ABSTRACT

NAKOD, PINAKI. The Development of a Textile Wound Dressing for Vacuum Assisted Wound Therapy. (Under the direction of Dr. Martin W. King).

The use of vacuum assisted closure (VAC) or negative pressure wound therapy (NPWT) has become a preferred treatment for various wounds such as burn injuries, skin grafts, diabetic ulcers, pressure ulcers, thoracic and abdominal injuries as well as fasciotomy wounds. This technique involves the application of a suction pressure of about 125 mm Hg under ambient conditions through the medium of an open-cell foam or filler material. This filler, usually a 1 inch thick polyurethane foam, ensures the uniform distribution of pressure, and protects the wound from physical tissue trauma and necrosis. But, in cases such as the treatment of diabetic foot ulcers, folding the foam over the toes is difficult due to its high flexural rigidity and limited ability to bend. Also, some clinical studies have reported complications due to the growth and infiltration of granulation tissue into the foam, which leads to wound trauma at the time of dressing removal and retention of foam pieces in the wound bed. To overcome such complications, this research proposes to replace the filler material in VAC with a knitted textile spacer fabric, which has superior compression resistance, increased flexibility, high porosity and excellent liquid adsorption capacity. Based on the perceived requirements of VAC wound dressings, prototype polyester (PET) spacer fabrics are being compared to demonstrate their superior performance over commercially available polyurethane foams. Properties of all the prototype and control samples, such as tensile strength and elongation, compression resistance, total porosity, pore size distribution, flexural rigidity, liquid adsorption and retention capacity, have been evaluated to determine the validity of the hypothesis. It was found that the spacer fabrics have superior contractional characteristics, physical and mechanical properties as compared to the existing commercial product and thus could help in increasing the efficiency
of the vacuum assisted wound therapy. Thus, the use of spacer fabric will not only overcome the shortcomings of the existing product but will also enhance the efficiency of wound healing.
The Development of a Textile Wound Dressing for Vacuum Assisted Wound Therapy

by
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A thesis submitted to the Graduate Faculty of North Carolina State University in partial fulfillment of the requirements for the degree of Master of Science

Textile Engineering

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DEDICATION

To my beloved parents and friends.

To my advisor, Dr. Martin W. King
BIOGRAPHY

Pinaki Nakod was born in Maharashtra, India. She graduated from Veermata Jijabai Technological Institute with a degree of Bachelor of Technology in Textile Technology (2015). After graduation, she joined North Carolina State University in August 2015 to pursue a degree of Master of Science in Textile Engineering.
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CHAPTER 1. INTRODUCTION

Skin is the largest human organ that protects the body from various environmental physical, chemical and biological stresses. When the skin is injured, its ability to protect the body from the environmental factors is affected negatively. Amongst all the factors, burn wounds are one of the leading causes of accidental injuries around the world. Treating the burn wounds using donor site grafts is one of the most popular procedures. Skin grafting is done when a large area of the body that is damaged needs the cover of new skin to heal properly. Autografting is harvesting skin from another part of the body (donor site) to transplant it to the wounded area (recipient site). Autografts are one of the most commonly used grafting methods as they minimize the risk of graft rejection and other complications. When the skin is harvested, donor site injury occurs at that site. It is very important to protect this donor site wound from infection and physical damage. Unfortunately, there is no proper procedure designed to specifically treat the donor site wounds. Sometimes, these wounds are treated in the same way as the burn injuries despite the differences in the wound etiology. Often the donor site wounds are much more painful and produce more exudate as compared to the burn wounds. Donor site injuries are large open wounds. All such factors must be taken into consideration while treating the donor site injuries.

In the literature, the management and care procedure for such wounds are not been well documented. Some of the researchers have mentioned the use of vacuum assisted wound therapy, also known as negative pressure wound therapy (NPWT) or vacuum assisted closure (VAC), for the treatment of the donor site wounds. NPWT or VAC is based on the
basic principle of application of sub-atmospheric pressure in a controlled and uniform manner around the wound area to accelerate the process of wound healing. VAC has been proved to be successful in treating various injuries like burn injuries, surgical grafting, diabetic ulcers, pressure ulcers, thoracic and abdominal injuries, soft tissue injuries, deep infected injuries, chronic open injuries as well as fasciotomy wounds.

One of the more important factors responsible for the satisfactory function of the VAC is the foam used. The performance of the foam depends on various properties, such as wet tensile strength, compression resistance, porosity, liquid absorption/retention capacity, bending resistance and antibacterial performance. It has been observed clinically that due to the low tensile strength, it becomes difficult to remove the foam in an intact form. This can result in painful dressing changes. Also, if the porosity is too high, it can give rise to ingrowth of granulation tissue into the foam. When the dressing is changed, it disturbs the newly formed granulation tissue, thus hindering the process of healing and increasing the pain. Some cases are reported in which the particles of foam retained in the wound lead to serious complications and cytotoxicity. Another major concern is the flexibility of the foam. Usually donor sites are selected such that the injury or the scars can’t be seen. Some of the more common sites for VAC include the abdomen, diabetic foot and toes, sternum, heel, leg ulcer, Achilles tendon and bone. And because of the limitation in bending, it is difficult to use a less flexible foam to cover such parts. This in turn affects the appropriate application of vacuum pressure and the ease and speed of healing. Some manufacturers, like Mepilex, have designed foams for difficult anatomical locations like the heel or sacrum.
to ensure proper coverage of the wound bed and more even distribution of pressure. Instead of designing the foams for different locations and restricting the versatility, there is a need to create a dressing material that can provide enough flexibility to be used for all cases.

Spacer fabrics are 3D textile structures with two outer layers of fabric and a third inner spacer layer. Since, all three layers are knitted independently, distinct characteristics can be incorporated into the spacer fabric by modifying the machine parameters for each layer. Warp knitted spacer fabrics show unique characteristics such as a 3-dimensional structure, a high level of porosity, high compression resistance, good flexibility, uniform pore distribution, good tensile strength, superior fluid handling capacity and rapid fluid uptake. On account of these properties, spacer fabrics may serve as an alternative candidate to foam for use as a dressing material during vacuum assisted closure (VAC).

1.1 Aims and Objectives

The main aim of this interdisciplinary research is to evaluate the potential of using a spacer fabric as the dressing material in vacuum assisted wound therapy. In order to demonstrate the performance and functionality of this structure, it was proposed to use a range of analytical techniques to evaluate the architecture and structure as well as the physical and mechanical aspects.

To achieve this main aim, the three specific objectives mentioned below have been developed.
1. To successfully select an appropriate spacer fabric that has equivalent or superior properties to the current commercial foam dressing.

2. To determine whether or not the structural parameters and physical properties of the selected spacer fabric material are equivalent or superior to the existing foam product.

3. To determine whether or not the mechanical and moisture management properties of the selected spacer fabric material are equivalent or superior to the existing foam product.

1.2 Experimental Design and Sequence of Steps

In order to evaluate these three objectives, the following steps have been undertaken to complete the experimental study.

1.2.1 The general performance requirements of dressings used for vacuum assisted therapy, such as the constructional characteristics, the physical and mechanical properties have been discussed.

1.2.2 Any material problems associated with the current VAC product have been identified and the selection of more appropriate materials to overcome these problems have been proposed.

1.2.3 A practical plan for this experimental study has been created and the structure of the material candidates has been defined.

1.2.4 To analyze the surface morphology and measure the total porosity of the existing foam material and the proposed spacer fabric candidates.
1.2.5 To evaluate the impact of key constructional parameters on the physical properties of the existing foam material and the proposed spacer fabric candidates.

1.2.6 To determine the constructional characteristics and cross-sectional views of the existing and proposed materials using scanning electron microscopy and an image analysis system.

1.2.7 To measure the mechanical properties of the existing and proposed wound dressing materials, including the tensile strength under dry and wet conditions, the compression modulus and flexural rigidity.

1.2.8 To determine the moisture related properties of the existing and proposed wound dressing materials including the liquid absorption rate and liquid retention capacity over time.

1.3 Outline of Thesis

This thesis is organized into five chapters. The Chapter 1 describes the motivation and significance of this research for developing a textile wound dressing for vacuum assisted wound therapy. Aims, specific objectives and the steps to be followed in the experimental design are listed. Chapter 2 reviews the important literature that describes wound etiology, the need for wound dressings, vacuum assisted wound therapy, commercially available dressings and the design and structure of textile spacer fabric. The selected materials for this study are highlighted and discussed in detail. Chapter 3 describes the experimental design including the materials and methods used to observe the surface morphologies and test the mechanical
properties and the liquid interactions of the selected materials. Chapter 4 reports the results and includes a discussion of the findings from the characterization of the spacer fabric and foam samples as well as their mechanical and moisture interactive performance. Lastly, Chapter 5 gives a summary of the findings and conclusions, and lists recommendations for future work.
CHAPTER 2. REVIEW OF LITERATURE

2.1 Need for wound dressings

2.1.1 Issues related to burn injuries

Burn injuries are one of the leading causes of accidental injuries worldwide. More than 300,000 people die every year due to fire related injuries and many are severely injured and permanently disabled (Tropy et al., 2009). Burns are classified into four classes depending on the extent of the skin’s thickness involved.

Table 2.1.1 Degree of burn and skin layers damaged

<table>
<thead>
<tr>
<th>Degree of burn</th>
<th>Layers damaged</th>
<th>Signs</th>
<th>Loss of function</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-degree</td>
<td>Superficial-Epidermis</td>
<td>Redness, pain, dryness and no blisters.</td>
<td>Rarely long term tissue damage, changes in the skin color.</td>
</tr>
<tr>
<td>Second-degree</td>
<td>Partial thickness- epidermis and part of dermis.</td>
<td>Redness, blisters, swelling, greater level of pain, papillary dermis layer exposed.</td>
<td>Scarring can occur in some cases.</td>
</tr>
<tr>
<td>Third-degree</td>
<td>Full thickness- complete destruction of epidermis and dermis.</td>
<td>Pain levels minimized as the nerves are damaged.</td>
<td>Healing is very difficult and requires a long time. Can lead to shock and ultimately to death. Chances of infection are very high.</td>
</tr>
<tr>
<td>Fourth-degree</td>
<td>Complete destruction of skin layers. Bones, muscles and tendons are also burnt.</td>
<td>Burn site is charred.</td>
<td>Loss of feeling in that region due to destruction of nerve endings.</td>
</tr>
</tbody>
</table>
Most patients with more than 20 percent burns to their total body surface area (TBSA) require surgical treatment like donor site grafts, skin flaps or the use of tissue engineered products. One of the commonly used methods to treat burn injuries is by skin grafting. This is done by sectioning epidermis and dermis from a donor site on the patient's body in a way that it is completely separated from its blood supply. It can then be transplanted to another area of the body called the patient's recipient site. Such surgical procedures create another type of injury known as a donor site wound.
Xenografts, like bovine grafts, or allografts from other human donors, can result in complications such as a negative immune response and the possibility of rejection. This can be avoided by using an autologous skin graft from the same patient, which is easily accessible. Thus, autologous skin grafts are one of the best surgical options to treat burn injuries. There are two types of skin grafts: the partial thickness graft and the full thickness graft. The former is the more common type in which 95 to 100% of the epidermal layer is removed; whereas the full thickness skin graft involves complete removal of the epidermal layer along with part of the dermal layer from the patient's donor site (Andreassi et al., 2005). Usually anatomical sites such as the waist, thighs, buttock, back, chest, calf, forearm or upper arm are selected as donor sites because of their high fat storage as compared to other parts of the body. Some of the common donor sites for full thickness skin grafts are the pre- and post-auricular, supraclavicular and antecubital areas, upper eyelid, scalp, groin and areola (Beldon, 2007). Sites where the surgical scar can be easily hidden are usually selected as donor sites. The etiology of donor site wounds is different from that of burn wounds in terms of pain, blood loss and microbial growth. So the donor site wound requires a specific healing regime when all these factors need to be taken into consideration.

