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MESHR: A Modular, Economical Skin Graft Hand Roller

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Department of Bioengineering

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MESHR: A Modular, Economical Skin Graft Hand Roller

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ABSTRACT

In South Africa and around the world, the rates of severe burns are a significant health issue. Skin grafts are used to improve the function and appearance of the burned area and reduce the amount of time a patient is in the hospital. To minimize the amount of skin needed and maximize the coverage of the graft, the harvested sample is meshed in a lattice pattern so it can expand and graft a much larger surface area. Unfortunately, the current methods and devices used in both high and low-income countries have been optimized for hospitals with larger budgets and more readily available resources.

In this project, we developed a frugal skin graft expansion device for low resource settings in developing countries. After identifying the needs of low-resource countries, we prototyped possible solutions and tested them, achieving both the meshing pattern and graft expansion. We then created further iterations of our design to more fully meet the needs of developing countries.

We believe our frugal device will fill a need in the current field of burn care devices in developing countries and significantly increase the number of burn patients successfully treated in low resource settings, allowing them to reintegrate into society and live healthy and productive lives.

Keywords: skin graft, skin graft expansion, mesher, severe burn, roller, burn victim, low resource

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We dedicate our thesis to individuals in low-resource settings who are the victims of big corporations. We advocate for and stand with you.

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LIST OF ABBREVIATIONS

WHO	World Health Organization
HICs	High-income countries
LMICs	Low- and middle-income countries
TBSA	Total burn surface area
EWH	Engineering World Health

CHAPTER 1: Introduction

This chapter will provide context and data on burns in low resource countries and describe the state of burn care specifically in South Africa. We will give an overview of the skin grafting process and the current treatment methods in South Africa. From this information we will discuss the identification of the problem to be addressed by our project. We will then carefully review the existing meshing techniques used worldwide and conclude with our proposed solution to the problem as our overall goals for the project.

1.1 Data and Statistics of Burns and Burn Victims in Low- and Middle-Income Countries

The World Health Organization (WHO) classifies burns as a public health problem, for they account for 265,000 deaths worldwide annually.[1] The WHO defines a burn as an injury to the skin caused by heat (hot objects, gases, or flames), chemicals, electricity and lightning, friction, or radiation. Burn injuries are more common in developing countries–hereafter known as low- and middle-income countries (LMICs)–than in high income countries due to higher rates of poverty and illiteracy and higher population densities; additionally, burn injuries in LMICs result in higher mortality rates than in high-income countries (HICs). Treatment centers in LMICs lack adequate drugs and fluids, and there is often a critical delay between injury and hospital admission due to ignorance, superstition, and ties to cultural and traditional beliefs.[2]

Most young adults and men suffer burns in the workplace, whereas most burn injuries sustained by women, children, and the elderly occur in the home. Domestic burn injuries are often caused by traditional practices of cooking and cleaning and by clothing fabric catching on fire. Across all age groups, the most common burn injuries occur by flame, and the place of injury is most often the kitchen.[3] Over 90% of burn-related fatalities occur in low-income

[1] Forjuoh, S. (2006). Burns in low- and middle-income countries: A review of available literature on descriptive epidemiology, risk factors, treatment, and prevention. Burns, 32(5), 529-537. doi:10.1016/j.burns.2006.04.002
[2] Onuba, O., & Udoidiok, E. (1987). The problems and prevention of burns in developing countries. Burns, 13(5), 382-385. doi:10.1016/0305-4179(87)90128-8
[3] Atiyeh, B., A. Masellis, and C. Conte. "Optimizing Burn Treatment in Developing Low- and Middle-Income Countries with Limited Health Care Resources (Part 1)." *Annals of Burns and Fire Disasters* 22.3 (2009): 121–125. Print.

countries; the majority of the victims are children, and many of these fatalities are believed to be preventable.[4,5]

Burn injuries are devastating due to both physical wounds as well as emotional and mental trauma. Victims of burns are at an elevated risk of suffering from long-term psychological effects such as acute stress disorder, depression, suicidal thoughts, and post-traumatic stress disorder, for as long as two years after the initial burn injury.[6] Other long-term effects include social isolation due to disfigurement and financial burden due to the cost of the treatment required.[7] On a societal scale, burn management in LMICs proves to be an ongoing difficulty due to limited resources, inaccessibility to advanced skills and technologies, and lack of successful government-funded prevention program. In a study that took place across 458 hospitals in 14 LMICs, only 37.9% of hospitals were able to treat burn complications because of lack of education and/or infrastructural problems such as lack of technology.[8]

