it can be harmful. In acute wounds, the exudate has initially high concentrations of fibrinolytic agents. This contributes to breakdown of debris around the wound that marks the inflammatory stage (Okan, 2007). This concentration decreases with time in order to allow for re-epithelialization. In chronic wounds

however there is a prolonged inflammatory phase that results in high concentrations of MMP which degrades the wound to the point where it becomes difficult to heal. This inhibits the proliferative stage of wound healing (Okan, 2007).

While skin graft donor sites are considered acute wounds, they also tend to produce excessive exudate (Jones, 2013). Excess exudate can cause significant loss of proteins and electrolytes necessary for healing the area. It is also an issue for skin graft donor site dressings as they are unable to remain effective with the amount of exudate it is expected to handle (Lujan, 2020).

2.4 Existing Solutions

Several solutions currently exist, including nonocclusive and occlusive dressings, semipermeable membranes, and negative pressure wound therapy.

2.4.1 Nonocclusive Dressings

Nonocclusive dressings, like Xeroform™, are those that desiccate the wound, so there is no moisture, and the environment is dry. These dressings are inexpensive and only require a single application since there are no issues with leakage in these dressings and detachment does not occur. There are occasional issues with these dressings as they have slower healing rates and are more painful (Lujan, 2020). When weighing the pros and cons of both occlusive and nonocclusive dressings, the pros of occlusive dressings seem to outweigh the pros of non-occlusive dressings and have higher success rates (Serebrakian et al., 2018). These successes include higher re-epithelization rate and lower pain levels, which were aspects ranked very high on the matrix selection chart. When looking at the main contributing factor that drives the failure of donor sites, it is hypothesized that inadequate fluid management is this primary contributor. The group decided that it would be

smartest to keep the positive aspects of occlusive dressing that make them successful and alter the aspects that lead to the dressing failures, focusing specifically on fluid management.

2.4.2 Occlusive Dressings

Occlusive dressings have many properties, but they are most known for maintaining a moist environment for the wound. Other properties of occlusive dressings include enhanced epidermal migration, promote blood vessels and connective tissue development, allow gas exchange, maintain tissue temperature, protect against bacterial infection, and be able to remove easily (Tan, 2019). Occlusive dressings can be broken down into two different subcategories, absorbent, and nonabsorbent dressings like Tegaderm (Figure 2.7). Absorbent dressings are beneficial because they can absorb the wound exudate.

Figure 2.7 - Tegaderm™ Film Occlusive dressing. From 3M™ Tegaderm™ Film Dressing.

However, they do not have the capacity to absorb all the exudate that is produced, which is approximately 300 cubic centimeters in 5 days. Tegaderm™ is a frequently used absorbent dressing that was used in the final design. It is a clear absorbent dressing that allows moisture to be maintained and for gas exchange to occur. It can only handle low to moderate amounts of exudate, which is not ideal for the amount that the skin graft donor sites produce. It must be replaced every 3-5 days, and these dressing changes can sometimes be painful (Spear, 2020). Non-absorbent dressings are beneficial because they have higher rates of re-epithelialization and healing and have been reported by patients to be less painful. The downsides of non-absorbent dressings are that exudate production leads to dressing failure due to dressing leakage, which means there is more nurse or doctor intervention and frequent dressing changes (Lujan, 2020).

2.4.3 Semi-permeable Membranes

Another type of wound dressing is a semi-permeable membrane. A semi-permeable, or forward osmosis, membrane is a film that allows for the exchange of fluid and gas due to the natural movement of water from high osmotic pressure to low osmotic pressure (Weller & Sussman, 2006; Eyvaz et al., 2018). Since semi-permeable membranes are driven by osmosis, they are particularly useful in solutions, drawing water from the solution with a lower solute concentration into the solution with a higher solute concentration in order to equalize the water concentration, or osmotic pressure, on both sides. Due to this mechanism, they also do not require external pressure. Semi-permeable membranes have been used in industrial applications for decades (Eyvaz et al., 2018). However, more recently they have been investigated and used clinically in wound dressings to promote healing (Visscher et al., 2001).

When used in wound care, semi-permeable membranes are often permeable to gas and water vapor, but not liquids. However, the driving principle behind gas exchange is the same, but with the water vapor gradient instead of water. Semi-permeable membranes are commonly thought of as an intermediate between an occlusive and a non-occlusive dressing: they allow water vapor to escape to prevent maceration of the skin surrounding the wound, while also not drying or adhering to the wound too much (Visscher et al., 2001). Absorbent semi-permeable films are also often used in highly exudative wounds because of their ability to allow for the release of water vapor, lessening the load that needs to be absorbed (Talikowska et al., 2019). One study showed that when compared to occlusive dressings and non-occlusion, nonabsorbent semi-permeable membranes allowed for more healing of superficial wounds, as well as intermediate hydration, the best condition for barrier recovery (Visscher et al., 2001). However, nonabsorbent dressings should often be paired with other dressings on deep or exudating wounds (Weller & Sussman, 2006). It has also been shown that nonadherent semi-permeable membranes allow for better healing of skin, as well as prevent skin stripping (Visscher et al., 2001; Weller & Sussman, 2006).

Semi-permeable membranes have also been shown to be effective dressings on skin graft donor sites, along with other types of wounds. One study found semi-permeable membranes were found to decrease the amount of pain patients with split thickness skin graft donor sites faced significantly compared to occlusive dressings and non-occlusion, as well as speed up healing time in cases absent of infection. When used as a primary dressing however, the membrane was found to cause excessive leakage, which caused an increase in infection due to frequent dressing changes applied by poor technique, supporting the aforementioned idea that semi-permeable membranes are best used with other dressings on highly exudating wounds like donor sites tend to be (James & Watson, 1975). Another study also found that semi-permeable dressings reduced healing time

significantly and caused less pain, even upon removal (Iregbulum, 1983). Due to its favorable properties including allowing for vapor exchange while also maintaining a moist environment, semi-permeable membranes are seen as favorable dressings in different types of wounds, particularly donor sites when combined with another form of dressing.

There are many different semi-permeable membranes that are available on the market. One major membrane commonly used clinically is OPSITE™ (Figure 2.8), an adhesive film that is both waterproof and allows for water vapor to escape, made by Smith and Nephew.

Figure 2.8- Opsite™ Dressing. From Smith and Nephew.

It is made with silicone or polyurethane depending on the product (Smith and Nephew, 2022). Polyurethane foams are also commonly used and combined with other agents as an absorbent semi-permeable dressing in highly exudative wounds (Talikowska et al., 2019). Other semi-permeable dressings have also been made of polytetrafluorethylene (PTFE), polyolefin, and silicone (Visscher et al., 2001). Ultimately, semi-permeable membranes are made up of woven polymers with pores small enough that only gasses can pass through.

2.4.4 Negative Pressure Wound Therapy

Negative pressure wound therapy (NPWT) is a method of wound care that depends on suction to remove wound fluid, draw the edges of a wound together to encourage closure, and cause microdeformations at the wound interface to encourage cell division and healing (Figure 2.9). Negative pressure wound therapy devices typically consist of a porous foam to fill the wound cavity, a semi-occlusive wound dressing to cover the wound, a suction dressing and tubing over the wound, and a suction device connected to it (Huang et al., 2014). NPWT should not be used in all cases, especially when the wound is actively bleeding, there are veins or organs exposed, or there is necrotic tissue in the area of suction. Due to problems with tissue hypoxia, NPWT is typically used in an on-off cycle to allow blood to flow into the tissues. NPWT is usually used at a pressure of 125 mmHg but can change depending on the type of wound. If the pressure is too little, it will not have its desired effects. If it is too much, it can cause mechanical deformation (Agarwal et al., 2019).

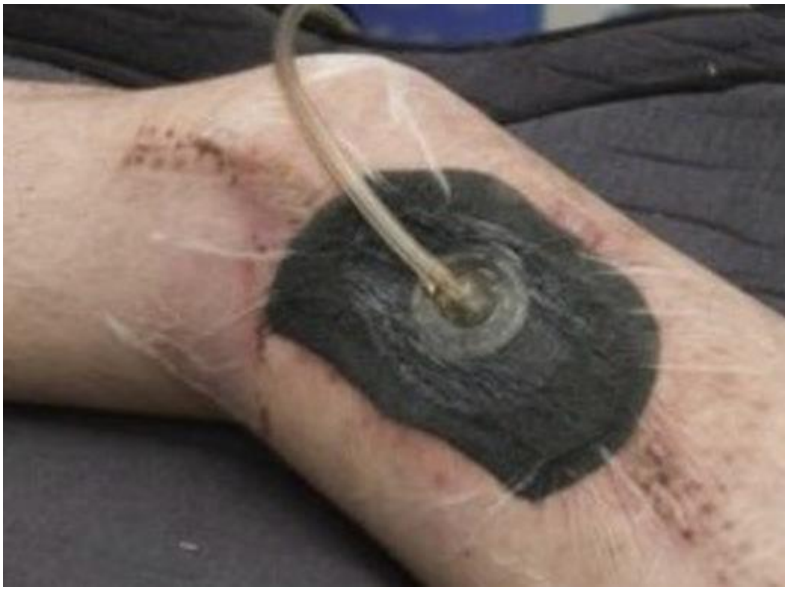

Figure 2.9 - Example of Negative Pressure Wound Therapy being used. Adapted from The Wound Vac Company, 2019.

NPWT can be used on many different types of wounds including diabetic foot ulcers, bed sores, fasciotomy wounds, and burns. NPWT functions on four main principles: macrodeformation of the wound bed, microdeformation of the cells, fluid removal, and stabilization of the wound environment. These effects have also been shown to contribute to improving growth of granulation tissue, increasing blood flow, regulating the inflammatory response, decreasing edema, removing wound exudate, and reducing bacterial load. All of these factors accelerate healing (Orgill & Bayer, 2013; Huang et al., 2014; Agarwal et al., 2019). NPWT is typically recommended for difficult to treat or slowly healing wounds and in some cases is cost effective due to needing less dressing changes, shorter hospital stays, and fewer reconstructive surgeries. This is especially true when it is performed with hospital wall suction and not commercial devices (Agarwal et al., 2019).

The data for the use of NPWT in donor sites is extremely limited. Very few clinical studies have been performed, and the ones that have been performed included only a small number of patients. One study found that in 10 patients with two donor sites, re-epithelialization was achieved faster in seven of the patients, unchanged in two, and slower in one when using NPWT (Genecov et al., 1998). Another study of 10 patients found NPWT to be as effective as traditional wound care methods with the main advantage being that it requires less maintenance and allows for earlier patient discharge (Mitchell et al., 2018). A study done in 10 dogs found that NPWT donor sites developed granulation tissue faster than donor sites without NPWT. It was also smoother. However, there was less contraction in NPWT donor sites and less re-epithelization overall. The lack of contraction was likely due to the dressing holding the edges of the donor site in place, as they also showed increased retraction compared to the traditionally treated donor sites (Demaria et al., 2011).