<table>
<thead>
<tr>
<th>Name</th>
<th>Thickness (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Split thickness</strong></td>
<td></td>
</tr>
<tr>
<td>Thin (Thiersch-Ollier)</td>
<td>0.15-0.3</td>
</tr>
<tr>
<td>Intermediate (Blair-Brown)</td>
<td>0.3-0.45</td>
</tr>
<tr>
<td>Thick (Padgett)</td>
<td>0.45-0.6</td>
</tr>
<tr>
<td><strong>Full thickness</strong></td>
<td></td>
</tr>
<tr>
<td>(Wolfe-Krause)</td>
<td>&gt;0.6</td>
</tr>
</tbody>
</table>
2.1.2 Donor site wound etiology

2.1.2.1 Healing

Donor site healing occurs through the process of re-epithelialization. In this, the epithelial cells remaining in the reticular dermis migrate from the remnants of hair follicles, sweat and sebaceous glands and spread across the wound bed to re-establish a basal layer. The time required for healing depends on factors like age, gender and the nutritional status of the patient. Normally re-epithelialization occurs in 7-10 days, during which moderate to heavy exudate levels are observed in the first 3-4 days. There are two phases involved in the healing of a donor site wound. First is the wet phase in which excessive exudate is produced and the dry phase when the exudate levels decrease dramatically leaving the wound bed dry (Beldon, 2007). The expected complete healing time of the donor site wound ranges from 7 to 42 days (Geary et al., 2009).

2.1.2.2 Pain

The most frequent complaint of patients with burn injuries is pain. The pain and discomfort associated with donor sites is substantially more painful than the pain associated with the grafted site. This pain is 6 to 10 times greater than the pain associated with the original burn injury (Summer et al., 2007). Donor site wounds result in the exposure of sensory nerve endings in the case of split thickness grafts, which are thus more painful and uncomfortable in comparison with the burn injuries. Split thickness grafts usually cause blisters due to edema, and they are moist in nature. (Myers et al., 2004). The pain experienced is lower in the case of full thickness grafts because of the removal of nerve endings.
2.1.2.3 Absorption rate

If the exudate absorption rate is high, it leaves the wound dry, which hampers the process of healing. Conversely, when the rate of absorption is low, it causes the exudate to accumulate, and this increases the chances of infection and delays the process of healing. The dressing or the foam should be designed in a way that it absorbs the exudate and locks the fluid within its structure, thereby leaving a moist, but not wet, wound environment, which is preferred for optimal wound healing. Woven, knitted or nonwoven dressings made of cotton rapidly absorb the wound exudate and leave the wound dry, thus impairing the process of healing.

2.1.2.4 pH

Both, the split thickness skin graft and the full thickness skin graft result in exposing the remaining skin tissue to the environment. Human skin routinely has a slightly acidic pH and attains a basic pH when the skin is not cleansed. An acidic pH between 4.5 to 6 helps in preventing the growth of microflora and the survival of micro-organisms, whereas a basic pH encourages the growth and survival of bacteria (Schneider et al., 2007).

2.1.2.5 Bacterial susceptibility

Bacterial colonization is another major challenge in the case of the donor site wounds. The ability to protect against infections caused by bacteria is lost in the case of third degree burns and deep skin wounds. Also, the nerve endings are exposed in the case of donor site wounds. Bacterial infection in such cases hinders the process of healing thereby increasing the pain. Bacterial activity can result in the secretion of harmful cytokines that cause vasoconstriction and decreased blood flow to the wound area thus delaying wound healing (Gabriel et al., 2006).
Therefore, it is important to protect the wound against bacteria and microflora. Metallic ions such as silver, copper and zinc are used to limit bacterial infection due to their bactericidal activity. However, the optimum amount of these metallic ions should be used because excessive amounts result in leaching from the dressing, causing wound toxicity and incomplete wound healing (Samberg et al., 2010).

2.1.2.6 Anatomy

Generally elliptical, round or triangular grafts are harvested from the donor site. In the case of split skin grafts, so as to ensure better closure of the wound together with enhanced contraction and overall healing of the tissue, the skin wounds take on an elliptical shape due to the state of tension that exists in the skin (Armitage et al., 2011). For a full skin graft, wound staples or sutures are used to ensure closure to prevent infection. The removal of these staples and sutures after healing is observed to be painful.

2.1.3 Management of donor site wounds

The proper management and care procedure for donor site wounds has not yet been established. Donor site wounds are sometimes treated like burn injuries, but efficient and complete healing is not always achieved due to the difference in the etiology of the donor site wound and the burn injury wound. Using the appropriate dressing or foam is necessary to minimize the level of discomfort or pain for the patient. It is expected that the removal of the foam or dressing should not cause pain to the patient or trauma to the wound site. There is no common dressing which can be applied to the donor site and left in situ because of the variability in patients in
terms of their age, sex, skin texture, site of wound and other factors (Beldon, 2007). Ideally, the foam or the dressing should not dry out the wound bed or adhere to it, as this will promote the process of healing along with its less painful removal. The material should be non-allergenic, non-adherent and should have an antimicrobial action. Foam dressings are being used in the management of wound dressings as they absorb excess exudate and are less adherent to the wound bed. Foam dressings that are prepared with ionic silver particles also render an anti-microbial action. Also, the dressing is expected to last for at least 7 days, thus reducing the numbers of dressing changes per week.

2.1.3.1 Dressing requirements for donor site wounds

The dressings are expected to be non-allergenic, non-adherent and should provide resistance against bacterial infiltration. The dressing should not give rise to any negative immune responses or severe foreign body reactions. Usually this phenomenon of negative immune responses occurs in the case of xenografts or allogenic grafts obtained from other human donors. This risk can be minimized using autografts, thus reducing the possibility of rejection of the graft. Also, the dressings that adhere to the wound bed make the process of dressing changes extremely painful and traumatic. To avoid this, currently xenografts are subjected to crosslinking before grafting them to the recipient site (Courtman et al., 2001). A dressing should not only resist adhesion to the wound bed but also to the surrounding skin to facilitate easy removal. As the depth of the skin graft removed is more in the case of full thickness grafts, nerve endings in the tissue layer are exposed to the environment. In cases of minor injuries, keratinocytes provide protection against bacteria, but in the case of deeper injuries this ability
to provide protection is lost (Falabella et al., 2005). Donor site wounds are susceptible to bacterial growth, and this is one of the major concerns. Thus, metallic ions such as silver, copper and zinc are used in the dressings because of their bactericidal action. Some dressing, for example made from cotton, have a high absorption rate that leave the wound bed dry, thus delaying the process of wound healing. Too much exudate can serve as an attractive site for bacteria and microflora, thus giving rise to infections. Therefore, optimal moist conditions should be maintained so as to achieve satisfactory healing in a shorter duration of time. A dressing should therefore absorb the excess exudate but leave the wound moist enough to obtain optimum healing. Also, the role of pH on wound healing should be considered while designing a dressing. A slightly acidic pH prevents bacterial growth and promotes cell growth and proliferation. All these factors along with the donor site wound etiology should be taken into consideration when designing a donor site wound dressing.

### 2.2 Wound dressings

The structure and properties of wound dressings have advanced over the years. In the ancient times, the only purpose of a wound dressing was to cover the wounds surface whereas nowadays wound dressings are manufactured in a way that they can perform extraordinary functions that are beneficial to the process of wound healing. This can be achieved by modifying the structures of the wound dressings or by using fibers that inherently enhance wound healing. Special properties can be imparted to the wound dressings by addition of bioactive ingredients like antibacterial, antimicrobial or anti-inflammatory agents. Thus,
dressings serve many purposes depending on the type of injury, position and severity. Some of the most common functions of dressings are to protect the wound area from infection due to microbial action, to stop the bleeding and thereby promote clotting, wound debridement, absorb the exudate and provide an environment beneficial for the wound healing.

2.2.1 Factors influencing selection of wound dressings

Some of the factors that influence the selection of a wound dressing involve the clinical characteristics like the location, size and depth of the wound, the level of pain, dryness and amount of exudate, presence of infection and stage of wound healing. The selection of a wound dressing is also dependent on the wound etiology. Different types of dressings are used for different types of tissues like necrotic, granulation, sloughing and epithelializing. Some of other factors that are considered while selecting a wound dressing are the rehydration properties, exudate absorption capacity, ability to provide a moist environment to promote granulation and thereby accelerate wound healing. Modern dressings not only protect the wound bed, but also contain various active compounds that promote wound healing.

2.2.2 Classification of wound dressings

Wound dressings can be classified based on different selection parameters. In ancient times, materials like honey, animal fat and vegetable fibers were used as dressing materials. In recent years, continuous developments have led to much advanced dressings made from synthetic fibers that can also exhibit unique and novel functions (Zahedi et al., 2010). Traditionally wet-to-dry dressings were used, but now dressings that can provide a moist environment around
the wound area are used as this condition is believed to promote rapid and optimum healing. The moist environment promotes the process of healing by increasing the rate of epithelialization and promotes other phases of wound healing such as the inflammatory phase (Jones et al., 2006). Zahedi et al., have classified the dressings into three types: passive, interactive and bioactive.

2.2.2.1 Passive dressings

Passive dressings such as cotton gauze and tulle serve the basic function of covering the wound surface to protect it. Gauze dressings are in the form of bandage rolls, sponges or stockings for minor wounds and their dressing changes can be extremely painful as they disrupt the wound bed on removal. Tulle has a greasy structure due to the addition of petroleum jelly, soft paraffin or chlorhexidine (Jones et al., 2006), and thus does not adhere to the wound surface. These non-adherent dressings are suitable for treating shallow wounds.