1.2 Case Study: South Africa

Annually, 3.2% of South Africa's population of 56 million people are affected by burn injuries. Of these 1.8 million victims, 50% of them are twenty years old or younger with a disproportionate number of infants and toddlers. Burns are the leading cause of death and injury for young children in South Africa, leading to the highest pediatric burn admission in the world.[9] The highest rates of hospitalization incidences are found in Western Cape, Cape Town, South Africa where there are about 700-800 cases reported annually.[10] Every year from 2003-2008, approximately 45% of burn patients sustained burns that covered between 10% and 40% of their

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[4] World Health Organization. (2017). Burns. Retrieved from http://www.who.int/violence_injury_prevention/other_injury/burns/en/

[5] Peck, M., & Pressman, M. (2013). The correlation between burn mortality rates from fire and flame and economic status of countries. *Burns*, 39(6), 1054-1059. http://dx.doi.org/10.1016/j.burns.2013.04.010

[6] Dalal, P. K., Saha, R., & Agarwal, M. (2010). Psychiatric aspects of burn. Indian Journal of Plastic Surgery : Official Publication of the Association of Plastic Surgeons of India, 43(Suppl), S136–S142. http://doi.org/10.4103/0970-0358.70731

[7] Jain, M., Khadilkar, N., & De Sousa, A. (2017). Burn-related factors affecting anxiety, depression and self-esteem in burn patients: an exploratory study. *Annals of Burns and Fire Disasters*, *30*(1), 30–34.

[8] Shailvi Gupta, Evan G. Wong, Umbareen Mahmood, Anthony G. Charles, Benedict C. Nwomeh, Adam L. Kushner. Int J Surg. 2014 Oct; 12(10): 1070–1073. Published online 2014 Aug 21. doi: 10.1016/j.ijsu.2014.08.353

[9] Niekerk, A. V., Tit, N., Lau, U., & Arendse, N. (n.d.). Chapter 3. In Burns. (2011) (pp. 24-43).

[10] Parbhoo, A., Louw, Q., & Grimmer-Somers, K. (2010). Burn prevention programs for children in developing countries require urgent attention: A targeted literature review. Burns, 36(2), 164-175. doi:10.1016/j.burns.2009.06.215

total body surface area (TBSA). Common causes were hot water scald (20%), flame burn (39%) and chemical/accelerant burns (21%), accidental burn (32%), intentional injuries (5.7%) and intentional self-harm (3.5%), and injuries due to shack fires and fuel stoves (21%), with kerosene stoves accounting for 71% of these injuries.[11]

Despite the prevalence of burns in South Africa, there are only six established burn facilities in the country for severe cases, and the rest are treated in general hospitals or trauma clinics. Additionally, less than 5% of the national healthcare budget is allocated to burns, and the average cost of treatment is twice as high as it is in the United States, an HIC.[12] Burns are a preventable injury in South Africa. The suggested measures to decrease the number of burn victims include urban regeneration, the provision of safe energy sources, reorganization of burn services, legislation to improve building standards, and heating and lighting facilities. In addition, the establishment of effective and preventative education measures and programs can reduce the number of burn incidents.[13] These prevention measures are expected to incur numerous costs to the government and take many years before measurable benefits are apparent. We hope to develop a simple yet effective solution that upon implementation will reduce the mortality and morbidity of victims of burns.

1.3 Skin Graft Purpose and Process

A skin graft is a piece of skin taken from either the patient's healthy skin (autograft) or a cadaver (allograft) and usually includes both the epidermis and the dermis. There are four main steps of skin graft surgery: debridement of the wound, harvesting of the skin graft from one or more donor sites, expansion/meshing the skin graft, and fixation (Figure 1).

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[11] Albertyn, R., Rode, H., & Numanoglu, A. (2014). Pediatric burn care in sub-Saharan Africa. African Journal of Trauma, 3(2), 61. doi:10.4103/1597-1112.154921

[12] Allorto, N., Clarke, D., & Thomson, S. (2011). A cost model case comparison of current versus modern management of burns at a regional hospital in South Africa. Burns, 37(6), 1033-1037. doi:10.1016/j.burns.2011.04.004

[13] Rode, H., Berg, A. M., & Rogers, A. (2011). Burn Care in South Africa. *Annals of Burns and Fire Disasters*, *24*(1), 7–8.