Despite the relative success of NPWT in donor sites, the data is limited, and many doctors choose not to use it for donor sites based on personal experience. Doctors have cited patient pain in

the donor site, as the pressure dressing holds the edges of the wound apart and pulls on it. They have also cited tissue growth inside of the foam utilized in the dressing, resulting in skin tearing and further patient pain according to experts in the field. Studies have mixed reviews of patient pain, with some patients claiming pain during NPWT and during foam dressing changes, while others claim no pain or very minimal pain. Studies about skin trauma are also limited, but multiple studies have found small numbers of patients have granulation tissue growth into the foam that results in bleeding and blistering (Upton and Andrews, 2013). There is currently little to no research into pain and trauma associated with donor sites specifically. Ultimately, pain and skin trauma associated with NPWT in donor sites are under researched areas of wound care that, combined with the firsthand experience of doctors, eliminated NPWT as a contender for further study.

2.5 Positive Pressure Therapy

Positive pressure therapy is a common first aid technique that when a wound is bleeding, applying direct pressure to it will reduce the bleeding and increase clotting. In both active combat and civilian treatment, pressure should be applied to bleeding wounds, if possible, when bleeding starts, followed by a tourniquet if the bleeding does not stop (Donley & Loyd, 2021). Most dressings recommend combining with direct pressure to stop bleeding, even if they have other ways to stop bleeding such as clotting factors (Bennett, 2017). Studies suggest that the applied pressure must be able to counteract peak arterial pressure, as blood will always try to flow in the direction with the least resistance (Naimer et al, 2004). While there is little research into the area of using compression to reduce donor site wound exudate, this theory of flow in the path of least resistance is used in other medical conditions to control excess fluid flow, and can be extended, in theory, to donor site fluid management.

The first advancement of using a positive pressure device in the medical field took place in the seventeenth century, where compression stockings were created to heal leg ulcers (Choucair, 1998). Since then, positive pressure has been widely used in the evolution of medical devices including compression socks for blood clots, compression garments in scar and burn treatment, and compressive bandages. Examples of compression garments are sportsware, chronic venous disease, body shaping, and many others.

Positive pressure is used to apply a specific amount of mechanical stress on underlying tissues in the body which accelerates the recovery timeline. The pressure for different types of applications could be localized to one point of the body or distributed throughout the entire garment. For wound dressings, a constant external pressure is confined to the affected area with the intention to minimize exudate and blood seeping out of the wound (Donovan, et al, 2016). As pressure is applied, blood flow is restricted from the area and the collagen fibers in the skin are reorganized to assist in new skin growth (Choucair & Phillips, 2013). A benefit to using positive pressure is that the wound can stay in a moist environment and avoid the chance of drying out. The amount of pressure applied is different for each compression garment and usage. According to (Donovan, et al, 2016), a strong compression is around 60 mmHg and a weak compression is around 20 mmHg.

Compression is often used in the treatment and prevention of seroma after surgery, yet there is not a clear consensus on whether it works. Seroma occurs when dead space is created after surgery and serous fluid leaks out of damaged blood vessels to collect under the skin (Janis et al., 2016). One review found that in the case of seroma after aesthetic surgery, there is no overall benefit to compression and sometimes negative consequences, such as patient pain and discomfort (Livermore et al., 2021). Another review of strategies to prevent seroma also found very little evidence to support or contradict the use of compression to prevent seroma, and no data about using compression

to treat active seroma (Janis et al., 2016) has been found. The authors suggest this is due to the inflammatory and exudative nature of seroma, which share properties with wound exudate (Janis et al., 2016).

Compression is also used in the treatment of edema and venous leg ulcers. When using compression in venous leg ulcers, the primary purpose is to increase venous return via constricting the blood vessels and reducing transmural pressure. This leads to decreased fluid filtration into tissues and increased lymph drainage. Due to the decreased edema, wound exudate is also reduced with the use of compression (Dissemond et al., 2016). The pressure required to see increased venous return is slightly lower than that of normal venous pressure (30-50 mmHg compression vs. 60-90 mmHg venous blood pressure), relating to the theory of staunching blood flow that compression must come close to peak pressures in the blood vessel it is trying to prevent flow out of (Rudolph, 2001). A similar principle can be applied to other wound exudates, where it cannot leave the vessels in the first place, because the pressure on the surrounding tissues makes it more favorable for the fluid to continue flowing in the blood vessels, instead of out of them.

2.6 Absorbent Materials

Other absorbent materials that can be categorized under occlusive dressings include hydrogels, polymer films, and polymer foams. The benefit of these and other absorbent dressings is that they are typically less painful and have faster rates of healing, though they cannot always manage the amount of wound exudate produced. Hydrogels are networks of hydrophilic polymers made of nearly all water that have the ability to absorb fluid that is produced by the body. The makeup of the polymer chains and the hydrophilic properties allow the hydrogels to absorb these large amounts of liquid (Ferreira et al., 2018). This makes them suitable for use in wound healing

methods like using them as part of an absorbent dressing. The large quantity of water in hydrogels allows them to maintain this moist environment that aids in epithelization rates and tissue granulation for quicker healing (Tan et al., 2019). Categories of hydrogels include smart hydrogels, thermo-responsive hydrogels, light, electric and magnetic hydrogels, pH responsive hydrogels, and bioresponsive hydrogels (Ferreira et al., 2018). Each type has their own specific purposes and can be used in a variety of applications in the biomedical field. Although, like all absorbent dressings, hydrogels have their downfalls. Due to the large quantity of wound exudate produced, hydrogels cannot manage this accumulation and issues of drying out and bacteria arise. This makes it sometimes necessary for hydrogels to have secondary dressings to manage the accumulation of wound exudate. Hydrogels are great at absorbing large amounts of fluid but its absorbance rate is quite low. This leads to the hydrogel drying out meaning the dressing would need to be changed more frequently. The other issue with hydrogels is that they are not good bacterial barriers, so infection is not uncommon (Tan et al., 2019). But hydrogels still have promising properties that can be altered or managed to obtain success in wound dressing management.

Polymer films and polymer foams are a few other types of occlusive dressings used to manage wound sites. The biocompatibility and biodegradability of natural polymers make them popular for this purpose (Wojcik et al., 2021). Polymer films are semi permeable dressings that are permeable to moisture but do not allow liquid or bacteria to permeate. They allow epithelial function to occur underneath the film to regain epithelialization so the wound can heal. Like all occlusive dressings, these films create a moist environment by keeping the exudate within the film. Issues arise with polymer films when too much exudate accumulates and leakage from the site occurs. Polymer foams have the same advantages as polymer films but they are absorbent, therefore eliminating the

disadvantages of the film. The foam is composed of a sheet of polyurethane with a hydrophilic coating adhesive. These are then bonded to the film layer which supports the absorption of the fluid. This foam is an added benefit of a normal occlusive dressing because it increases the absorbance while maintaining the moist environment The main weakness of the foam is that it requires a secondary dressing to hold in place since it lacks the adhesive properties (Tan et al., 2019).

Another type of polymer dressing that is commonly used is a hydrocolloid dressing. Hydrocolloids are permeable to water vapor, impermeable to bacteria, and are also capable of absorbing exudate as a liquid. They have also been used as a drug release system, controlled by the size of particles and permeability of gel membrane. Hydrocolloids can melt upon exudate absorption but shift into a gel, making removal of the dressing clean and leak-free. As opposed to the polymer foams, hydrocolloids do not need a secondary dressing to keep it intact and in place. Although, a large drawback of these dressings is the smell that arises upon mixture with an adhesive. Hydrocolloid dressings are also beneficial in preventing infection due to its ability to permeate bacteria, but not necessarily combat infection once it arises (Tan et al., 2019). But like most cases of occlusive dressing use, there are quicker healing rates and less pain involved upon removal of each dressing.

2.7 Adhesives

Another key component of a wound dressing is the adhesive. The adhesive must both be strong enough to stay on for the duration of healing, but also weak enough to be removed without causing damage to skin. There are many distinct factors that affect how adhesives behave on skin, including but not limited to skin dryness, sebum levels, and sweat, which means different adhesives work differently for different people and cannot be standardized. In choosing a wound dressing, the

two most crucial factors are adhesion and tack. Adhesion refers to two things sticking together, such as the wound dressing and skin. Tack refers to the instantaneous level of adhesion that is displayed when the materials are stuck together. Both are important when deciding on an adhesive for a wound dressing. Tack is needed to ensure the dressing sticks while also allowing for the dressing to be removed. Adhesion is important as it is a property that changes throughout the duration of dressing attachment and is primarily responsible for ensuring the dressing does not slide around the skin during the duration of healing (Rippon et al., 2007).

Skin adhesives are separated into two classes: pressure-sensitive and structural. The vast majority of adhesives in wound care are pressure-sensitive, and require pressure to reach their full adhesion, which will then decrease over time. There are two different types of adhesion in wound dressings: chemical and physical. In physical adhesion, the adhesive moves into the pores of the skin to stick. In chemical adhesion, there is either chemical bonding between the adhesive and the skin, electrostatic forces holding the adhesive to the skin, van der Waals forces between the adhesive and the skin, or diffusion of the adhesive into the skin followed by hardening of the adhesive. Fracturing of the adhesive can also occur in different ways, either by cohesive or interfacial failure (Figure 2.10).

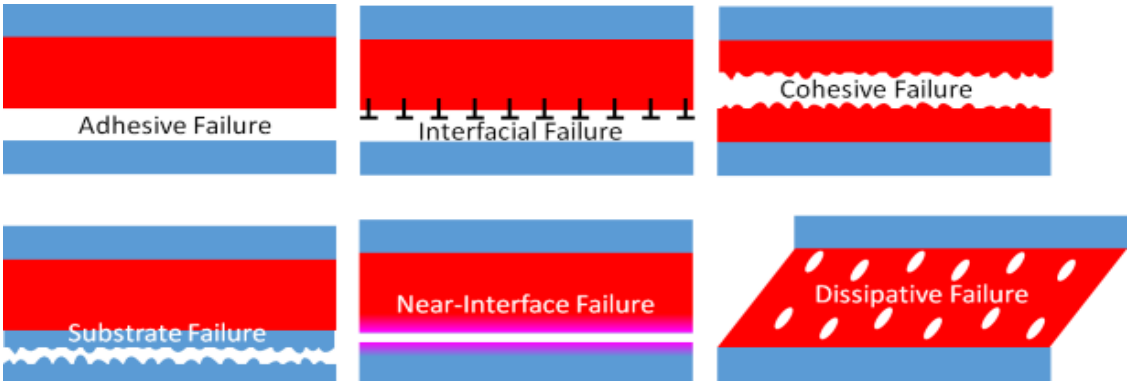

Figure 2.10- Different types of failure leading to adhesive separation. Adapted from Abbott, 2022.

Cohesive failure occurs when a crack forms in the adhesive itself and it splits, leaving adhesive behind on both of the bonded materials. Interfacial failure occurs when the adhesive is no longer bonded to the adherents, either the dressing or the skin, and causes them to separate, leaving adhesive behind on only one of the bonded materials (Rippon et al., 2007).