Figure 2.2.2.1 Passive dressings- Gauze (left) and Tulle (right). (McKesson, 2017; Jelonet, 2017)
2.2.2.2 Interactive dressings

The interactive type of dressings includes semi-permeable films, semi-permeable foams and amorphous hydrogels. These wound dressings are usually made of polymers and are permeable to oxygen and water vapor. Semipermeable films consist of sterile plastic sheets of polyurethane coated with acrylic adhesive and are usually transparent. Tegaderm manufactures films to treat shallow wounds with low exudate. Opsite by Smith and Nephew produces semipermeable acrylic adhesive films that are mainly used for the protection of donor site and burn wounds. A common problem associated with films or meshes is the moisture vapor transport rate is either very high or very low which leads either to dryness or infection respectively (Wiechula et al., 2003). Semipermeable foams have an open-cell structure, which is soft and hydrophobic. They are designed for deeper wounds with higher exudate levels. Kendall and Allevyn manufacture polyurethane foams that are 6-8mm thick for treating deeper injuries. Amorphous hydrogels are non-crosslinked structures that are applied to necrotic wound beds to remove of dead tissue and encourage rehydration. An example of an amorphous hydrogel is Intrasite, which is used for wounds with moderate to heavy exudate levels.

Figure 2.2.2.2 Interactive dressings- Semipermeable film (left), Semipermeable foam (middle), Amorphous hydrogel (right). (Transparent film, 2017; Suprasorb, 2017; IntraSite, 2017)
2.2.2.3 Bioactive dressings

The third type is a bioactive wound dressing that can be also be referred to as an active wound dressings. They modify the chemical environment around the wound area to enhance the process of healing. They have many advantages compared to conventional dressings. For example, they can be manufactured using biopolymers like alginate, hyaluronic acid, collagen, elastin and containing active ingredients like antimicrobial agents to provide protection against microbial activity. Also, antibiotics like gentamicin, ofloxacin and minocycline can be applied to different dressing materials. Some of the types of bioactive dressings include hydrocolloids, alginates, hydrofibers and collagen. Hydrocolloid dressings consist of gel forming agents, such as sodium carboxymethylcellulose (NaCMC) and gelatin (Guide, C.S.I. ‘healthy skin’). They absorb the wound exudate and form a gel. It is waterproof, adheres well to the wound site and can be used for burn injuries and clean, granulating and necrotic wounds with low to moderate exudate. Some of the manufacturers of hydrocolloid dressings are CombiDERM, DuoDERM, Tegasorb and Alione. Alginates consist of calcium and sodium salts of alginic acid found in phaeophyceae, a form of brown seaweed (Jones et al., 2006). Usually the dressings are in the form of a fibrous fleece with the sodium and calcium salts in a 80:20 ratio. These are suitable for heavily exuding wounds and they need to be changed daily. Some of the manufacturers of alginate dressings are Kaltostst, Algisite and Melgisorb. Alginate dressings are used for treating venous and arterial ulcers, and pressure ulcers in the third and fourth stages. Hydrofiber dressings are in the form of a soft nonwoven pad made from sodium carboxymethylcellulose fibers. Aquacel and Intrasite manufacture hydrofiber dressings that
can be used for necrotic and packing wounds that have minimum exudate levels. Collagen dressings are manufactured in the form of pads or particles that can enhance the formation of collagen in the wound bed and provide a moist environment for optimal healing.

Figure 2.2.2.3 Bioactive dressings- Hydrocolloids, Alginates, Collagen, Hydrofibers (from left to right). (McKesson, 2017; Alginate, 2017; Kollagen, 2017; Aquacel; 2017)

2.2.3 Other dressings

Smith & Nephew, Medline, Coloplast and others provide dressings with antimicrobial agents like silver and iodine (Ovington et al, 2007). Some of the other dressings that are available on the market are silicone dressings, odor absorbing dressings and dressings with medical grade honey. Hydrofiber Aquacel Silver dressings by Convatec have been found to efficiently treat burns, skin graft wounds, pressure ulcers, diabetic wounds and other injuries. The silver is found to reduce the bacterial burden and prolong the inflammation of burn wounds (Coutts et al., 2005). Therabond dressings use spacer fabric structures to heal ulcers and burn wound injuries but their removal is very traumatic. Thus, the type of dressing is also selected based on product factors like antibacterial activity, ease of use, volume of dressing, flexibility, conformability, liquid absorption capacity, ease of removal and fluid locking properties along with the promotion of faster healing.
2.2.4 Treating donor site wounds

It has been reported that Integra, Tegaderm, Adaptic, EZDerm and Xeroflo have all been used to treat split thickness skin grafts (Rahim Jindani, 2013). To keep the wound moist and protected from microbial action, antimicrobial agents, such as zinc and neomycin, are included in the dressings. The anatomy of the skin being harvested for skin grafting plays an important role (Reed et al., 1995). Other than the wound etiology, the other factors that need to be considered are age, gender and demographics (Gambichler et al., 2006). Flabella et al., have reported that skin is usually grafted from the waist region in men and the thighs and hips in the case of women, as fat content is generally higher in these parts. Also, the literature has reported that wounds heal better and fewer complications are observed when the wound area is kept moist. Antimicrobial agents in wound dressings are found to provide the donor sites an effective protection by minimizing the bacterial burden. Wainwright et al., have reported that an Integra dressing with a cross-linked matrix is as effective for treating burn wounds as it is for full and partial thickness donor site wounds.

2.3 Vacuum Assisted Closure

2.3.1 Introduction

This technique involves the insertion of an open-cell structure like a foam or gauze into the wound, and then a wound drain with lateral perforations is laid on it and is connected to a vacuum source. The wound is then subjected to an optimum suction pressure of around 125 mmHg below ambient (negative pressure) and this ensures that the exudate or the blood is
drawn efficiently from the wound and collected in a canister. To ensure that the partial vacuum is properly maintained, the foam or gauze dressing is covered with a thin transparent adhesive drape. This drape or membrane is sealed to the surrounding skin so as to prevent the entry of surrounding air which helps in exudate removal. The open-cell foam ensures the uniform distribution of the negative pressure while causing micro-deformation and thereby preventing localized areas of high pressure that would cause necrosis (Thomas, 2001). Also, the open structure facilitates proper drainage and removal of exudate or blood, thereby enhancing the process of healing. Obtaining the required pressure and proper blood flow response depends on the type of dressing used, and this can affect the results of the therapy. The main principle used behind this technique is that the exposure of wounds to sub-atmospheric pressure for an extended period accelerates the process of debridement and healing (Hunter et al., 2007). The application of negative pressure to the wound can be classified into two types: continuous and intermittent therapies. The former is based on the continuous application of negative pressure to the wound, whereas the latter is a cyclic process of applying pressure for 5 mins and then resting for 2 mins. Vacuum assisted closure is a superior and widely accepted method to drain the excess of exudate and blood from the wound. Vacuum assisted closure (VAC) is also known as topical negative pressure wound therapy (NPWT), microdeformational wound therapy (MDWT) (Huang et al., 2014) or vacuum therapy or vacuum sealing.
2.3.2 Principle mechanisms involved in VAC

The use of NPWT for the management of acute as well as chronic wounds has increased over the past ten years. The negative pressure applied to the foam causes undulations in the wound bed. This results in stretching and division of cells resulting in the proliferation of reparative granulation tissue (Gabriel et al., 2006). Vacuum assisted closure in wound care management promotes the process of healing and debridement. VAC has been found to remove the exudate in a consistent and reproducible manner, which thereby minimizes edema. As per Kamolz et al., and Wackenfors et al., VAC was found to increase the blood flow and partial pressure of oxygen in severely burnt wounds. A negative pressure of 125 mmHg is found to enhance the formation of granulation tissue as the mechanical forces stimulate a biological response at the
wound site (Hunter et al., 2007). Also, the use of a dressing with an open-cell structure ensures that the wound bed does not dry out, and a moist environment is maintained around it to accelerate the healing process.

2.3.3 Advantages of Vacuum Assisted Closure (VAC)

VAC is found to enhance the process of wound healing by accelerating the preparation of the wound bed. The wound volume has been found to be significantly reduced (in terms of macro-deformation) in cases where ulcers use VAC therapy. The edema is minimized due to the efficient removal of the interstitial fluid. Scientific studies have proven that the use of the negative pressure therapy promotes the blood flow in the wound area (Gabriel et al., 2006). The negative pressure applied during VAC results in mechanical stresses that enhance the protein synthesis and thereby the process of angiogenesis and epithelialization. This increased blood flow enhances the removal of interstitial fluid and debris thus increasing the protection against bacterial pathogens. VAC has also been found to significantly enhance the rate of healing following reconstructive surgery. Also, it was observed that the application of negative pressure minimizes the risk of infection, blood coagulation and catabolism, which in turn reduced the length of hospital stays (Jeschke et al., 2004). Since VAC significantly reduces the duration of a hospital stay, it reduces the overall expenditure per patients. VAC is also found to improve the appearance of a healed split-thickness skin graft (Moisidis et al., 2004). As it is a closed system, the number of dressing changes is reduced to once a week as compared to the traditional method of a minimum dressing change once per day. Thus, the levels of pain and
discomfort for the patient are significantly reduced. This greatly limits the wound exposure, thus reducing the risk of infection and post-surgical complications. As a result, the rate of patient survival is drastically improved (Hunter et al., 2007). VAC has several advantages as described above and can also be used for a wide variety of wounds thus making it an increasingly popular option over the last decade.

![Figure 2.3.3 Effects of micro-deformational wound therapy observed at wound site (Huang et al., 2014)](image)

2.3.4 Applications of VAC

VAC promotes a moist wound environment along with positive stimulation of the biological response, thus promoting angiogenesis and accelerating wound healing. VAC has several advantages as described above along with the major benefit of its application to a variety of anatomical sites throughout the body. Thus, VAC is an advanced method to manage the therapy of major wounds in order to obtain optimum results. VAC is used for treating both
acute as well as chronic wounds. It plays an important role following reconstructive surgery or tissue grafting, which is explained further in Section 2.3.5. Kamolz et al. have demonstrated the clinical feasibility of incorporating negative pressure therapy and have shown that it improves efficiency and the rate of healing of burn wounds. They observed that the skin graft rate was more than 95%, and thus suggested its use in the treatment of major burns and pressure ulcers (Kamolz et al., 2014). Negative pressure therapy (VAC) has been successfully used for the treatment of degloving injuries affecting the limbs and extremities, in which an extensive section of skin is severed from the tissue lying beneath it thus removing it from its natural blood supply. It is used for treating deep infected wounds where controlling the infection is a primary concern. Such injuries include soft tissue injuries prior to surgical closure, thoracic and abdominal injuries (Thomas, 2001; Kirkby et al., 2009). VAC promotes the proper healing of open wounds like diabetic ulcers, venous ulcers and chronic open wounds, because it increases wound bed granulation, promotes macro-deformation and protects from microbial action. As per Lee et al, 2011, VAC was found to show significantly improved results in the treatment of exposed bones and joints by accelerating the granulation of the wound bed and enhancing wound healing. VAC has been proven to be a viable option for the treatment of open high-energy injuries (Herscovici et al., 2003; Kang et al., 2010). It is also used for the treatment of frostbites, fasciotomy wounds and spinal cord injuries (Pham et al., 2003). Use of negative pressure wound therapy was found to decrease the average duration of hospital stays by one week and minimize the chances of infection in the treatment of deep sternal wound infection (Damiani et al., 2011). NPWT serves as a superior method to drain infectious wounds
compared to conventional drainage methods (Huang et al., 2014). Thus, the introduction of NPWT has revolutionized the management of wounds over the last decade.