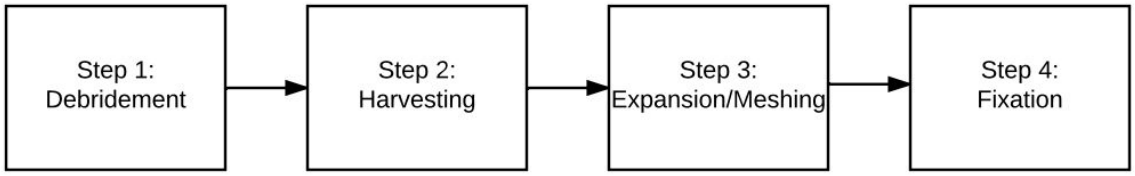

Figure 1. Overview of Skin Graft Process

Debridement is the process of preparing and cleaning the wound site for the skin graft. Harvesting the skin graft is commonly performed with a dermatome, which is a tool that provides rapid and consistent fragments of uniform-thickness skin grafts.[14] Next, the harvested skin graft is expanded by making small, parallel cuts in the skin graft and stretching it to form a mesh pattern. The meshed grafts will cover a larger area with reduced morbidity and allow for blood and fluids to drain easily.[15] The final step is fixing the skin graft to the wound site. Multiple fixing methods exist, including skin staples, sutures, glue, and fibrin sealants.

1.4 Current Methods for Treatment of Burn Injuries in LMICs

Clinical treatment methods of burn injuries are similar in LMICs and HICs. Clinical management of burn injuries is determined by the initial assessment of the burn area. The first, critical step is a clinician estimation of the TBSA, which is generally assessed using the "Rule of Nines" (Figure 2). The Rule of Nines is an assessment of burn percentage and used to help determine appropriate treatment. This rule is acceptable for patients over the age of 10 and must be modified for children. Although this is a general rule followed for multiple burn types, electrical burns may have a greater burn area than what can be seen on the surface.

[14] https://emedicine.medscape.com/article/876290-overview#showall
[15]http://plasticsurgery.stanford.edu/content/dam/sm/plasticsurgery/documents/education/microsurgery/FlapsSelectedReadings.pdf

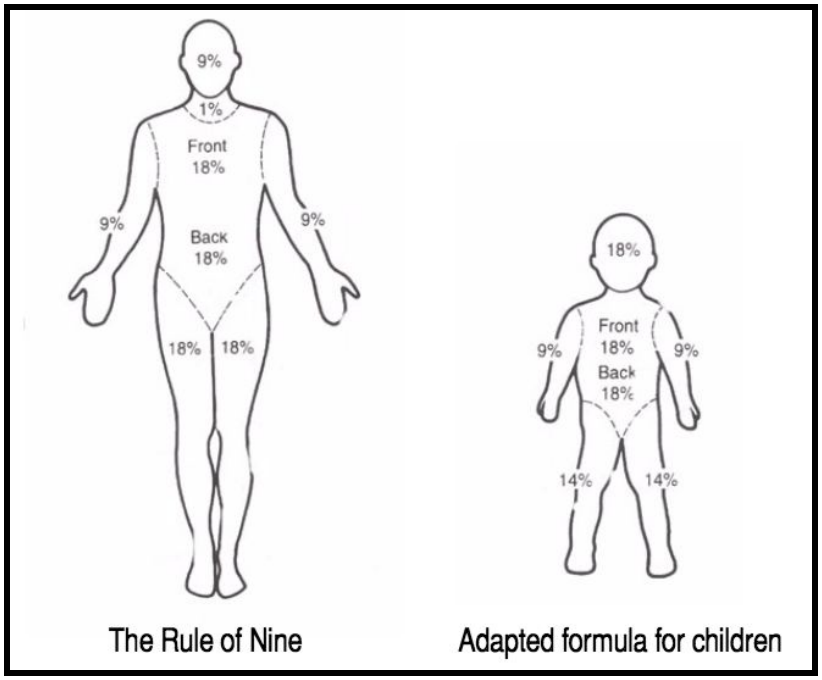

Figure 2. Body Surface Area Distribution

The other important clinical evaluation that will determine further management and outcomes is estimation of the burn wound depth, which may take up to three to four days to become evident. For clinical purposes, there are only two main types of skin grafts: split-thickness and full-thickness (Figure 3). A split thickness graft includes the epidermis and part of the dermis, and a full-thickness graft has the epidermis and the whole dermis. The MESHR is primarily designed for patients with full-thickness burn wounds, as split-thickness wounds rarely require skin grafts.