There are many different types of adhesives with many different properties. Acrylic is a strong adhesive that is difficult to remove and therefore should never touch the wound bed. It should only be used to anchor dressings to the skin. Hydrocolloids can be used on both the skin surrounding the wound and the wound bed, as it forms a gel upon interaction with wound exudate. This however causes adhesion to lower, as well as increases the chance for skin maceration. Hydrogels are biocompatible, transparent, breathable, and have an analgesic effect. However, they also lose adhesion when wet and can cause skin maceration. Rubber-based adhesives have low strength and cause movement over skin which can lead to skin stripping and maceration. Polyurethane is a common adhesive that is typically used on the skin surrounding the wound, not the wound bed. Its strength commonly leads to skin stripping and maceration. Cyanoacrylate is liquid adhesive used to form a film over damaged skin in the presence of fluid but is rarely used on external adhesives. It is more commonly used as a tissue adhesive. Soft silicone is another adhesive with rare properties. It has many contact points with the skin and can therefore conform to odd placements and form a seal around the wound when used on the surrounding skin. This locks the exudate in and prevents maceration. Its adhesion also does not increase over time, meaning it causes less damage than some other adhesives (Rippon et al., 2007). There are many different properties to consider when choosing a skin adhesive for use in wound dressings, and soft silicone adhesives have many favorable properties, primarily related to their ability to bond tightly to the skin surrounding the wound, while also allowing for atraumatic removal.

Chapter 3: Project Strategy

This project was worked on under the supervision and guidance of Dr. Raymond Page of the Worcester Polytechnic Institute Department of Biomedical Engineering, Dr. Raymond Dunn of UMass Medical School, and Dr. Jorge Lujan of UMass Medical School. This chapter outlines the strategy used to develop the ideas that resulted from this project.

3.1 Initial Client Statement

This project, being performed in concert with UMass Medical School, was provided with an initial client statement from Dr. Page, Dunn, and Lujan:

> "The goal of this project is to develop a dressing using new and existing materials that reduce the flow of exudate. The dressing should have semipermeable properties that allow the exudate to absorb away from the donor site and into the material. This dressing is sought to be user friendly, cost-conscious, and durable for inpatient and outpatient settings."

3.2 Technical Design Requirements

In order to begin addressing the initial client statement, a variety of factors had to be taken into consideration, including the project objectives, constraints, product functionality, and product specifications.

3.2.1 Objectives

When designing a skin-graft donor site dressing, the patient using the device must be always kept in mind. Thus, the patient's needs and wants must be addressed. Of major importance to most

patients is comfort and ease-of-use. The designed dressing must not inflict any increased pain to the user. It should be comfortable to wear and not affect the patient's daily life. Because of this, softer material that does not cause pain when in contact with the skin should be used. In addition, the dressing should be as close to "set it and forget it" as possible. What this means is that once the dressing has been applied to the skin-graft donor site, little to no patient interference should be required. This again means that the patient should be able to go through their daily life as normally as possible. Ease-of-use is important as it can not only set the patient's mind at ease, knowing they have tended to it correctly, but this also can improve patient adherence to any guidelines associated with the dressing. If the guidelines and protocols are easier to follow, it is more likely the patient will adhere to them.

3.2.2 Constraints

The dressing design must consider a number of constraints. When the dressing is ready to be applied, a surgeon must be able to easily remove it from its packaging and set it over the entirety of the donor site. Over time, it must stay adhered to the patient's skin and not cause maceration resulting in skin damage and the possible detachment of the device. The device must effectively manage the exudate produced from the skin-graft donor site by absorbing it or draining the exudate away. It should also maintain a moist environment at the wound site, as occlusive dressings have been shown to improve wound healing.

The dressing should also be capable of lasting most of the wound healing process, to ensure the least amount of patient interference as possible. Any exudate that is produced must not leak out of the dressing and must not overwhelm the dressing. When it is time for the dressing to be removed, it must easily separate from the skin and not result in skin tearing. Another constraint of the design is

the cost. Current dressings are relatively inexpensive, making a novel design difficult to implement while still being cheaper and more effective than current designs. Because of this, any solution must also factor in the cost of the materials and manufacturing into the evaluation of the product.

Another major constraint with this project is the inaccessibility of human patients to measure and test dressings on. Instead, a model must be created that can mimic the conditions of a skin graft donor site. This project should include a design portion dedicated to creating a model for skin graft donor sites.

3.2.3 Functions

The dressing will be applied over the entire donor site and left there for long enough to absorb or drain most exudate produced. By applying pressure to the donor site, less exudate will be produced, which means less exudate to manage. For the exudate that is produced by the donor site, the dressing will wick the fluid upwards through a polyester layer, where it encounters a layer of hydrogel where it is absorbed and locked in place. In a drainage dressing, the excess exudate will be stored in the dressing until a removable bag is attached, which drains the exudate into a biohazardous waste bag that can be attached at any time to remove the fluid.

3.2.4 Specifications

The device must be capable of dealing with exudate rates of around 80 milliliters of exudate per day, for at least the first five days. Ideally, it should be capable of remaining attached for around two weeks. It must also be able to function under normal external physiological conditions. The device should be designed to be functional at various locations of the donor site, with the most common being the thigh, back, and upper arm. The dressing should also be able to cover a donor site

of approximately 75 square centimeters. In addition, for a hydrogel dressing, once absorbing the maximum amount of exudate it should ideally remain less than around 3 centimeters in width, to ensure minimal perturbation to the patient's daily activities.

3.3 Design Standards

Since the wound dressing is a medical device that meets human skin, it is subject to controls set forth by the FDA and ISO. The dressing classifies as a "hydrogel wound dressing and burn dressing" by the parameters outlined in 21 CFR 878.4022, and therefore it is a Class I medical device and is subject only to general controls (1999). However, these controls do require that the dressing provides benefit to the user without posing unreasonable risk of injury. The standards outlined in ISO "109933-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests skin sensitization" are the most relevant to ensuring the safety of the dressing. This standard includes testing in vivo skin sensitization procedures to ensure skin safety (2021).

3.4 Revised Client Statement

Based on the background research and literature review performed, the group discussed an updated project goal with advisors to settle on the final revised client statement, to be used as guidance for the rest of the project. The most important addition to the client statement came from the need to develop a model system to measure wound exudate and test prototypes and current dressings against. Because of this, the following client statement was adopted:

> "The goal of this project is to develop a dressing using new and existing materials that reduce the flow of exudate. The dressing should have semipermeable properties that allow the exudate to absorb away from the donor site and into the material. This dressing is sought to

be user friendly, cost-conscious, and durable for inpatient and outpatient settings. In addition, the team should seek to create a donor site model capable of replicating the clinical conditions of a skin graft donor site. The model should be used as a method of testing prototypes and current dressings against one another to compare effectiveness."

3.5 Management Approach

At the end of this project, there will be a wound dressing design that is the ideal candidate for the fluid management of skin graft donor sites. At the start of the project, goals for the design process were outlined in a Gantt chart that was added to as the project progressed. Figure 3.1 shows the Gantt chart and the deadlines that were projected to both keep the goals in order and to encourage the team to meet deadlines to finish the project on time.

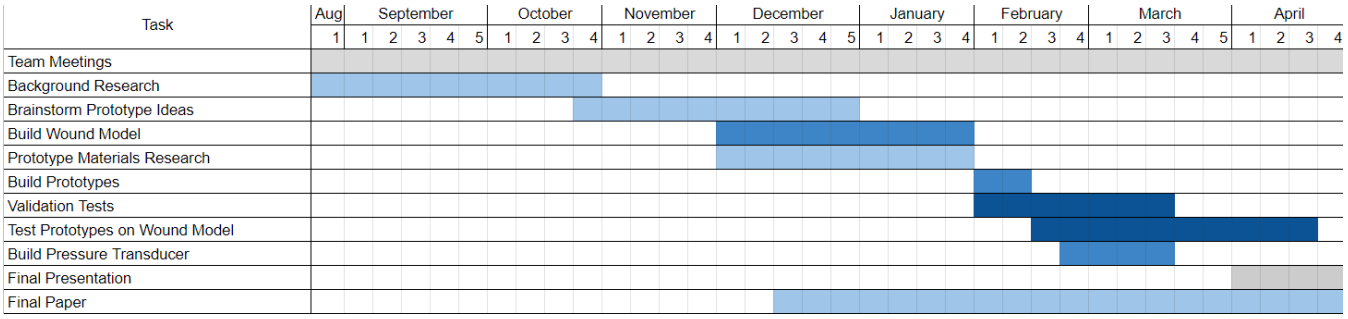

Figure 3.1 - Gantt Chart outlining the planning schedule over the course of the 2021-2022 academic year.

Chapter 4: Design Process

In this chapter, the process the team went through to solve the challenges of choosing a final design based on the client statement is discussed. Several literature reviews were considered to narrow down the selection of relevant hydrogels and semi permeable materials that were used in the final design. This section includes initial concepts and alternative potential solutions that were a part of the design process. This section will conclude with the final design of both the donor site model and the multilayered dressing.

4.1 Needs Analysis

In the process of designing an appropriate skin graft donor site dressing, the team created a set of requirements important in the final design. These requirements are improvements that can be made from prior skin graft donor site wound dressings, as well as important characteristics of a dressing on the market. Current donor site dressings have a highly exudative nature which cause constant dressing changes, dressing leaks, and a high level of maintenance. Other challenges current dressings face include infection, pain, and scarring. The goal of this project is to create a dressing that is cost effective, pain free/comfortable, low maintenance, low risk of infection, durable, user friendly, with good fluid control. The overall design requirements and weight of importance are listed in Table 4.1.

Table 4.1- Weighted requirements for dressing: Importance was ranked using a scale of low (1) to high (5).

Requirements	Weight of Importance
Cost Effective	2
Pain Free/Comfortable	4
Low Maintenance	4
Low Risk of Infection	5
Durable	3
User Friendly	3
Fluid Control	4

The requirements were weighted using a scale from one to five to rank the significance regarding the final design choices. A weight of one signified a lower importance than a weight of five which signified the highest importance. The most important requirement that the team weighted a five was low risk of infection because the dressing would be nonviable if this was not the main priority. By following this needs analysis, the team's final design of a skin graft donor site dressing would have all the necessary requirements to be a useful advancement in post operative donor site dressings. After ranking the requirements, a design matrix was used on a scale from zero to five. Zero meant the requirement was not able to be achieved and five meant the requirement was

successful in the design. The team used the top three concepts as columns and the same requirements from Table 4.2 as the rows.

Table 4.2 - Design Matrix for Final Design Decisions: Score was from 0 (poor) to 5 (very good).

	Dressing with sodium polyacrylate	Hydrogel bladder	Drainage system
Cost Effective	5	3	0
Pain Free/comfortable	4	4	0
Low Maintenance	4	2	0
Low Risk of Infection	4	2	1
Durable	5	4	0
User Friendly	5	3	0
Fluid Control	4	4	3
Total	108	77	17

Going down each column the score of the designs were multiplied by the ranking of importance and the ranking in the design matrix. Table 4.2 shows the design that scored the highest, the final design, was the dressing with sodium polyacrylate. The team continued with this initial concept because it covered all of the necessary needs and requirements, each column scored at a 4 or above making it the best choice to move forward. The concept that scored the least and that was not

further considered was the drainage system. This design did not meet all the requirements that were set and deemed necessary to have a functioning skin graft donor site dressing.