2.3.5 VAC for the treatment of donor site wounds

Vacuum assisted closure plays an important role following reconstructive surgery and tissue grafting. Significant results are obtained in cases of both split-thickness grafts as well as full thickness grafts following a burn injury or extensive removal of cancerous tissue. Also, it is used in treating the donor site injuries that are created after harvesting skin grafts for the treatment of burn injuries. In a study by Schmedes et al., 2012, VAC was found to promote the healing of large dorsal donor sites that were created while harvesting skin grafts in the reconstruction of the neck and head by minimizing healing complications. Fleischmann et al. observed efficient cleaning and conditioning of the wound bed when VAC was used in the treatment of soft tissue damage in open fractures (Fleischmann et al., 1993). Genecov et al. compared the healing rate of skin graft donor sites by applying a sub-atmospheric pressure of 125 mmHg. Seven out of the ten donor sites treated with VAC showed faster re-epithelialization as compared to the use of traditional Opsite dressing (Genecov et al., 1998). Vacuum assisted closure can be used for almost any anatomical location due to its versatility. VAC significantly promotes the healing rate of donor site wounds by accelerating the process of epithelialization, decreasing the wound size and protecting against microbial infiltration and infection. Thus, VAC can be used as a practical clinical solution for the treatment of donor sites.
Figure 2.3.5 Potential anatomical sites for treating wounds using NPWT (Huang, et al, 2014)
2.4 Materials presently used for VAC

2.4.1 Required properties of dressings

First of all, the dressing or filler materials should transfer and distribute the pressure uniformly around the wound area when sub-atmospheric pressure is applied during negative pressure wound therapy. The dressing material should have an open-pore structure that can help in the uniform distribution of negative pressure at the wound site. It should be non-adherent, facilitating easy and painless removal during dressing changes. The dressing should allow the easy removal of liquid exudate and thereby allow its passage into the negative pressure canister. Thus, it should efficiently absorb exudate, but at the same time, not adhere to the wound bed. This provides effective protection of the newly formed tissue. The dressing should contain antibacterial agents, like Ag, that offer protection against a wide variety of pathogens. Thus, it should protect the wound area by functioning as an effective barrier against bacteria.

The dressing should effectively manage moderate-to-heavy levels of exudate when treating pressure ulcers, venous ulcers, donor site wounds, diabetic ulcers as well as traumatic and surgical wounds.

The dressing should have a flexible design to help adapt to the contours of deep and irregular shaped wounds. It should be easy to use and should be designed to treat a variety of wounds of different shapes and sizes. Also, it should promote the formation of granulation tissue in the wound. The effective management of exudate and maintaining a moist environment around the wound area promotes faster healing. The dressing should have high wet tensile and wet tearing strength that would allow for intact removal of the foam or the dressing, thus reducing the risk
of adherence to the wound bed. It should have a high density and low average pore size, thus restricting the in-growth of granulation tissue and allowing more comfortable dressing changes.

The dressing should be designed so that it can be used for up to 7 days in vivo, which means that the frequency of changes is minimized. It should have a high compression resistance, thus facilitating efficient functioning. It should be non-cytotoxic when used in vivo. The dressing should prevent the formation of hematoma and seroma as well as minimizing graft shearing. It should be compatible with enzymatic debridement agents and other growth promoting biomolecules, such as fibroblast growth factors (FGF).

2.4.2 Types of foams or other dressings

It has been observed that the cell size of the foams produces a tangential strain leading to the micro-deformation of cells (Saxena, et al., 2004). This in turn promotes the proliferation and formation of granular tissue. McNulty et al. observed that the application of negative pressure therapy using a reticulated open cell foam induced an average tissue micro-strain between 5% to 20% which promoted cell proliferation. Also, the high micro-strain was found to significantly decrease the wound surface area on application of NPWT. Researchers have observed that foams stimulate fibroblast migration and increase cell proliferation. Also, the granulation tissue formed was found to be thick, thereby promoting faster healing. Foams have also been reported to be used with NPWT of sternotomy wounds and fasciotomy wounds in
the upper and lower limbs. Some of the common types of foams used in VAC are explained below.

2.4.2.1 Black foam

It is an open-cell well reticulated polyurethane foam. It is hydrophobic in nature. It is available in multiple sizes, and thus can be used for the negative pressure wound therapy for a wide variety of wounds. It is designed such that it enables apposition to the wound bed to provide an intimate foam-tissue interface. It allows efficient removal of exudate from the wound.

2.4.2.2 White foam

It generally has higher density and a smaller average pore size as compared to the black foam. It is a hydrophilic structure. It is designed such that it is more flexible. It is used for VAC for treating wounds in tunnels and shallows cavities. White foam is also found to be useful in the NPWT for exposed tendons and bones.

2.4.2.3 Green Foam

Green foam is an open cell polyurethane foam that allows easy monitoring of exudate and bleeding as blood can be easily seen against the green complementary color. It has similar pore size and structure as black foam. Also, the characteristics of granulation tissue formed by the green foam are similar to that formed by the black foam. Green foam generally has higher tensile strength (165kPa) as compared to the black foam (108kPa), thus causing lesser problems of foam residues in the wound bed (Malmsjö et al., 2011). In an experiment by Malmsjö et al. it was observed that green and black foam perform similarly in all regards under NPWT except that wound exudate and bleeding could be more easily visualized using the
green foam. The wound area was found to contact to about 93% using the green foam and about 92% using the black foam.

2.4.2.4 Blue Foam

Blue foam is generally an open-celled polyvinyl alcohol (PVA) structure designed for heavy drainage. It has good wicking and exudate retention properties. The Hydrofera Blue Foam Dressing by Hollister Incorporated formed by binding two organic pigments (methylene blue and gentian violet) offers superior resistance against the bacterial colonization (Shanbrom, 1998).

2.4.3 Overview of commercially available dressings for Negative Pressure Wound Therapy (NPWT)

Acelity, Smith & Nephew, Molnlycke, Medela, Convatec, Hollister Incorporated and Derma Sciences are some of the leading manufacturers in the advanced woundcare market and produce various types of dressings required for Vacuum Assisted Care (VAC) or Negative Pressure Wound Therapy (NPWT). The Mepitel and Melgisorb dressings by Molnlycke are designed for highly exuding wounds and are non-adherent. It was observed that the Mepitel dressings do not disturb the wound area or cause pain during dressing changes (Vloemans et al., 1994; Williams, 1995). Melgisorb is claimed to be a highly absorbent calcium/sodium alginate dressing that is very soft and controls exudate by its gelling technology (William, 1998). The Mepilex foams by Molnlycke contain silver sulphate and thereby reduce the bacterial burden in the wound area and have the patented Safetac soft silicone layer (Barett,
2009). It can also be used for medium to high exuding wounds. They are manufactured in
different shapes to be used for difficult anatomical sites like the sacrum and heel. MacBride
and colleagues found that Mepilex has a soothing and cooling effect on the wound area without
compromising the efficiency of wound healing. In a study to compare the levels of discomfort
experienced on dressing changes, Mepilex was found to cause the least discomfort as compared
to Duoderm, Allevyn, Biatin and Versiva dressings (Dykes et al., 2003). Kimura et al., have
reported the efficiency of Mepilex when used in NPWT to treat pump pocket infection that can
occur in the left ventricular assist device (LVAD).
Convatec manufactures the Aquacel dressing with hydrofibers composed of sodium
carboxymethylcellulose that holds the absorbed exudate in a soft gel while still maintaining a
moist environment around the wound (Ip et al., 2006). Barnea and colleagues observed that
Aquacel dressings significantly reduced the pain and increased the rate of epithelialization
while using NPWT to treat split-skin donor site injuries (Barnea et al., 2004). The Hydrofera
Blue Foam Dressing by Hollister Incorporated is formed by binding two organic pigments
(methylene blue and gentian violet), which provides an antibacterial property. It is an open cell
foam that can be used for heavy exuding wounds. When this antibacterial dressing was used
for the treatment of lower extremity chronic wounds, it resulted in improved surface critical
colonization and low pain levels along the margins of the contracting wound (Coutts et al.,
2014). Coloplast produces a non-adhesive three-dimensional polyurethane foam structure
called Biatain that can be used for highly exuding wounds. The unique 3-D foam structure
ensures superior absorption and exudate retention properties. The exudate is vertically
absorbed and the fluid is held in place due to the 3-D structure, which also promotes a moist environment around the wound. It is non-adhesive and antibacterial in nature and is durable for up to 7 days (Care, 2001). In a study by Gottrup et al., the Biatain foam together with an Ibuprofen anti-inflammatory active agent was found to minimize the wound pain levels and significantly increase the rate of contraction of chronic wounds in patients. Medela manufactures Invia foam from polyether or polyurethane. The foam pads have a dry tensile strength of 20 psi and a cell count of 30±5 pores per inch, which results in the efficient removal of exudate and responds to applied pressure uniformly.

2.4.3.1 GranuFoam

VAC GranuFoam is a silver coated open-celled reticulated polyurethane foam that is manufactured by Kimberly Clark Inc (KCI). It has an average pore size of 400-600 microns. This foam is reported to be commonly used for negative pressure therapy of infected wounds and soft tissue injuries. The foam consists of silver nanoparticles that ensure efficient protection against bacterial action (Ambrosio et al., 2005). Sachsenmaier et al. observed a superior antimicrobial effect of GranuFoam against Staphylococcus aureus and Staphylococcus epidermidis at a negative pressure of 25 mmHg. They found that there was a steady increase in silver ion concentration, that led to an increasing zone of inhibition for the colony in bacterial culture. In a pilot study by Gabriel et al., GranuFoam silver dressing used in the negative pressure therapy was found to significantly reduce the mean time for healing of ankles and ulnar wounds in patients to around 13 days. Enhanced wound closure, infection clearance, antibacterial resistance and granulation of the wound area were achieved in around
7 days (Gabriel et al., 2006). It was also observed that VAC GranuFoam with a silver dressing provides better results in reducing the healing time and recurrence rate of infected diabetic foot ulcers compared to conventional GranuFoam (Günl et al., 2015).