4.2 Concept Map, Designs, Prototyping, and Feasibility Studies

To narrow down which absorbent hydrogel to use for the dressing, Table 4.3 shows the swelling ratios, price, and crosslink abilities of a variety of hydrogels. The two hydrogels that stood out with an enormous swelling ratio while being cost effective were sodium polyacrylate and sodium alginate. Sodium polyacrylate was chosen as the hydrogel because of its abilities to gel immediately and stay moist for a long duration of time.

Table 4.3- Potential Absorbent Hydrogels

Material	Swelling Ratio	Price	Crosslinked with
Sodium Alginate	4343.4%	Alginate - $143/1kg Chitosan - $75/50g	Chitosan
Sodium Alginate	60-180%	Cannot find specific G concentration	N/A
Collagen	300-800%	Collagen - $265/30mg	Alginate + cellulose
Carboxymethyl cellulose	150-5000%	CMC - $139/500g PEG - $58/25ml CA - $45/100g	PEG + citric acid
Hydrocolloid (SIS + PIB)	150-300%	SIS - $68/500g PIB - $163/100g	liquid paraffin, sodium alginate, PVP, poloxamer, sodium CMC, HPMC, PVA
PVA (most commonly used as an adhesive)	N/A	$43.54/500g Lab-grade 87% hydrolyzed	dialdehydes, dicarboxylic acids, tricarboxylic acids, diisocyanatos and boric acid, hydrocolloids, chitosan

PLGA	Below 5%	$236/1G	PEG
PNIPAAM	510-520%	$691/10G	PBS Nanocomposites HEA
PVP	93%	$32.60/50G	UV photocrosslinking
HEMA	150-400%	$37.50/500G	EGDA
PAA	N/A		Dually crosslinked
Sodium Polyacrylate	4630-40480%	SP-$46/250G Chitosan - $75/50g	Chitosan
Sodium polyacrylate	1700%	N/A	N/A

4.3 Alternative Designs

Upon starting this project, several alternative designs were looked into, including a drainage system, a hydrogel system, and an initial proposal for the donor site model.

4.3.1 Drainage System

To solve the issue of excessive exudate overwhelming skin graft donor site dressings that exist on the market, this design was created to attempt to remove the exudate from the system entirely. It utilizes a semi-permeable membrane directly against the graft site that would allow for the passage of wound exudate. Above this would be an impermeable membrane that would prevent any bacteria from entering the graft site and any exudate from leaving. The two membranes would be sealed off and adhered to each other only on the outer edges, allowing for any exudate to collect between them. Embedded into the impermeable membrane would be a tube that is able to access the exudate that collects within the dressing. The semi-permeable membrane prevents this tube from

coming into direct contact with the graft site, preventing pressure injuries in that region. This tube would have a stop valve attached to the end that is outside of the dressing to control the flow of exudate through the tube.

A separate collection system would consist of a tube connected to a vacuum ball and bag as shown below in Figure 4.1. To drain the exudate, the collection system would be attached to the stop valve, the valve would be opened, and the vacuum ball would be squeezed. This would pull exudate out of the membranes without relying on gravity, since gravity would be unreliable depending on the location of the donor site. The stop valve would be closed, and the collection system would be removed and disposed of. This could prevent the dressing from becoming overwhelmed by exudate and make sure that only a tolerable amount stays within the dressing.

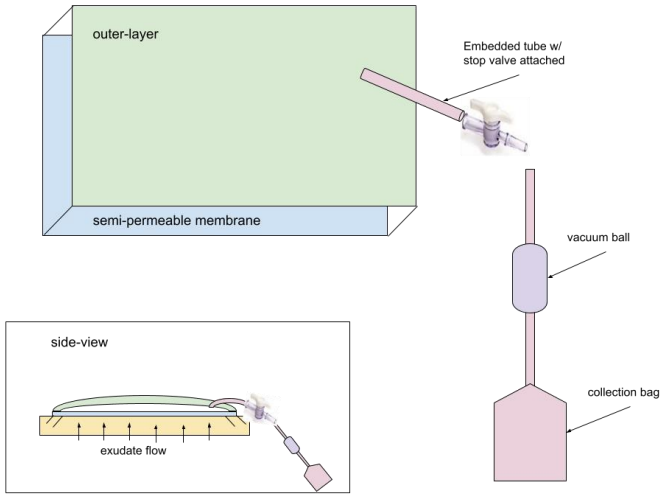

Figure 4.1 - Diagram of alternate drainage system design with membranes and separate collection system. Side view demonstrates how exudate flows through one membrane to collect for drainage.

4.3.2 Initial Donor Site Model

The initial model of the donor site used a plastic water bottle as a base and polyethylene tubing connecting it to a reservoir of continuously running water. As seen in Figure 4.2, a five by ten centimeter hole was cut in the water bottle to act as the donor site. This model failed due to

leaking at the point where the tube and the water bottle were connected. This flaw was remedied by using a plastic carboy container instead of the water bottle.

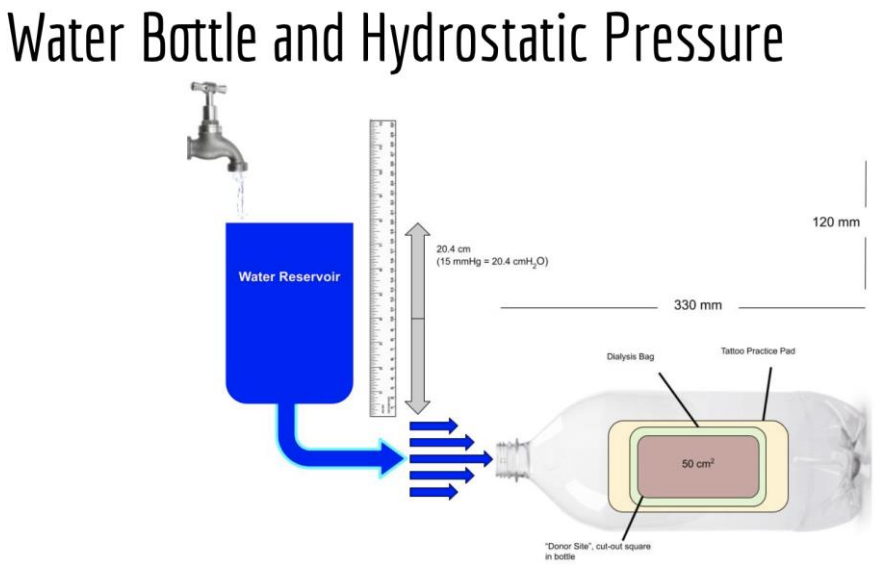

Figure 4.2- Schematic of preliminary donor site model set-up.

This next concept was designed to be a donor site model that used a plastic carboy, dialysis tubing and a tattoo practice pad. A hole cut in the carboy acted as the wound site which would be the thigh, arm, or trunk on a human. A six by twelve-centimeter hole was cut in the carboy which was then covered with a dialysis tubing to act as the wound site. The dialysis tubing was then covered with a tattoo practice pad that had the same diameter hole cut into it and glued to the carboy, as seen in Figure 4.3 below.

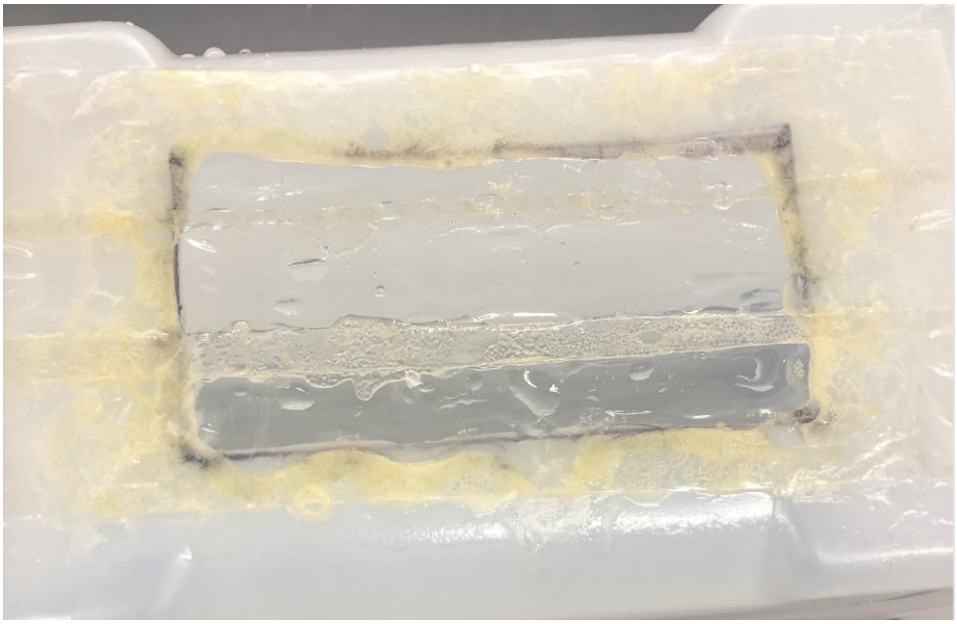

Figure 4.3 - Dialysis tubing glued to the carboy covering the donor site hole.

The carboy was filled with a mixture of water and glycerin, the ratio being 2.4:1 (water to glycerin) by volume. The mixture of water and glycerin was filled to a hole that was cut into the side of the carboy at about 19.4 centimeters, as seen in Figure 4.4 below. This hole was attached to a tube going into another carboy to keep the height and hydrostatic pressure at a constant 15 mmHg. To measure the 15 mmHg, a manometer was attached using polyethylene tubing to measure the height and pressure of the mixture.

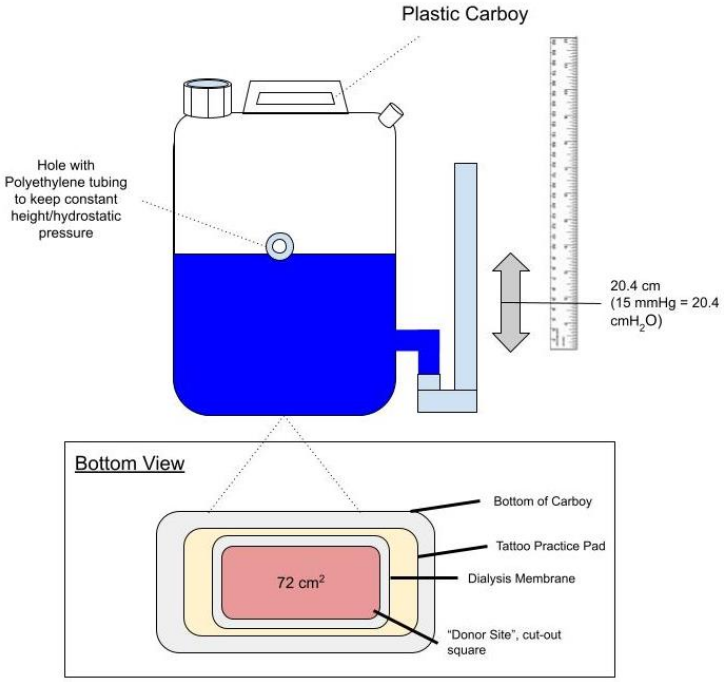

Figure 4.4 - Schematic of donor site model set-up.