Figure 2.4.3.1 Granufoam - Black polyurethane foam for VAC (GranuFoam, 2017)

2.4.3.2 Medifoam

Medifoam is a non-adhesive polyurethane open cell reticulated foam that has been successfully used in vacuum assisted closure for treating various types of wounds. It is a porous, nontoxic and hydrophilic polyurethane foam dressing having a high capacity for liquid absorption and retention. The foam has good conformability and serves as a good cushioning and protection surface for the wound area. In a study by Lee et al., the physical properties of Medifoam, such as thickness, density, tensile strength, elongation, moisture vapor transmission, liquid retention and absorptivity were compared with Biatain, Mepilex and nine other foams from different
manufacturers. Medifoam has a transparent protective film layer that ensures easy assessment
of the exudate being absorbed through the absorptive layer. Medifoam was observed to have a
uniform pore size of 25-75 microns, a typical cell size of 100-350 microns and a homogenous
morphology compared to other foams. Also, it showed enhanced liquid absorption/retention
capacity (0.47 g/cm$^2$), fluid absorption pattern and optimized physical properties compared to
the other polyurethane foams. No detachment of the re-epithelialized tissue layer was observed
when the Medifoam dressing was changed after 3, 6, and 9 days (Lee et al., 2016). On
comparing the physical properties and mainly the water-vapor transmission (WVT),
Medifoam Silver showed a rapid liquid absorption rate, enhanced absorption/retention
capacity, good antibacterial properties and superior WVT values compared to Mepilex,
Allevyn and others (Lee et al., 2016). Medifoam was found to successfully reduce the hospital
costs by 10% during negative pressure therapy for pressure sores and decubitus ulcers (Lee et
al., 2004).

Figure 2.4.3.2 Structure of Medifoam used in VAC (Medifoam, 2017)
2.5 Problems associated with the foams

In some cases, pieces of foam break off during removal at the time of dressing changes. Mazoch et al. reported two cases where the patients suffered from chronic wound drainage, expensive diagnostic work-ups and complicated surgeries due to the retention of the foam in their surgical wounds. Thereby, the use of radio-opaque markers was suggested to be added to vacuum foams that would aid in early detection of foam remnants in deeper wounds. When the granulation tissue grows into the pores of the foam, it results in painful and traumatic dressing changes. Also, the formation of new and continuous granulation tissue will be disturbed. In the case of irregularly shaped injuries in certain sites, the issue of flexibility of the foam becomes a major challenge. Because the foam resists bending, it is difficult to mold the foam over regions such as the toes, heel and sacrum. When the vacuum is applied, the foam loses more than half of its thickness, which in turn affects its structural properties and mechanical performance. This hypothesis needs to be studied.

2.6 Spacer Fabric

2.6.1 General structure of the spacer fabric

Spacer fabrics are three-dimensional knitted fabric structures with a face and back side knitted separately. These two outer layers are joined and kept apart by filling yarns called spacer yarns that lie in the thickness dimension. This spacer layer contains either monofilament or multifilament yarns. Thus, it has a sandwich structure consisting of three layers that are all knitted together, but with independent designs. Distinct characteristics can be incorporated
into this structure by changing the stitching notation and modifying the yarns in each layer. This three-dimensional structure consists of three layers; the inner layer for moisture release, the middle layer of spacer yarns for air or material flow and the outer layer for heat dissipation. Spacer fabrics have excellent compression resistance, and due to their multilayered construction they find their applications in geotextiles, the automotive industry, home and furnishing sectors, sports industries and, over the last decade, in biomedical and healthcare applications.

Figure 2.6.1 Geometric structure of 3D spacer fabric (Han et al., 2016)
2.6.2 Manufacturing

Spacer fabrics can be produced by two ways, using either warp knitting or weft knitting technologies. Warp knitted spacer fabric is knitted on a double needle bed rib raschel machine with several guide bars, whereas weft knitted spacer fabrics are manufactured either on a flat V-bed machine, or on a double jersey circular machine with a rotating needle cylinder and fixed needle dial (Yip et al., 2008). On the raschel warp knitting machine, fabrics with open structures can be fabricated due to the higher yarn tensions and the fabric being drawn down at an angle of 120 to 160 degrees to the needles. This leads to the warp knitted spacer fabric being thicker compared to the weft knitted one.

2.6.3 Properties

3D knitted spacer fabrics behave in a different manner compared with traditional 2D knitted structures in terms of porosity, compression resistance, flexibility, liquid absorption capacity, stretchability, softness, tensile and bursting strength. Spacer fabrics are open structures and thus have a considerable amount of space within the thickness of the fabric. This type of construction, together with the spacer yarns oriented in the Z direction, contribute towards the excellent compression and recovery properties. Also, being a knitted structure, it has performance properties like superior bursting and tensile strength, high total porosity, moisture transport, breathability, high elongation and a high volume to weight ratio (Rajendra et al., 2003).
2.6.4 Medical related usage

As described earlier, spacer fabrics have a unique architecture along with excellent physical properties and mechanical performance. On account of these properties, it has been suggested by medical researchers that spacer fabrics be used for both internal and external biomedical and healthcare applications. Spacer fabrics have an impressive total porosity and breathability, thus contributing to enhanced moisture transport and the prevention of heat build-up (Davies, 2009). Spacer fabrics show excellent compression resistance and uniform transferance of applied pressure. These properties make it suitable to be used for various external applications to provide comfort cushioning and shock absorbency (Rajendra, 2003). Spacer fabrics can be used as scaffolds for tissue engineering applications as their 3D structure provides a layered surface area useful for cell attachment and guided migration through the thickness. The high porosity helps in superior liquid transport performance of nutritional fluid and waste by-products. These fluids can flow into and then be held within its 3D structure depending on the end application. As the different layers of the spacer fabric are fabricated independently, the pore size distribution of the inner and outer surfaces can be easily altered by changing the number of needles and the number of guide bars knitting at any one time. Thus, a single piece multilayered structure can be fabricated with different structures and porosities within the same scaffold. As the pores in this construction are 100% open, they ensure enhanced transport of nutritional fluid and the elimination of waste by-products and thus can be used as a scaffold to promote cell proliferation. Also, as fabrication does not involve the use of chemicals, toxic organic solvents or excessive heat, it reduces the chance of cytotoxicity when used for
biomedical applications. Thus, different structures can be obtained by changing the manufacturing process parameters like the gauge of the needle bed, the number of yarn guide bars, the gap between the two needle beds, which modify the orientation of the spacer yarns. In addition, different combinations of yarns and polymers can be used to achieve the structure appropriate for a specific end use.
CHAPTER 3. MATERIALS AND METHODS

3.1 Experimental Design

This study involves the selection and evaluation of three different kinds of wound dressings, that is two samples of spacer fabrics and one sample of foam. The different approaches and testing methods that were used are described in this chapter. In order to meet the requirements of a wound dressing, appropriate spacer fabric samples were selected. The spacer fabric samples were selected in a way that they were constructed using the same number of guide bars but with different gauges (i.e. needles per inch). This made it possible to evaluate the effect of gauge on the mechanical properties of the spacer fabric. So spacer fabric samples that had been knitted with 24 gauge needles and 4 guide bars, and 12 gauge needles and 4 guide bars, were selected to test the mechanical properties. Of the commercially available dressing materials, GranuFoam® foam dressing manufactured by KCI was selected due to its popular use with vacuum assisted wound therapy. There are several varieties of GranuFoam® available on the market. There are a variety of sizes and some contain silver nanoparticles (GranuFoam® silver dressing). For this study, the regular GranuFoam® was selected so as to measure its physical, mechanical and moisture related properties.

3.1.1 Materials

3.1.1.1 Spacer fabric

The spacer fabric was obtained from NC State University. It was knitted from 150-denier, 48-filament textured polyester (PET) yarn that was obtained from Unifi Inc. The spacer fabric
samples were knitted from 72 ends on a double needle bed with a narrow width (26 inches) Raschel Karl Mayer DR 10 warp knitting machine (Ting, 2011). Polyethylene terephthalate (PET) was used because of its superior properties like good mechanical stability, non-resorbability, biocompatibility and low cost. The properties of the PET yarn used to warp out all four beams and to knit the spacer fabrics are listed in the following table.

Table 3.1.1.1 PET yarn properties.

<table>
<thead>
<tr>
<th>Type</th>
<th>Cross-section</th>
<th>Tenacity</th>
<th>Elongation</th>
<th>Shrinkage</th>
<th>Density</th>
<th>Twist Direction</th>
</tr>
</thead>
<tbody>
<tr>
<td>PET yarn</td>
<td>Round</td>
<td>4.7 gpd</td>
<td>20.40%</td>
<td>14.8% (180F)</td>
<td>1.38 g/cc</td>
<td>S</td>
</tr>
</tbody>
</table>

3.1.1.2 GranuFoam

The GranuFoam® dressing was manufactured by KCI (now called "Acelity"). It was purchased on eBay. V.A.C. GRANUFOAM™ Large Dressing Kits were used for all the experiments. It is a polyurethane foam with an open-cell reticulated structure. It has a hydrophobic construction that claims to effectively remove the exudate.

Table 3.1.1.2 GranuFoam® properties.

<table>
<thead>
<tr>
<th>Type</th>
<th>Polymer used</th>
<th>Property</th>
<th>Pore diameter</th>
<th>Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>GranuFoam®</td>
<td>Polyurethane</td>
<td>Hydrophobic</td>
<td>400-600µm</td>
<td>26 X 15 X 3.2 cm</td>
</tr>
</tbody>
</table>

Note: The pore diameter mentioned in the table reflects the value listed on the KCI website. In Chapter 4, the results list the experimentally measured pore size values, which are different from these values quoted on the KCI website.

Terminology used: For this study, the characteristics of the GranuFoam® have been evaluated for two layers. The layer that is in contact with the wound surface is referred to as the wound contact layer and the thickness of the foam that is mainly responsible for the absorption is referred to as the absorption layer.
3.2 Evaluation of Constructional Characteristics

3.2.1 Thickness and Density

The thickness of the spacer fabric was determined following ASTM D1777-96 (2015) Standard Test Method for Thickness of Textile Materials. Thickness was measured on a SDL 94 thickness gauge from Shirley Developments Ltd, Stockport, England. The area of the presser foot was 412mm² and the gauge measured the thickness up to a precision of 0.01 mm. Ten specimens of each, 12 E 4 GB and 24 E 4 GB samples, were cut in the dimensions of 5cm x 5cm and were kept free of folds or wrinkles. The dimensions of the specimens were measured using vernier calipers. All the samples were kept in a standard atmosphere of 21 ± 1°C (70 ± 2°F) and 65 ± 2% relative humidity for 24 hours before the testing. The distance between the base and the circular weighed presser foot gave the thickness value of the specimen. The thickness of a specimen depends on the pressure applied. A pressure of 20 g/cm² was applied for testing thickness of the spacer fabric samples. The average of 10 readings gave the mean thickness of the sample.

As the thickness of the foam exceeded 1", it was not possible to measure its thickness using the SDL 94 thickness gauge. Five specimens of the polyurethane foam were cut in the dimensions of 5cm x 5cm each and were measured using the vernier calipers. All the samples were kept in a standard atmosphere of 21 ± 1°C (70 ± 2°F) and 65 ± 2% relative humidity for 24 hours before testing. The density of the foam was determined according to the ASTM 3574-16 Standard Test Methods for Flexible Cellular Materials- Slab, Bonded, and Molded Urethane Foams.
All the specimens were weighed on a Model AG 245 weighing balance with a precision of 0.1 mg.