This design of the donor site model had a complication with the dialysis tubing. The dialysis tubing when glued on for a duration of time dried out which then caused it to leak and curl up. The complication made this version of the donor site nonviable. In section 4.4, the changes were made to overcome this flaw of the initial design of the donor site model as described.

4.3.3 Hydrogel Bladder

One initial idea was a hydrogel bladder made of mylar that was placed directly on the donor site causing the exudate to wick up into the bladder and expand putting positive pressure on the donor site. The bladder was filled with sodium polyacrylate, a absorbent cross-linked hydrogel, and as the bladder expanded with the exudate more pressure was put on the donor site. As seen in Figure 4.5, the side of the bladder directly on the skin had a micro knit polyester layer that acted as a semipermeable membrane. This allowed exudate to flow into the bladder and away from the donor

site. The side of the bladder away from the skin was rigid and curved toward the skin on all four sides, adhering it to the skin and not allowing leakage.

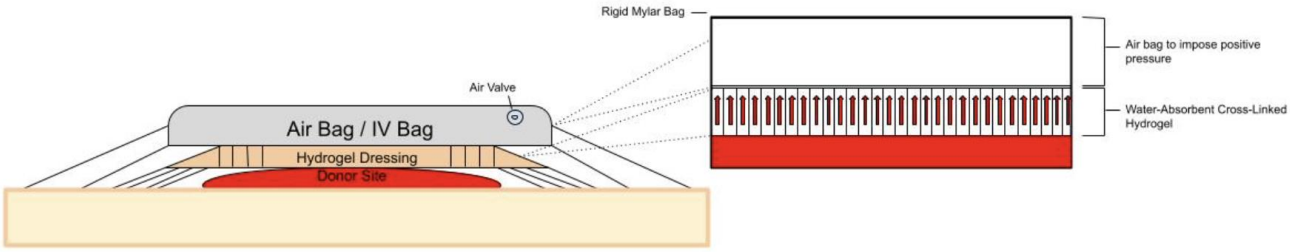

Figure 4.5 - Schematic of the hydrogel bladder applied over the donor site.

This concept was not investigated further because there was not enough positive pressure on the donor site to get to 15 mmHg. The hydrogel inside the bladder was not able to absorb and put enough pressure on the donor site to cause a decrease in exudate production. There was also a challenge with securing the adhesive on the other end of the bladder with enough force that there was no leakage, but with no pain to the patient's skin.

4.4 Final Design Selection

With a variety of iterations complete and many initial experiments performed, the final designs were settled upon.

4.4.1 Final Donor Site Model

The final design of the donor site model is similar to the one in Figure 4.4, without using dialysis tubing at all. Instead, a tattoo practice pad was glued directly onto the six by twelve-centimeter hole in the carboy to act as a layer of skin. An 18-gauge needle was used to poke ten

holes into the practice pad to let the mixture of glycerin and water leak out at a flow rate of 0.80 mL per minute, as seen in Figure 4.6.

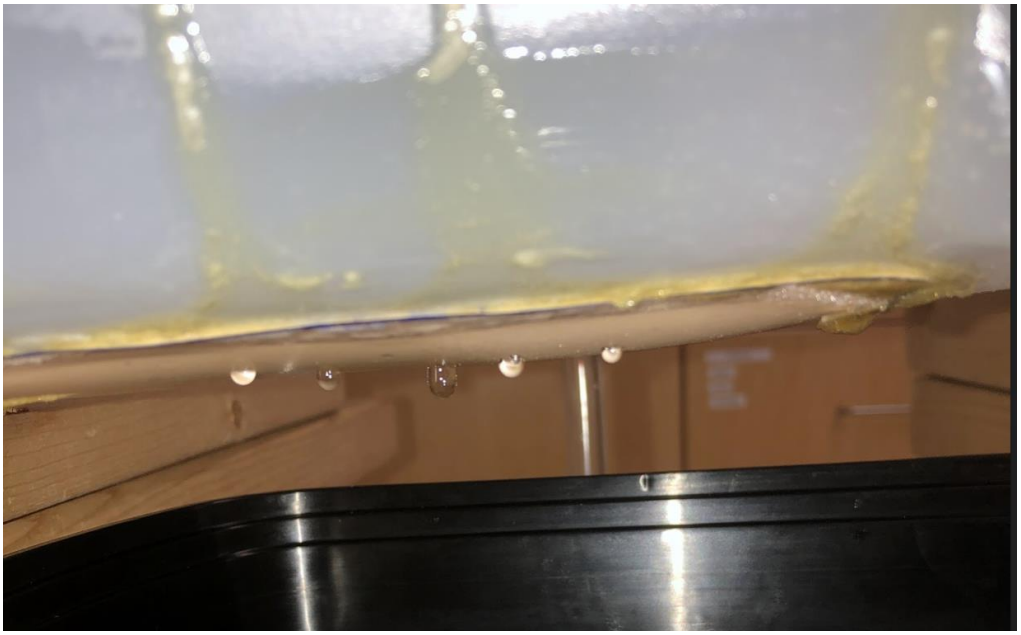

Figure 4.6 - Tattoo practice pad with holes leaking out the mixture of glycerin and water at a rate of 0.80mL per minute.

The ratio of water to glycerin and the pressure height was kept the same from Figure 4.6, a picture of the system can be seen below in Figure 4.7 and Figure 4.8.

Figure 4.7 - Final design set-up of donor site model.

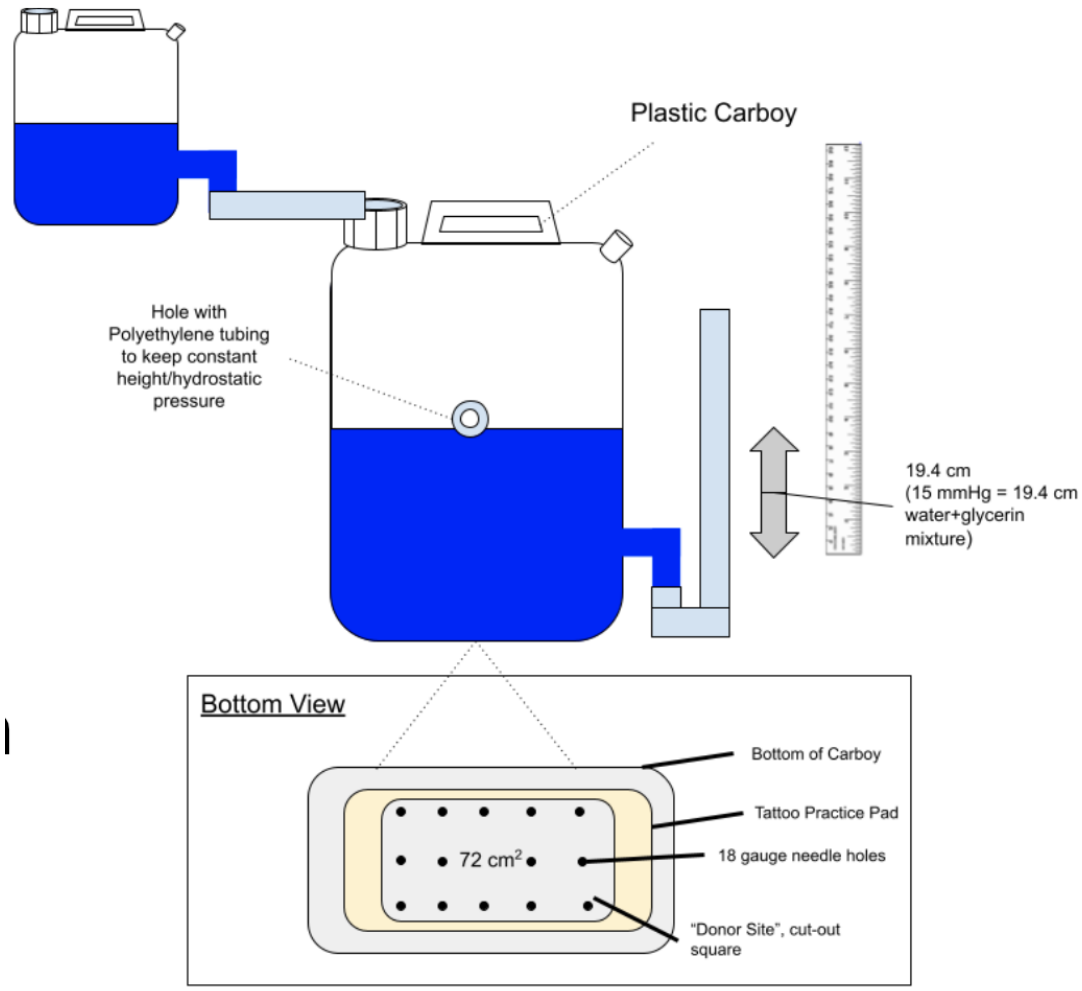

Figure 4.8- Final schematic design of donor site model.

4.4.2 Positive Pressure Dressing

The final design of the dressing, as seen below in Figure 4.9, consisted of four layers: Tegaderm™ film, micro knit polyester bag with sodium polyacrylate, polyvinyl chloride bag, and an elastic bandage.

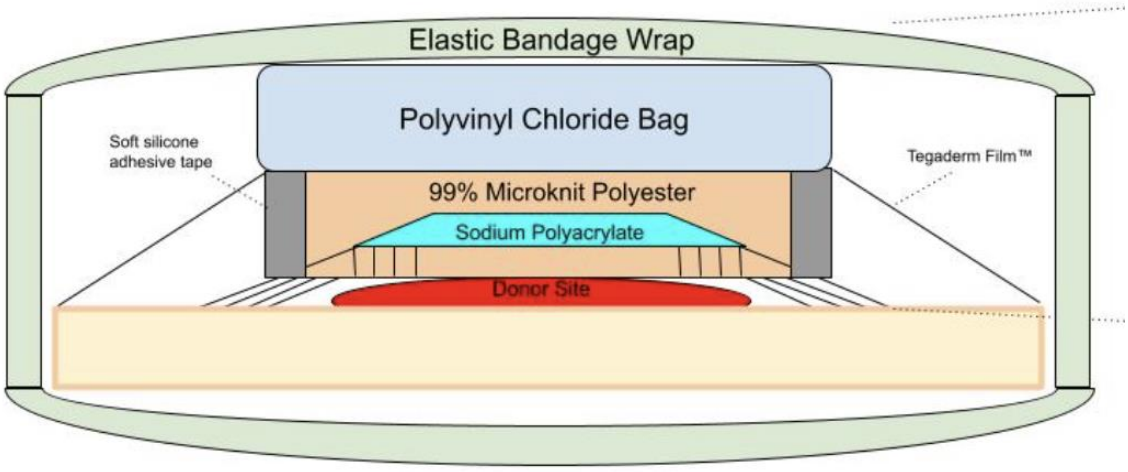

Figure 4.9 - Final schematic of positive pressure multilayer dressing.

The Tegaderm™ layer is closest to the skin and covers the donor site completely with a two-centimeter overhang on each side. The next layer is a micro knit polyester bag filled with sodium polyacrylate that covers the donor site. The bag is secured on all four edges with silicone tape so the sodium polyacrylate cannot leak out. The sodium polyacrylate will absorb the exudate and the polyester will keep the exudate away from the donor site. The last two layers, the polyvinyl chloride bag and elastic bandage wrap, ensured the pressure to be 15 mmHg on only the donor site. The polyvinyl bag was blown up to full capacity and the elastic bandage was then pulled as far as it needed to wrap around the limb keeping the constant pressure. The amount of pressure applied was able to be measured using a pressure transducer, as seen in Section 5.2.

Chapter 5: Design Verification

Before any results on specific prototypes could be produced, the skin graft donor site model needed to be created and have baseline exudation results verified. Once the donor site model was able to effectively replicate the conditions of exudate production in a skin graft donor site, the ability to verify the pressure applied by the positive pressure dressing was necessary. Before the prototypes could be tested, their individual components had to be validated via benchtop tests. Finally, once each of these conditions were satisfied, the prototypes could be built, and their efficacy could be tested.

5.1 Skin Graft Donor Site Model Verification

With the final design of the skin graft donor site model in place, the exudate production of the model system was tested. Model exudate was produced by making a mixture of 1 mL glycerin to 2.4 mL water and mixing fully. This ratio gives a viscosity of 2.5 cP, halfway between the viscosity of serum (1.5 cP) and blood (3.5 cP), based on the glycerin-water mixture viscosity equation described in Cheng 2008 (Labcorp, 2022; Nader et al., 2019). After ensuring the tattoo practice pad had been entirely sealed to the sides of the carboy by filling it with both water and the model exudate, leaving the carboy full overnight to ensure no leaking occurred even when shear stress was applied by the force of the liquid inside. Once the seal was confirmed to have no leaks, holes were poked in the practice pad with a 18-gauge needle in the center of the pad. Table 5.1 shows the resulting flow rates produced when poking between 2 and 30 holes into the tattoo practice pad.

Table 5.1 - Flow rates of exudate produced with different number of holes poked in tattoo practice pad. Time to achieve 300 mL of exudate production included as this represents the first five days of exudate production.

Holes in Practice Pad	Volume Leaked (mL)	Time Leaked for (minutes)	Flow Rate (mL/minute)	300 mL Exudate Production (hours)
2	3	30	0.10	50
4	7	30	0.23	21.7
6	12	30	0.40	12.5
8	16	30	0.53	9.4
10	24	30	0.80	6.3
15	35	30	1.16	4.3
30	84	30	2.8	1.7

Over the first five days of exudate production, approximately 300 milliliters of exudate is produced, thus the time needed to reach this amount is included in the table as well. With this data in mind, the existing tattoo practice pad was removed and replaced with a fresh one, repeating the process of ensuring the pad was entirely sealed. Ten holes were then inserted with a 18-gauge needle into the center of the pad to simulate exudate flow of approximately 300 milliliters in six hours. Six hours was chosen to ensure multiple tests could be run in one day, as well as to ensure mold would not grow inside the donor site, an issue which is discussed later in section 7.1. In addition, exudate flow of up to 1 mL/hour proved to consistently overwhelm each dressing due to the inability to handle the shear forces.

To ensure the results were reproducible, the new donor site model was tested to ensure the holes poked resulted in a flow rate close to the values provided above. When leaving the model running for six hours, 291 milliliters of fluid was collected in a plastic container underneath the

donor site model. This resulted in a flow rate of approximately 0.81 mL/minute, similar to the 0.80 mL/minute exhibited previously.

5.2 Pressure Generation

Next, a pressure transducer was built to ensure the design exerted the needed amount of pressure back on the donor site. An Arduino UNO Rev3 and a Pololu 1.5 in^2 Force Sensing Resistor were used to create the current-to-voltage converter circuit suggested in the Interlink Electronics FSR Force Sensing Resistor Integration Guide (2021). This circuit was capable of recording variations in pressure as values of voltage. By testing various known masses, converted to pressure using the area of the resistor, on the force resistor and recording the voltage output, a standard curve was created to determine the relationship shown in Figure 5.1. The equation generated was logarithmic, as stated in the Integration Guide, and it was $P = e^{\frac{V-0.456}{0.0599}}$ where P = pressure and V = voltage. From here, the dressing and elastic bandage was applied to a model carboy to determine how tightly it should be pulled to where a steady pressure above 15 mmHg could be maintained. This was found to be at 17.2 mmHg and the bandage was marked at the corners to show correct placement for constant pressure across all trials.

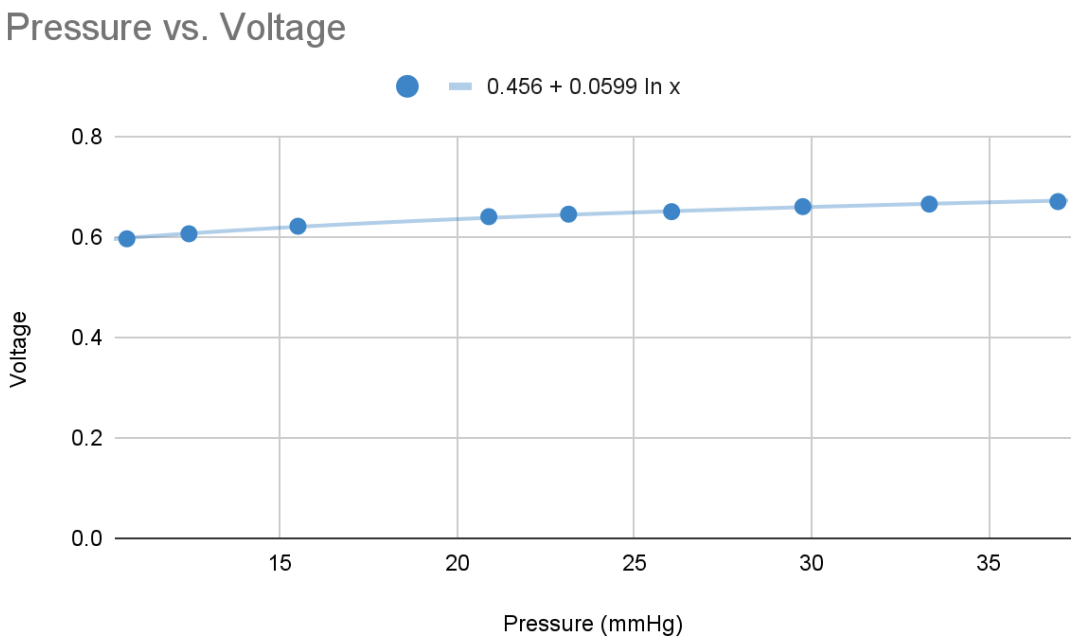

Figure 5.1 - Force resistor standard curve determined using known masses to generate a current.

5.3 Simple Absorption Test

The upper limits of absorption of the sodium PAA were tested to determine how much fluid it could hold. To do this, 5 g of PAA was mixed with 25 ml water to form a gel. Next, the gel was placed in polyester, to model the wound dressing wicking layer, on top of a weigh boat filled with 85 ml model exudate. As the PAA absorbed the mixture, more mixture was added to the weigh boat until absorption stopped entirely. Table 5.2 shows the results of three simple absorption tests, with the upper limits of absorption of 5 g of PAA being about 201.3 ± 8.4 ml, not counting the 25 ml water primer. The upper absorption limit and expansion of PAA can be visualized in Figure 5.2.

Table 4.2 - Simple PAA Absorption Test Results.

Trial Number	PAA mass (g)	Fluid Absorbed (ml)	Time to Total Absorption (min)
1	5.0094	193.8	63.7
2	5.0058	213	71.4
3	5.0089	197	67.6

Figure 5.2 - Sodium polyacrylate gel before and after upper absorption limit testing.

5.4 Pressure Absorption Test

When PAA absorbs fluid, it does so by expanding. Since the final design utilizes pressure pushing down on the dressing, it must be determined if PAA is still capable of absorbing fluid while under up to 20 mmHg of pressure. To do this, 5 g of PAA soaked with the 25 ml water primer to form a gel was inserted inside a polyester pouch. The edges were sealed all the way around with tape to ensure the hydrogel could not escape and that water would only go through the polyester. Next, a pitcher was filled with water until the pressure exerted by the pitcher across the bottom would be 20 mmHg. A shallow dish was filled with 85 ml of the mixture, and the pouch with the pitcher on top was placed on the bottom was placed on the bottom of the dish, ensuring the pouch would not absorb

any fluid outside the limits of the pitcher. The PAA was then left to absorb the fluid for 1 hour. Tests were stopped after 1 hour as more time did not change absorption. The gel was weighed before and after to determine the amount of fluid absorbed. Under 20 mmHg of pressure, 5 g of PAA was able to absorb an average of 27.9 ± 2.0 ml, shown in Table 5.3.

Table 5.3 - PAA Absorption Under 20 mmHg Pressure Results.

Trial Number	Pitcher mass (g)	PAA mass (g)	Gel Initial Weight (g)	Gel Final Weight (g)	Fluid Absorbed (ml)
1	2408.54	5.0078	27.4168	52.7735	25.2567
2	2408.54	5.0023	27.2719	55.5390	28.2671
3	2408.54	5.0054	27.6129	57.8236	30.2107

5.5 Wicking Test

A wicking test was next performed on the polyester wicking layer. This is because the polyester wicks both vertically and horizontally. When it wicks vertically, it wicks into the hydrogel, however when it wicks horizontally it wicks into what would be the free space inside the dressing. To prevent this, soft silicone tape was applied around the edges of the layer to keep fluid from moving beyond the edges. To test this, two dressings were made with the 5 g PAA and 25 mL water primer placed inside a polyester pouch. One dressing was sealed along all edges, while the other was sealed along only the long edges. The pouches were laid in shallow weigh boats containing 80 ml mixture with the short edges touching the table, so that wicked mixture would be visible. After 30 minutes, results were observed. Figure 5.3 shows the taped and untaped pouches, as well as the

mixture that wicked to the table from the untaped pouch. There was no horizontal wicking from the taped pouch.