Density (D, g/cm$^3$) of all the specimens was determined using the values of mass (M, g) and volume (V, cm$^3$) that was calculated using length (L, cm), width (W, cm) and thickness (h, cm).

\[ V = L \times W \times h \text{ cm}^3 \]

\[ D = \frac{M}{V} \text{ g/cm}^3 \]

Figure 3.2.1 SDL 94 thickness gauge in the Biomedical Textile Laboratory at College of Textiles, NCSU (Ting, 2011)
3.2.2 Total Porosity

Total porosity is the measure of the total void content within a material. For a filling material to be used in vacuum assisted closure therapy, the characteristics of the porous structure greatly affects the performance. According to ASTM F2450-10 Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products, the total porosity is determined using the ratio of void volume to the total volume of the porous material. It was expressed as a percentage.

The total porosity was measured using,

\[ p = (1 - \frac{D_s}{D_p}) \times 100 \]

Where,

- \( p \) = total porosity (%)
- \( D_s \) = Density of sample (g/cm\(^3\))
- \( D_p \) = Density of polymer (g/cm\(^3\))

For the spacer fabric calculations, density of polyester (Dp) was assumed to be 1.38 (g/cm\(^3\)) and for the foam, the density of polyurethane (Dp) was assumed to be 1.2 (g/cm\(^3\)). Ten specimens of each, 12 E 4 GB and 24 E 4 GB spacer fabric samples, were cut in the dimensions of 5cm x 5cm and were kept free of folds. The dimensions of the fabric were measured using vernier calipers. Five specimens from the foam samples were also cut in the dimensions of 5 cm x 5cm. All the samples were kept in a standard atmosphere of 21 ± 1°C (70 ± 2°F) and 65 ± 2% relative humidity for 24 hours before the testing. The thickness of spacer fabric specimens was assessed using SDL thickness gauge while the thickness of the foam was
measured using vernier calipers. All the specimens were weighed on a Model AG 245 weighing balance with a precision of 0.1 mg. The density of the fabrics and foam was calculated using these values. The total porosity (p, %) for each sample was reported in terms of a mean ± standard deviation value.

3.2.3 Pore Size Distribution

ASTM F-2150 defines a pore as an inherent network of channels and open spaces within an otherwise solid structure. Pore size and pore size distribution are different from total porosity. Pore size is the measurement of the dimensions of an individual pore within the structure. There are various techniques to characterize the pore size such as the scanning electron microscope, stereo optical microscope, liquid or mercury adsorption or optical imaging. In this study, scanning electron microscopy was used to determine the average individual pore size and the pore size distribution of the foam specimens. The pore sizes of the foam were assessed in the wound contact layer and also in the cross sectional (absorption) layer. The samples were first sputter coated with gold-palladium as the foam is composed of a non-conductive polyurethane polymer. The images obtained were analyzed using the Java-based image processing software ImageJ (NIH). Pores were defined and constructed in each plane by constructing geometrically the biggest inscribed circle in each of the pores. The average pore size was then calculated and statistically reported in terms of its mean ± standard deviation.

The values of pore size and pore size distribution for the two spacer fabric samples were obtained from the thesis of Ting He, 2011. As the knitted structures are flexible and easily
deformable, it was difficult to analyze the pore size and its distribution directly from the cross section. The readings were obtained by embedding the spacer fabric specimens in epoxy resin with 5% methyl ethyl ketone peroxide (MEKP) initiator and were hardened overnight at 44% relative humidity and 19°C. The specimens were then cut into sections and observed using a Nikon Eclipse L150 optical microscope with a Nikon DMX1200 digital capture camera at magnifications of x50 and x100 times. The images were analyzed using ImageJ software.

3.3 Mechanical Testing

3.3.1 Tensile Strength and Elongation

Skin is a viscoelastic material which is permanently subjected to low stresses in a range of different directions. The tensile strength of human skin is reported to be in the range of 1.8 (N/mm²). Any wound dressing developed ought to have tensile strength higher than this value. Otherwise, even with slight stress at the near vicinity of the wound, the dressing is likely to get ruptured. (Chellamani et al., 2014)

The tensile strength was measured using ASTM D 5035-11 Standard Test Method for Breaking Force and Elongation of Textile Fabrics (Strip Method). In this test, 24 samples were cut into 2.5cm x 8cm in both directions, that is, 12 in the warp direction and 12 in the weft direction. The 24 foam specimens were also cut in the dimensions of 2.5cm x 8cm in both directions, that is, 12 length-wise and 12 width-wise. Out of all these samples, 6 specimens of each cut
sample were used for wet tensile testing. The maximum tensile strength of the fabric samples was measured in both directions for the fabric and the foam.

Tensile strength was measured using a material test machine Model 2712-864 Bluehill Instron Universal Tester (Instron, Norwood, MA, USA). The test specimen was mounted in between two clamps with an initial gauge length of 2.5 cm, and the clamps were moved apart at a constant speed of 300 mm/min until the specimen failed. For the wet testing condition, the specimens were immersed in distilled water with a few drops of Triton X-100, a non-ionic agent at a conditioning temperature of 21°C (70 °F). The specimens were tested within 2 mins after removal from the water. Six specimens were tested for each sample. The values for breaking force, the elongation at maximum load and elongation at break were obtained from the computer interfaced with the testing machine. The average maximum tensile strength and Young's modulus values were calculated from these individual measured values.

Using the slope of the stress/strain curve in the initial linear portion of the curve, the Young's modulus (E) was reported as the steepest slope between the lower and upper bounds. The Young's modulus was calculated using the formula-

\[
E = \frac{\text{tensile stress}}{\text{tensile strain}} = \frac{\sigma}{\varepsilon} = \frac{F/A}{\Delta L/L} = \frac{F \times L}{A \times \Delta L}
\]

Where,

E = the Young's modulus (MPa),

F = the absolute force applied to the fabric (N),

A = the original cross-sectional area through which the force was applied (mm²)
ΔL = the amount of increase in length of the specimen during the test (mm),

L = the original specimen length (mm).

Figure 3.3.1 Bluehill Instron Model No. 5544 Universal Tester with tensile strength apparatus

3.3.2 Compression Resistance

The compression modulus was determined using ASTM D575-91 Standard Test Method for Rubber Properties in Compression. This test was carried out on an MTS 30/G with a load cell having a 100N capacity and a constant rate of compression of 12 mm/min. The compression
cell measured 5.5mm in diameter. In this test, 5 specimens of each sample type are cut in the
dimensions of 4.5cm x 4.5cm in order to fit inside the dimensions of compression cell. All the
samples were conditioned at 23°C and 65% relative humidity before performing the test. The
test limit was set to a deformation of 80% of the initial thickness of each specimen. The values
of stress, strain, and modulus were recorded from the software. The compression modulus
gives the ratio of the mechanical stress to the mechanical strain in an elastic material when the
specimen is being compressed. This the value signifies the stress needed to destroy the sample
by crushing.

\[
\text{Modulus} = \frac{\text{Compressive stress}}{\text{Compressive strain}}
\]

\[
\sigma^*_e = \frac{F^*}{A_0} \quad \epsilon^*_e = \frac{l^* - l_0}{l_0}
\]

where;

\( F^* \) = load applied just before crushing (N)

\( A_0 \) = Original specimen area (m²)

\( l^* \) = specimen length just before crushing

\( l_0 \) = Original thickness of the specimen (mm)
3.3.3 Flexural Rigidity

3.3.3.1 Cantilever Bending Test

This test was done to determine the flexural rigidity of the spacer fabric specimens. This test followed ASTM D1388-08 Standard Test Method for Stiffness of Fabric and was performed on a Model S0015 Cantilever Bending Stiffness Tester from IDM Instruments Pvt Ltd. Melbourne, Australia. The specimens were cut in dimensions 2.5cm x 20cm and conditioned for 24 hours at 21°C and 65% relative humidity. Each specimen was pushed forward in a parallel direction at a specific rate till its leading edge projected from the edge of the horizontal
surface. The specimen fell under its own mass on the line joining the top to the edge of the platform making an angle of 41.5°. This overhang length was recorded. For each specimen four readings were taken, one in each direction and two from each side.

The bending length was calculated using the formula:

\[ c = \frac{O}{2} \]

Where,

c = bending length (cm),

O = length of overhang (cm)

Flexural rigidity (G) of the specimen was calculated using the formula:

\[ G = 1.421 \times 10^{-5} \times W \times c^3 \]

Where,

W = fabric mass per unit area (g/cm²)

The stiffness value for all the specimens was recorded for each sample in terms of mean ± standard deviation
3.3.3.2 Three-point bending test

The flexural rigidity of the foam is evaluated using the three-point bending test. This test was performed as per the ASTM D 790-15 Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials. This test was done on the MTS mechanical test frame with a three-point bending accessory. The compression load cell of 100N was used and the test speed was set to be 10 mm/min. It was difficult to bend a thick piece of the GranuFoam® with a thickness of 3.2cm as the compressive force acted before the bending force. Also, if the compressive force exceeds the strength of the GranuFoam®, then failure will occur. Rectangular thin sections of the samples were taken in
order to restrict the development of compressive stresses. To overcome this, the GranuFoam® was frozen for 24 hours before the test and sliced into sections with the smallest projectile thickness of 1 cm. It is challenging to cut thinner sections than this thickness maintaining the uniformity of the surfaces. Five specimens of GranuFoam were sliced in the dimensions 9 cm x 6 cm x 1 cm and tested to obtain the bending modulus. Also, the theoretical value of flexural rigidity was calculated by scaling up the bending modulus to be applicable for 3.2 cm thickness.

The following formulae were used for the calculations:

\[
Bending\ Modulus\ (N/cm^2) = E = \frac{Stress}{Strain}
\]

\[
Specific\ Flexural\ Rigidity\ (N - cm) = \frac{E \times (t^3)}{12}
\]

1 N.cm = 101.97 g.cm

Where,

E = bending modulus (N-cm)

b = width of the specimen

t = thickness of the specimen

Note: The SI metric units for bending modulus are N/m² and for flexural rigidity, N.m. However, in this study, decimal units involving cm were used in order to compare the flexural rigidity of the spacer fabric samples obtained using the cantilever bending test. Also, the specific flexural rigidity was measured in units of \((N.cm^2)/\text{width (cm)}\). In this experimental
study, the specific flexural rigidity was quoted in units of N.cm so as to compare with the values of flexural rigidity obtained from the cantilever bending test.