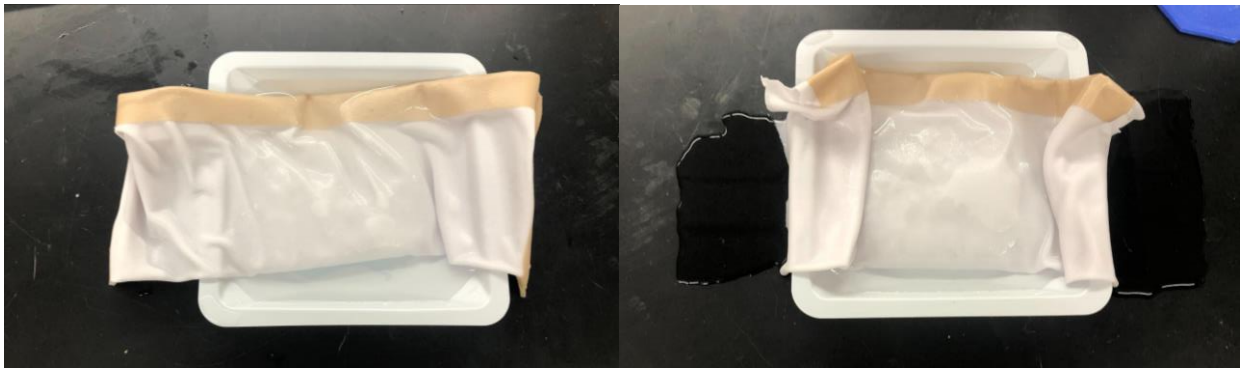

Figure 5.3- Wicking Test Results.

5.6 Tegaderm™ Testing

To compare the dressings' ability to effectively manage exudate production, Tegaderm's™ ability to manage exudate from the donor site model was first tested. To do this, a Tegaderm™ film was applied over the entirety of the donor site, as is commonly done in clinical settings. The time needed for the Tegaderm™ to completely detach from the donor site model was then recorded. This time was then used to determine the amount of exudate that caused the Tegaderm™ to detach based on the results section 5.1. Table 5.4 shows the results of each trial used to measure Tegaderm™ detachment. Detachment was defined as any amount of fluid leaking out of the dressing and into a plastic container situated below the donor site model.

Table 5.4 - Detachment time of Tegaderm™ dressing over multiple trials.

Trial Number	Tegaderm™ Detachment Time (min)	Volume Managed (mL)
1	24	20
2	19	15.8
3	33	27.5

Overall, the Tegaderm™ detached after approximately 21.1 ± 5.9 mL of exudate leaked out of the donor site.

5.7 Prototype Testing

After testing the Tegaderm™ dressing for detachment, the same process was used to test the final prototype of the design. Like section 5.6, the dressing was secured to the donor site model. First, the polyester bag with hydrogel was built and lined with the soft silicone tape. Then, the polyester bag was applied to the donor site model and covered with a Tegaderm™ film. Then, the polyvinyl chloride bag was applied on top, and the elastic bandage was wrapped around the model and secured at the markings created in section 5.2. A pressure of 17.2 mmHg was applied by securing the elastic bandage as stated in section 5.2, wrapping the bandage around the model, and attaching a clip at the specified locations. This pressure was then confirmed by sliding the pressure transducer underneath the prototype and measuring the voltage.

Three separate trials were recorded, with the detachment time, change in mass of the dressing, and volume of fluid collected being measured. Detachment time was again determined by the time until any amount of fluid was released from the dressing and into a plastic collection bin underneath. The mass of the dressing was recorded both before and after the test to measure how much volume of fluid the hydrogel absorbed. The total volume of fluid was also measured at the end

of the test by removing the dressing and collecting any excess fluid that was not absorbed by the dressing. Table 5.5 summarizes these results.

Table 5.5 - Results of pressure dressing experiments. Initial, final, and change in mass were recorded, as well as excess fluid trapped between the dressing and donor site that was not absorbed.

Trial Number	Time to Detachment (mins)	Initial Dressing Mass (g)	Final Dressing Mass (g)	Dressing Change in Mass (g)	Excess Fluid (mL)
1	N/A	44.4985	150.8337	106.3352	50
2	309	42.6266	122.9649	80.3383	77
3	320	42.0148	139.3370	97.3222	49

In trial one of this experiment, the positive pressure dressing never detached over the entire six hour period. In both other trials, the dressing detached after slightly longer than 300 minutes. The average change in mass of the dressings, which is equivalent to the mass of mixture absorbed by the dressing, was 94.7 ± 13.2 mL. In addition, the excess fluid trapped by the dressing was found to be an average of 58.6 ± 15.9 mL. By performing an unpaired T-test between the Tegaderm™ and positive pressure dressing, the results were found to be significantly different ($P<0.001$).

Chapter 6: Final Design and Verification

This project aimed to create a skin graft donor site dressing that effectively managed exudate production in a safe, user-friendly, and cost-effective manner, each of which were key tenets of the work. To ensure the safety of the product, no materials known to be toxic to humans were used. Sodium polyacrylate is the only chemical that could be of concern, however it is currently labeled as "Generally Regarded as Safe (GRAS)" by the FDA. In addition, at no point would sodium polyacrylate meet bodily fluids except ones that have already been removed from the body.

Regarding being user-friendly, this project did not succeed to the highest degree hoped for. The product is complex for the average user and may not be easier to use than current options on the market. Ideally, this product can be simplified to have very easy to follow instructions. In addition, it would ideally be a "set it and forget it" product, where once the patient leaves the clinician's office, they are able to ignore the device until a follow up examination. Due to this, it is possible that this product is more user-friendly than current standards, however this cannot be confirmed with confidence.

For the cost-effectiveness of the product, many portions of the design can be found in normal hospital settings, including elastic bandages and IV bags. The other materials cost less than $4 per unit, making it a relatively cheap and cost-effective option. Most of the cost ($3.36 per unit) is due to the soft silicone tape, making it an option for future research due to its high price. Because this is a single-use product that ideally lasts the entirety of exudate production, it is a viable product to

replace the current options. As for the donor site model, the entire design was created with less than $60 worth of material, making it a cost-effective method to test dressings without the need for human patients.

To test the efficacy of this prototype, a number of tests were performed and analyzed. Each of these tests were outlined and described in previous sections, including the creation of the donor site model (section 5.1), pressure generation (section 5.2), validation tests (sections 5.3-5.5), Tegaderm™ control (section 5.6) and pressure dressing testing (section 5.7).

One important step in data analysis was comparing the exudate management results between the Tegaderm™ and the positive pressure dressing prototype. The values of three separate trials were used to determine if there was a statistically significant difference between Tegaderm™ and this product. To determine the difference, an unpaired T-test was performed and compared to the value necessary to prove statistical significance.

In addition to the initial tenets of this work, it is important to consider a variety of factors based around the impacts of this design. Namely, the economic impacts, societal impacts, environmental impacts, ethical concerns, health and safety issues, manufacturability, and sustainability of the product must be taken into account.

6.1 Economic Impacts

If exudate is not managed within a donor site, or any wound site, the location could suffer severe consequences including the development of a chronic wound. The effects of chronic wounds can have profound economic impacts. Alliance of Wound Care Stakeholders estimated in 2018 that chronic wounds can cost the US upwards of $32 billion, with surgical wounds and infections

accounting for the largest category at around 4%. Through the creation of a skin graft donor site wound dressing, a portion of chronic wounds can be eliminated, saving patients significant healthcare costs.

6.2 Societal Impacts

Our product ideally should have a beneficial effect on society, as it can reduce the amount of visits a patient needs to make to the hospital. By decreasing hospital visits and stays, patients are able to spend more time in the comfort of their homes with loved ones. In addition, this should help alleviate the burden of hospital fees for prolonged stays. By reducing exudate production, patients will also not be under the burden of slow recovery and will not have to see their own medical devices fail them. This can be a disturbing experience for some users, which could hinder the healing process and patient adherence.

6.2 Environmental Impacts

The largest environmental impact this product would affect occurs in the manufacturing process. The materials used, namely polyester, sodium polyacrylate, polyvinyl chloride, and silicone tape will need to be disposed of as biohazardous waste. Biohazardous wastes can have many impacts on the environment, including negative impacts on humans, wildlife, and the surrounding ecosystems. However, through the successful implementation of this product, many environmental impacts could actually be reduced compared to current levels. Current skin graft donor site dressings need to be replaced consistently due to oversaturation, skin maceration, or detachment. Because of this, multiple dressings may be used, each of which must be disposed of as hazardous waste. The implementation of this dressing would ideally reduce the number of dressings to one per wound.

6.3 Ethical Concerns

The medical industry has an obligation to its patients to provide them with the utmost comfort, safety, and best practices to return them to full health. Patients in need of skin grafts deserve comfortable, effective, and safe dressings for donor sites. By creating this product, the group aims to fulfill the ethical obligation to patients placed upon the industry. Standard dressings fail to meet all requirements of health, safety and efficacy, while the product attempts to improve on current best practices.

6.4 Health and Safety Issues

The health and safety of people is a main concern for the project. Patients who need skin grafts require dressings to effectively manage wound exudate. Excess exudate can lead to infection, skin maceration, and dressing detachment. Each of these issues can present serious health complications that could compromise the safety of the patient. By managing donor site exudate, the product aims to reduce any possible negative effects that could result from excess exudate.

6.5 Manufacturability

Our product does not utilize materials that are not already widely available to the public or medical device manufacturers. Due to its simple fabrication method, manufacturability is of little difficulty to any large-scale production or distribution centers. The wound model poses some difficulty in reproducibility due to the unreliability of using needles to make holes in the silicone pad. However, only one standard would be needed to test the effectiveness of a batch, ensuring that manufacturability would not affect batch to batch variability.

6.6 Sustainability

The largest effect on sustainability from this project stems from the fact that the dressing is single-use and must be discarded in biohazard waste once it has been used. While this may seem like a waste, it is still a better option than current best clinical practices. Current dressings are also single-use and must be discarded, however due to high failure rates more dressings are used to begin with. Thus, while the product is still single-use and must be dealt with post-operation, the ability to effectively manage exudate over the entire period of high exudate production should improve the sustainability of the skin graft donor site dressing market.

Chapter 7: Discussion

This project aimed to create a wound dressing capable of reducing the flow of exudate from skin graft donor sites in inpatient and outpatient clinical settings. Based on previous experiments from Dr. Jorge Lujan of UMass Medical School, the average donor site of approximately 72 cm^2 produces exudate at a rate of 300 cm^3 over the first five days post-operation, or 60 cm^3 per day (Lujan, 2020). As wound healing progresses, exudate production decreases significantly (Tickle, 2013). Because of this, the first five days post-operation were simulated by measuring the time needed to produce 300 cm^3 of exudate.

7.1 Donor Site Model System

Upon arriving at the final design of the Donor Site Model System, it was found that by puncturing ten holes with an 18-gauge needle in the tattoo practice pad, consistent exudate production could be produced. Over a period of six hours, 300 cm^3 of exudate was produced in multiple trials. This fluid production effectively modeled the exudate production of donor sites over the first five days, allowing for multiple tests to be run to compare the dressings with the current standard of care, Tegaderm™.

In creating the model, many issues were run into that should be updated in further research. Firstly, if the model exudate, which was a 1.0:2.4 mixture by volume of glycerin to water, was left exposed to air for too long, mold would grow inside the exudate which produced a variety of problems. For example, the initial model produced a rate of exudate production of 300 cm^3 over a period of 60 hours. However, when the glycerin and water mixture was left in the model system for this long without consistent mixing, mold grew on the interior surface of the tattoo practice pad and

stopped flow out of the holes. Figure 7.1 shows an image of the mold that was discovered inside the donor site model.