Figure 3.3.3.2 MTS 30/G with three-point bending test apparatus
3.3.4 Evaluation of moisture related properties

3.3.4.1 Absorption rate

Absorption rate and moisture retention capacity were determined using the standard BS EN 13726-1:2002 test methods for primary wound dressings: Aspects of absorbency. Specimens were cut in the dimensions of 5 cm x 5 cm. The initial weight (W1) and thickness (T) of the prepare specimens were recorded. Distilled water was maintained at 37 ± 1°C. Distilled water 40 times the mass equivalent of the specimen was added slowly to the specimens. These samples were maintained in an incubator at body temperature for 30 minutes. The specimens were then suspended and weighed for 30 secs (W2).

The absorption rate was calculated using the formula:

\[
\text{Absorption (g/cm}^2\) = \frac{W2 - W1}{\text{Initial area of the specimen}}
\]

3.3.4.2 Moisture Retention Capacity

After the measurement of the absorption rate, each specimen was subjected to a weight of 5kg for 20 secs and then the weight (W3) was recorded again. The moisture retention weight was calculated using the formula:

\[
\text{Retention capacity (g/cm}^2\) = \frac{W3 - W1}{\text{Initial area of specimen}}
\]
CHAPTER 4. RESULTS AND DISCUSSION

4.1 Effect of Constructional Characteristics on Basic Physical Properties

The basic physical properties like thickness, mass, fabric density and total porosity were evaluated for the spacer fabric samples and the foam. For the spacer fabric samples, the number of guide bars and the take up speed used for the construction of both the knitted structures were the same. The main difference was the gauge used. The 24-gauge samples had twice as many yarns knitted together in the same width as the 12-gauge samples. Despite this, the thickness of the 24-gauge samples was less than for the 12-gauge samples. The mass of the 24-gauge knitted samples was higher than the 12-gauge knitted sample. In addition, the fabric density of the 24-gauge sample was significantly higher. Thus, the gauge had a positive impact on the fabric density. The gauge had a negative impact on the total porosity of the fabric. Even though the 24-gauge sample had twice the number of yarns knitted together in the same width as the 12-gauge sample, the difference in the porosity was minor. This was primarily due to the highly porous structure of the spacer fabrics, and the total porosity of the two spacer fabric samples was in the range of 84%-91%. Another difference between the two spacer fabric samples was the lapping sequence and stitch type on the face and back of the fabrics.

The thickness and mass of the GranuFoam® was much higher than that of the 24-gauge knitted spacer fabric. The density of the GranuFoam® was significantly lower than both the spacer fabric samples. GranuFoam® is a highly porous structure with a mean total porosity of around 98%.
Table 4.1.1 Surface morphology of the spacer fabric samples (Ting, 2011)

<table>
<thead>
<tr>
<th>Sample name</th>
<th>12 E 4 GB</th>
<th>24 E 4 GB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gauge</td>
<td>12</td>
<td>24</td>
</tr>
<tr>
<td>Guide bars</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Technical face structure (Mag 10x)

Technical back structure (Mag 10x)

Cross section cut Warpwise (Mag 20x)

Cross section cut Weftwise (Mag 20x)

Note: Stitch type on face and back- Single guide bar tricot stitch.
Table 4.1.2 Lapping sequence diagram for knitted spacer fabric samples. (Ting, 2011)

<table>
<thead>
<tr>
<th>12 E 4 GB:</th>
<th>24 E 4 GB:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front:</td>
<td>Front:</td>
</tr>
<tr>
<td>Bar 2 : 0-0/1-0/1-1/1-1-2</td>
<td>Bar 2 : 1-0-0/0-1-2/2-2/1-0/0-0/1-2/2-2/</td>
</tr>
<tr>
<td>Spacer Yarns:</td>
<td>Spacer Yarns:</td>
</tr>
<tr>
<td>Bar 4 : 1-0/1-2/2-3/3-2</td>
<td>Bar 4 : 3-2/1-0/1-2/2-3/3-2/1-0/1-2/3/</td>
</tr>
<tr>
<td>Back:</td>
<td>Back:</td>
</tr>
<tr>
<td>Bar 5 : 1-0/1-1/1-2/0-0</td>
<td>Bar 5 : 1-1-1/0/1-1/1-2/1-1/1-0/1-1/1-2/</td>
</tr>
</tbody>
</table>

Wound contact layer cross section (Mag 20x)  Absorptive layer cross section (Mag 20x)

Figure 4.1 Surface morphology of GranuFoam®
Table 4.1.3 Constructional characteristics of spacer fabric samples and GranuFoam® sample

<table>
<thead>
<tr>
<th>Variables</th>
<th>Thickness (cm)</th>
<th>Fabric Density (g/cm³)</th>
<th>Total Porosity (%)</th>
<th>Fabric stitch count</th>
</tr>
</thead>
<tbody>
<tr>
<td>12E 4GB</td>
<td>Mean 0.26</td>
<td>0.12</td>
<td>91.36</td>
<td>wpi= 14.5</td>
</tr>
<tr>
<td></td>
<td>Std. Dev. 0.02</td>
<td>0.01</td>
<td>0.90</td>
<td>cpi= 20.5</td>
</tr>
<tr>
<td>24E 4GB</td>
<td>Mean 0.22</td>
<td>0.21</td>
<td>84.60</td>
<td>wpi= 15.5</td>
</tr>
<tr>
<td></td>
<td>Std. Dev. 0.03</td>
<td>0.02</td>
<td>1.72</td>
<td>cpi= 25.5</td>
</tr>
<tr>
<td>GranuFoam</td>
<td>Mean 3.10</td>
<td>0.02</td>
<td>98.27</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>Std. Dev. 0.00</td>
<td>0.00</td>
<td>0.12</td>
<td>NA</td>
</tr>
</tbody>
</table>

Note: Calculated porosity assumes,

density of polyester=1.38 g/cc

Density of polyurethane= 1.2 g/cc

Also, wpi= Wales per inch; cpi= Courses per inch

4.2 Pore Size Distribution by Image analysis

It was observed that the average pore size of the wound contact layer was smaller than that of the cross-section. For GranuFoam®, the mean pore size of the wound contact layer was around 369 µm whereas that in the cross-section it was around 451 µm. The pores were larger in the cross-sectional layer than in the wound contact layer.

The pore size of the wound contact layer needs to exclude fibroblast and keratin, thus resulting in reduced secondary damage and trauma upon dressing change. The cell size of the absorptive layer affects the capacity of the foam to absorb the exudate. When the spacer fabric is used as a dressing material, the wound contact layer has the pore diameter in the range of 45-80 µm and the absorptive layer or the spacer layer has pore diameters in the range of 147-242 µm.
These small and uniform pore sizes of the spacer fabric in the wound contact layer would be able to effectively exclude tissue formed, absorb the exudate in a superior way and maintain a moist condition. Due to its small pore size, the spacer fabric will be able to exclude the newly formed tissue and keratin during the healing process, thus precluding tissue ingrowth. The small pore size can also be expected to prevent the entry of fibroblasts into the dressing material. The remarkably small pore size and high degree of pore size uniformity, unlike traditional dressings, will help in reducing the dressing-wound adhesion and will therefore minimize the number of dressing changes.

Figure 4.2.1 SEM images of wound-contact layer (left) and absorption layer (right)
Table 4.2.1 Mean and standard deviation values of pore diameter. (Ting, 2011)

<table>
<thead>
<tr>
<th>Pore diameter (µm)</th>
<th>24E 4GB</th>
<th>12E 4GB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weft outer layer</td>
<td>Mean</td>
<td>45.59</td>
</tr>
<tr>
<td></td>
<td>Std. dev.</td>
<td>0.01</td>
</tr>
<tr>
<td>Warp outer layer</td>
<td>Mean</td>
<td>72.82</td>
</tr>
<tr>
<td></td>
<td>Std. dev.</td>
<td>0.03</td>
</tr>
<tr>
<td>Weft spacer layer</td>
<td>Mean</td>
<td>147.12</td>
</tr>
<tr>
<td></td>
<td>Std. dev.</td>
<td>0.15</td>
</tr>
<tr>
<td>Warp spacer layer</td>
<td>Mean</td>
<td>242.01</td>
</tr>
<tr>
<td></td>
<td>Std. dev.</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Figure 4.2.2 Outer layer (face/back layer) pore size distribution of trend lines of the two different spacer fabric samples (0-0.1mm) (Ting, 2011)
Figure 4.2.3 Spacer layer pore size distribution trend lines of the two spacer fabric samples (0-0.4mm) (Ting, 2011)

Table 4.2.2 Mean and standard deviation values of pore diameter.

<table>
<thead>
<tr>
<th>Pore diameter (µm)</th>
<th>GranuFoam®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound contact layer</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>369.11</td>
</tr>
<tr>
<td>Std. dev.</td>
<td>130.26</td>
</tr>
<tr>
<td>Absorptive layer</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>451.25</td>
</tr>
<tr>
<td>Std. dev.</td>
<td>164.55</td>
</tr>
</tbody>
</table>
4.3 Mechanical Properties

4.3.1 Tensile Strength and Elongation

The tensile strength and Young's modulus at 20% elongation were evaluated for the spacer fabric in both the warp and weft directions, and in the length-wise and width-wise directions for the foam specimens. It was observed that the spacer fabric specimens could withstand higher tensile strength in the warp direction than in the weft direction. The gauge has a positive impact on the tensile property of the spacer fabric samples. The spacer fabrics have larger elongation in the weft direction as compared to the warp direction which results in lower weft Young's modulus values. The clearly aligned wales in the warp direction have a significant impact on the tensile performance in the warp direction. The gauge exhibits a positive impact.
on the resistance to tensile deformation. Thus, the tensile modulus can be improved by increasing the gauge.

For both, dry and wet tensile testing, the spacer fabrics exhibited higher tensile modulus in the warp direction as compared to the weft direction. Higher tensile modulus was observed in the dry conditions as compared to the wet testing conditions for spacer fabric samples as well as the foam samples. The GranuFoam® exhibited significantly lower tensile properties as compared to the spacer fabric samples. For the GranuFoam®, the tensile modulus observed in the length-wise specimens was higher than the width-wise samples. The 24 gauge 4 guide-bar spacer fabric sample exhibited the highest tensile modulus.