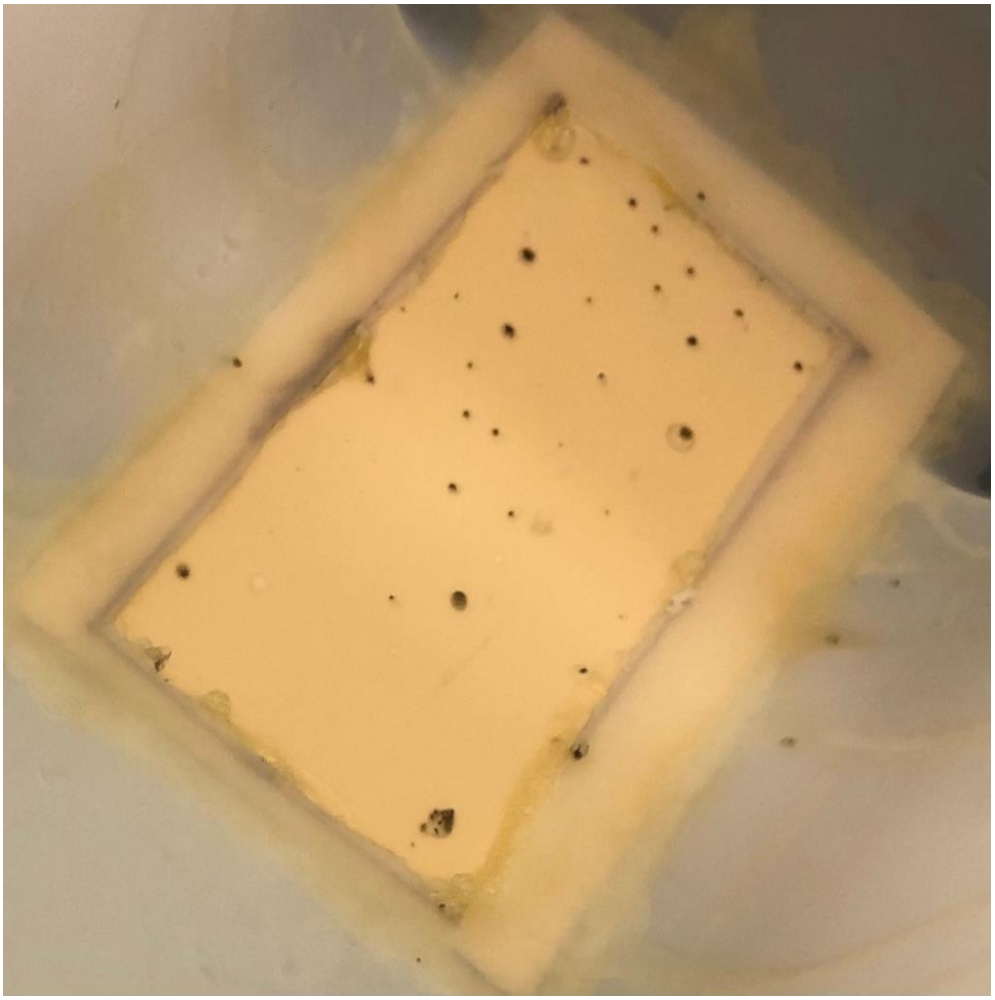

Figure 7.1 - Image of mold growing on interior side of tattoo practice pad due to prolonged exposure of glycerin and water mixture to ambient air.

To remedy this issue, further research should be done to replace the model exudate with a non-carbon-based mixture. Because glycerin is a sugar, it provides a source of carbon for the mold to grow inside the donor site model. Instead, a highly viscous substitute should be used that can be combined with water to produce a similar viscosity to that of the model exudate, which was around 2.5 cP with a density within 1.08-1.11 g/cm^3.

7.2 Disposable Drainage Dressing

Initially, the goal was to create a dressing to cover the donor site and allow for the drainage of exudate into a disposable pouch. A stop valve would prevent the fluid from draining out when the bag was not attached, and a vacuum ball attached to the Penrose tubing would allow for drainage when the bag was attached. However, throughout the course of the prototyping and design phase, it was found unable to form a proper seal between the Penrose tubing and the dressing covering. Immediately as testing began, exudate could be seen leaking out of the "sealed" edges of the Penrose tubing. Super glue, waterproof spray sealant, and a combination of the two were used to improve the seal, but to no avail.

The price of the individual pieces of the product, as well, were likely to result in a much higher product cost than the currently available options. In addition, concerns were raised about the ease of use for patients in outpatient settings, as they would need to drain the dressings and remove their disposable bags on their own. This could pose issues if patients are uncomfortable doing so, or if there was a small failure in the dressing itself. Since cost-consciousness and ease-of-use was a part of the initial and final client statement, it was determined that while the drainage dressing was a novel idea that should be explored further, it should be eliminated from the final design process of the project.

To continue with research into the possibility of a disposable drainage dressing, there are two main issues that need to be addressed. Firstly, a proper and sufficient seal must be created between the Penrose tubing and the dressing itself. Without a complete seal, the dressing is inefficient and is less effective than currently available options. Secondly, the raw materials and manufacturing costs must be lowered to ensure the product is able to reach as large a market as possible.

7.3 Positive Pressure Wound Therapy

Unlike the disposable drainage dressing design, success was found in the approach utilizing positive pressure to reduce the flow of exudate out of a skin graft donor site model. The design of the prototype, as explained in earlier sections, involved using a hydrophobic microknit polyester fabric to wick fluid upwards and away from the donor site. Enclosed in this polyester bag was five grams of sodium polyacrylate, a hydrogel which is known to be capable of absorbing up to 1000 times its original weight in liquid (21CFR173.73, 2022). The edges of the polyester fabric were surrounded and sealed with soft silicone tape, which was found to be able to prevent fluid from wicking horizontally towards the edges of the fabric. This ensured the fluid taken up by the dressing traveled through the polyester and interacted with the enclosed sodium polyacrylate.

The polyester bag was created to hang over the edges of the donor site by approximately one centimeter in each direction. A Tegaderm™ film was applied over the polyester bag as a precaution to keep exudate contained within. Over this, the inflated polyvinyl chloride bag was attached and secured with an elastic bandage. Markings on the elastic bandage were used to indicate the location needed to produce a pressure of at least 15 mmHg. For each trial, a pressure of 17.2 mmHg was produced, which was slightly greater than the 15 mmHg intended. Greater pressure should only aid in decreasing exudate production, so 17.2 mmHg was found to be an acceptable value.

Ideally, the prototype serves to effectively manage donor site exudate through two methods: reduction of total exudate production through the use of positive pressure, and absorption of all exudate by sodium polyacrylate. To measure the effectiveness of the positive pressure dressing, it is necessary to compare the exudate management results to the results from Tegaderm™, the current best practice on the market.

In all three trials of the Tegaderm™, the film detached from the model within less than 35 minutes of testing. On average, the Tegaderm™ remained attached for 25.3 ± 7.1 minutes. Based on the flow rate of the model system, this corresponds to approximately 21.1 ± 5.9 mL of exudate production. Essentially, the Tegaderm™ was overwhelmed by slightly over 21 mL of exudate, synonymous with the first day post-dressing placement in a patient.

In comparison, the positive pressure dressing was capable of remaining attached for at least 309 minutes in all three trials. In one trial, the dressing remained attached for the duration of the entire trial, effectively managing exudate for the entirety of the test. On average, the dressings absorbed 94.6 ± 13.2 mL of model exudate while trapping another 58.7 ± 15.9 mL of fluid. In total, the dressings managed an average of 153.3 ± 6.1 mL of exudate per dressing. This value is obtained by adding the absorbed exudate (change in mass of dressing) and the excess exudate (exudate trapped in dressing but not absorbed), as represents the total exudate the dressing could prevent from leaking.

By comparing the total amount of exudate managed and using an unpaired T test, this data was found to be statistically significant ($P < 0.001$). While these values were found to be significant, there is some concern with the high variation within the positive pressure dressing. There was a large range for both the amount of exudate absorbed (123.0 mL - 150.8 mL, range = 27.8 mL) as well as the excess exudate (49 - 77 mL, range = 28 mL). What this suggests is a possible inconsistency in the way the sodium polyacrylate is able to absorb the exudate. However, even when performing an unpaired T-test between the amount of exudate absorbed by the positive pressure dressing and exudate managed by Tegaderm™ ($P = 0.0013$) and between the excess exudate and exudate

managed by Tegaderm™ ($P = 0.0294$), the results are still found to be statistically significant ($P < 0.05$).

To determine the amount of exudate produced in comparison to the expected values, it is possible to compare the total exudate managed with the values expected to be produced over the period the dressing remained attached. For example, attachment for 300 minutes is equivalent to managing 250 mL of exudate, as 300 minutes is 83.3% of the total time (360 minutes) to exude 300 mL of fluid. Based on this, trial 1, 2, and 3 would be expected to produce 300 mL, 257.5 mL, and 266.6 mL of exudate, respectively, or an average of 274.7 ± 22.4 mL of exudate. Instead, trial 1, 2 and 3 produced a total of 156.3, 157.3, 146.3 mL of exudate, respectively, or an average of 153.3 ± 6.1 mL. This means that the positive pressure dressing reduced exudate production by an average of 121.4 ± 23.2 mL, or around 40.5% of the total exudate expected over the first five days post-operation.

Based on these results, it can be concluded that positive pressure therapy appears to be a novel and effective approach to exudate management of skin graft donor sites. For the positive pressure dressing prototype created, it appears to significantly reduce exudate production and improve exudate management. The model system created here is an effective method to test possible prototypes when human patients are inaccessible and can provide valuable insight into the effects different dressings can have on patients.

Chapter 8: Conclusions and Recommendations

After completion of the project, there is still a large need for a dressing for skin grafts that is cost effective and low maintenance. Although, there was success in developing a model that replicated the production and flow rate of wound exudate in skin graft donor sites. In addition, positive pressure therapy is a novel treatment for exudate management and has shown promising initial results in the experiments previously outlined.

If the project were to be continued there are a few recommendations for better success. The first is in regard to the positive pressure aspect of the final design. It would be beneficial to investigate different amounts of pressure to find the optimal amount of pressure that will keep wound exudate flow at its lowest, while not harming the patient with pressure that is too high. There were also issues with glycerin-water mixture leaking out of the Tegaderm™ dressing in the donor site model. Even with the limited exudate flow and absorption into the sodium polyacrylate, the Tegaderm™ still leaked. So there must be other methods to manage leaking from the dressing. Another complication that should be avoided in the testing phase would be to avoid using glycerin. When the system was left running for too long there would be a buildup of mold on the dressing due to the sugar in glycerin. A recommendation would be to use a different solution that has approximately the same viscosity as exudate. If glycerin was to continue to be used, a wound model setup with a magnetic stir bar may help prevent the buildup of mold. This would allow the glycerin mixture to maintain movement which may reduce the chance of mold building up. Also, further

research should be done on the concept and effects of positive pressure, since it is not studied and is a slightly novel topic, and the project did not cover all possibilities of solutions incorporating positive pressure. Overall, it would also be beneficial to decrease the overall cost of the final design of the dressing.

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