The spacer fabric owing to its excellent tensile properties can serve as a superior dressing material as compared to the foam. The higher tensile properties reduces the problem of foam residues in the wound bed by ensuring intact removal of the foam. This will thus minimize the risk of adherence of the dressing material to the wound area.
Figure 4.3.1.1 Dry Condition: Tensile strength in warp/lengthwise direction.  
( Error bars = ± standard deviation )

Figure 4.3.1.2 Dry Condition: Tensile strength in weft/widthwise direction. 
 ( Error bars = ± standard deviation )
Figure 4.3.1.3 Wet Condition: Tensile strength in warp/lengthwise direction.
(Error bars = ± standard deviation)

Figure 4.3.1.4 Wet Condition: Tensile strength in weft/widthwise direction.
(Error bars = ± standard deviation)
Figure 4.3.1.5 Dry Condition: Young's modulus at 20% elongation in warp/lengthwise direction. (Error bars = ± standard deviation)

Figure 4.3.1.6 Dry Condition: Young's modulus at 20% elongation in weft/widthwise direction. (Error bars = ± standard deviation)
Figure 4.3.1.7 Wet Condition: Young's modulus at 20% elongation in warp/lengthwise direction. (Error bars = ± standard deviation)

Figure 4.3.1.8 Wet Condition: Young's modulus at 20% elongation in weft/widthwise direction. (Error bars = ± standard deviation)
4.3.2 Compression Resistance

The compression modulus gives the ratio of the mechanical stress to strain in an elastic material when the specimen is under compression. The spacer fabric specimens exhibited a higher compression modulus compared to the foam. Thus, it can sustain higher forces per unit area than the foam. The number of the gauge was observed to have a negative impact on the compression modulus. The 12 gauge 4 guide bar sample exhibited the highest compression modulus. Generally, the compression resistance is higher for the fabric with higher gauge as there are more number of fibers to withstand the force that is applied to the fabric. In this case, unexpected results are obtained because the two fabrics were constructed using different lapping sequences (Refer Table 4.1.2).

During vacuum assisted wound care, the filling material is constantly subjected to compression due to the applied negative pressure around it. Thus, the filler material is expected to have a higher compression modulus in order to withstand this compressive force. The spacer fabric can serve as an excellent filler material due to its superior compression resistance.
4.3.3 Flexural Rigidity

According to ASTM D1388-08, flexural rigidity is the resistance of a fabric to bending when a force is applied along one edge while the opposite edge is held in a fixed position. Structures with high flexural rigidity are difficult to bend easily. The gauge has a positive impact on the flexural rigidity. The spacer fabrics with same number of guide bars but with a higher gauge resulted in stiffer fabrics with higher flexural rigidity. Also, the flexural rigidity was significantly higher in the warp direction compared to the weft direction. The spacer fabric samples were more flexible weft-wise. The 12 gauge 4 guide bar spacer fabric sample showed highest flexibility. When the spacer fabric is used as a dressing, owing to the superior flexibility, it can be easily contoured over parts such as the toes, knees, sacrum, heel, etc. This will improve the efficiency of treating deep and irregular shaped wounds.
The GranuFoam® is very stiff compared to the spacer fabric samples and has a high specific flexural rigidity value. Even after slicing the foam to the thickness of 1 cm, significantly higher stiffness values were observed. By scaling up the experimental value to the actual thickness of the GranuFoam®, it was found that the GranuFoam® has a high specific flexural rigidity value. Thus, problems have arisen in the clinic due to this high stiffness of the GranuFoam®. It is very difficult to mold the GranuFoam® in certain anatomical sites when treating wounds in the toes, heels, joints and others locations. This issue can be resolved by using a pliable material such as a spacer fabric, which can enhance the effect of the vacuum therapy when used as a dressing for these specific wound sites.

![Figure 4.3.3 Flexural rigidity (stiffness) (Error bars = ± standard deviation)](image)
4.3.4 Absorption Rate and Moisture Retention Capacity

The spacer fabric samples rapidly absorbed the water as compared to the GranuFoam®. The 12-gauge spacer fabric sample had significantly higher liquid absorption capacity (0.33 g/m²) and good retention capacity (0.21 g/cm²) as compared to the 24-gauge sample. The GranuFoam® had a much higher absorption capacity (0.56 g/cm²) as compared to the spacer fabric samples. The retention capacity of GranuFoam® (0.31 g/cm²) is comparable to that of the 12-gauge spacer fabric sample. The lower absorption capacity of the spacer fabric samples can be related to significantly lower porosity of the spacer fabric samples as compared to the GranuFoam®. Interestingly, the 12-gauge spacer fabric showed relatively lower liquid absorption capacity while its retention capacity was similar to GranuFoam®. Thus, it is likely that most of the absorbed water was retained in the spacer fabric layer. The various absorption and retention capacities of the dressings affect the product performance mostly by varying the moisture permeabilities of the outer film layer. These results indicate that the rapid absorption as well as the superior retention capacity of the spacer fabric sample (12E 4GB) may help to minimize the risk of maceration of skin around the wound periphery and ensure superior exudate drainage when used as a dressing for vacuum assisted wound care devices.
Figure 4.3.4.1 Absorption rate (Error bars = ± standard deviation)

Figure 4.3.4.2 Moisture retention capacity (Error bars = ± standard deviation)
CHAPTER 5. CONCLUSIONS AND FUTURE RECOMMENDATIONS

In this chapter, the main aims described previously in Chapter 1 are revisited and discussed as the main conclusions. Each of the specific objectives is addressed with concluding statements. Finally, the findings and limitations of the study are discussed, and directions for future work are proposed.

5.1 Conclusions

**Main Conclusion:** The spacer fabric structures with multifilament spacer yarns have fulfilled the desired requirements of a wound dressing for vacuum assisted wound therapy that were described in Chapter 2, the Literature Review. An experimental procedure to characterize the wound dressing’s properties using the latest analytical techniques has been developed and applied to foam and textile wound dressings. This has enabled the completion of a comprehensive study on the performance and functionality of spacer fabrics with the potential use as wound dressings for vacuum assisted wound therapy.

**Conclusion 1:** The two selected spacer fabrics: 12-gauge, 4-guide bars and 24 gauge-4 guide bars have successfully shown superior performance properties compared to the existing foam product: GranuFoam®.

1.1. The general requirements of wound dressings for vacuum assisted wound therapy have been identified and summarized. This has included the constructional characteristics as well as the physical and mechanical properties.
1.2. The currently available wound dressings for vacuum assisted wound therapy have been reviewed and compared. The pros and cons of the existing dressings have been highlighted. The warp knitted spacer fabrics has shown certain advantages over other commercially available dressings. The spacer fabrics have superior properties such as high porosity, 100% interconnected pores, high specific surface area, and adequate compression and recovery properties.

1.3. A practical approach to this experimental study has been identified, and it consists of three steps: 1) selection of samples, 2) evaluation of properties and 3) analysis of results. The spacer fabric samples were selected such that they were constructed using the same number of guide bars but different gauges (i.e. needles per inch). The effect of changing the needle gauge on the constructional characteristics and mechanical properties has been reviewed.

**Conclusion 2:** The constructional characteristics and physical properties of the spacer fabric samples (12E, 4GB and 24E, 4GB) were found to be superior compared to the GranuFoam®.

2.1. Scanning electron microscopy was used for analyzing the surface morphology and the constructional characteristics of the GranuFoam®. The morphological details of the spacer fabric were obtained from Ting He's MS thesis, whereas the other general characteristics have been measured experimentally. Also, an image analysis system was adapted to view the sections of the structures and quantify the pore size distribution.
2.2. Comparing the two spacer fabric samples, the gauge has a positive impact on the fabric density. But gauge has a negative impact on the total porosity as well as the fabric thickness. The density of GranuFoam® was significantly lower than the spacer fabric structures, but it had a high porosity.

2.3. Considering the pore size characterization, the gauge had a negative impact on the mode for the pore size distribution in the outer layers. The GranuFoam® has larger pores in the absorptive layer as compared to the wound contact layer. The smaller pore size on the surface of the spacer fabric will minimize the chances of tissue ingrowth within the dressing.

**Conclusion 3:** The warp knitted spacer fabric samples showed superior mechanical properties such as tensile strength, compression resistance and flexural rigidity and equivalent moisture management performance as compared to GranuFoam®.

3.1. The spacer fabrics showed superior properties of tensile strength, compression modulus and flexibility as compared to the GranuFoam®. The tensile strength was lower for all the samples when performed under wet conditions. The gauge had a positive impact on the tensile strength and Young's modulus of the spacer fabric samples in the warp direction, but a negative impact on the tensile strength and Young's modulus in the weft direction.

The gauge was observed to have a negative impact on the compression modulus of the spacer fabric samples. The spacer fabrics exhibited superior flexibility as compared to the
GranuFoam®. The gauge was found to have positive impact on the stiffness of the fabric. GranuFoam® exhibited significantly lower tensile strength, Young's modulus and compression modulus and higher stiffness.

3.2. The absorption rate and the moisture retention capacity of the spacer fabric samples was found to be equivalent to that of GranuFoam®. The GranuFoam® sample showed higher moisture absorption and retention capacity in the non-compressed state. Under vacuum, the GranuFoam® was subjected to compression and it lost thickness, which negatively impacted its moisture management properties. The spacer fabrics had much higher compression moduli and thus their moisture management performance did not change significantly. Also, in case of the spacer fabric samples, the gauge was observed to have a negative impact on the absorption rate and the moisture retention capacity.

It was concluded that the spacer fabric samples could satisfy the physical and mechanical requirements of dressing materials to be used in vacuum assisted wound therapy. They showed superior properties compared to the existing foam product, GranuFoam®. These properties ensure superior flexibility of the spacer fabric when used as a dressing for vacuum assisted wound therapy for the treatment of toes, heels, sacrum as well as other curvaceous parts. Also, as seen from the results, the spacer fabrics are expected to perform better than the existing foam product.
5.2 Contribution

In addressing the problems currently faced by dressings used for vacuum assisted wound therapy, this study has for the first time been successful in the applying the latest warp knitted spacer fabric structures to develop an experimental procedure and evaluate the performance of three dimensional porous knitted structures. In this study, the desired physical and mechanical properties of the spacer fabrics have been successfully demonstrated for use as wound dressings for vacuum assisted therapy. The relationship between the knitting conditions and the mechanical performance has also been determined.

As such, this study has provided a new approach for the dressings used in vacuum assisted wound therapy, and has therefore made a significant contribution to the research in the field of biomedical textiles.

5.3 Recommendations for Future Research

This study evaluated the physical and mechanical properties of spacer fabrics when used in vacuum assisted wound therapy. Some recommendations for continuing studies have been identified and are listed below:

1. In vitro cell culture studies with fibroblasts and keratinocytes to evaluate their interaction with the spacer fabric.
2. *In vivo* animal studies and clinical trials are important and necessary to evaluate the clinical capability of these three-dimensional warp knit spacer fabrics for their application as wound dressings with vacuum assisted therapy.

3. As the dressing material is constantly under vacuum during vacuum assisted wound therapy, it is recommended that the effect of this constant vacuum be evaluate experimentally in terms of the properties of the spacer fabric. Any changes in the dressing's properties should be identified and quantified.

4. As the three layers in the spacer fabrics are knitted independently of each other, it is recommended to construct the spacer fabric such that it has smaller pore sizes on the face layer and larger pore sizes and a more open structure on the back side. This will prevent the problem of tissue ingrowth on the wound contact surface while improving the absorption of the exudate with larger pores on the back layer.

5. The use of antimicrobial dressings have proven to be advantageous in the healing of several types of wounds. It is recommended that silver nanoparticles be impregnated into these spacer fabric dressings and their antimicrobial performance be evaluated.
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