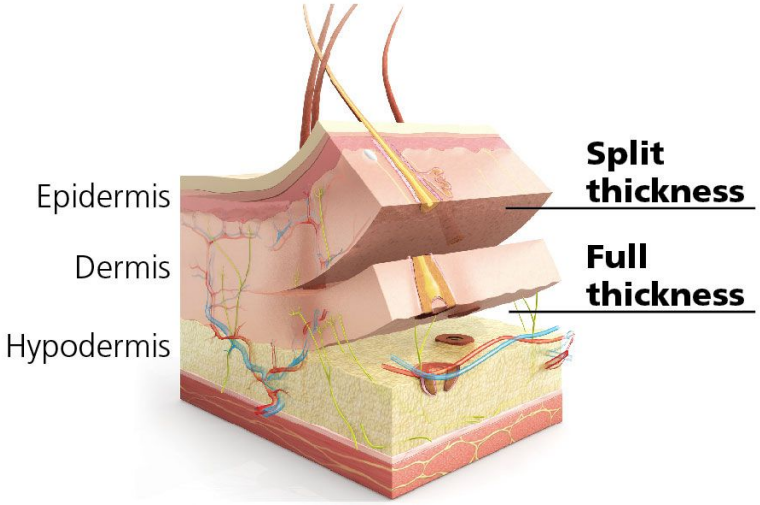

Figure 3. Full Thickness vs. Split-Thickness Graft

Definitive clinical management for any major burn injury must begin during the first 24 hours after injury for successful outcomes, which is a problem in LMICs where patients do not have access to nearby treatment centers or are otherwise not equipped to seek immediate treatment. Once patients arrive at the treatment center, they should undergo a primary assessment, which includes:[16]

- airway maintenance with cervical spinal control
- breathing and ventilation
- circulation with haemorrhage control
- disability and neurological status
- exposure and environmental control
- fluid resuscitation proportional to burn size

Intravenous fluid resuscitation is key to the success of burn management. The most common formula for calculating resuscitation fluids for burn patients in Africa is the Parkland formula. The Parkland formula estimates the amount of replacement fluid in the first 24 hours in a burn patient needed to keep the patient thermodynamically stable.[17] Eighty-nine percent of clinicians surveyed at the Pan-African Burn Society Congress of 2012 use Ringer's lactate solution, a saline solution, for resuscitation purposes.[18] Once patients have received a resuscitation solution, clinicians must determine how long they must wait to excise the burns and apply grafts. In the meantime, burn wounds are treated with dressings and antimicrobial agents to prevent infection. If the treatment center has the appropriate resources and a well-trained staff, a full- or split-thickness skin graft will be applied to the wound for 3-5 weeks.[19]

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[16] Karpelowsky, J., & Rode, H. (2008). Basic principles in the management of thermal injuries. *South African Family Practice,* 50(3), 24-31. http://dx.doi.org/10.1080/20786204.2008.10873712

[17]Parkland formula - fluid resuscitation in burns patients 1: Using formulas. (2008, April 8).Retrieved from https://www.nursingtimes.net/clinical-archive/accident-and-emergency/parkland-formula-fluid-resuscitation-in-burns-patients-1-using-formulas/1060595.article

[18] Rode, H., Rogers, A., Cox, S., Allorto, N., Stefani, F., Bosco, A., & Greenhalgh, D. (2014). Burn resuscitation on the African continent. *Burns*, 40(7), 1283-1291. http://dx.doi.org/10.1016/j.burns.2014.01.004

[19] Gallaher, J., Mjuweni, S., Shah, M., Cairns, B., & Charles, A. (2015). Timing of early excision and grafting following burn in sub-Saharan Africa. *Burns*, *41*(6), 1353-1359. http://dx.doi.org/10.1016/j.burns.2015.02.011

1.5 Problem Identified

The third step in the grafting process (Expansion/Meshing) is the area with the greatest opportunity for improvement for treatment of burn injuries in LMICs. As mentioned earlier, not only does meshing the skin graft provide a larger coverage over the burn, but it will also provide more donor sites for regeneration in patients with very large TBSA and minimize the donor site area needed for all patients.[20] Meshing can increase the amount of area one graft can cover by up to 9 times. Any faults in this step can inhibit these processes and cause infection, poor healing, severe scarring, and even death. The current methods and devices used in treatment centers in LMICs have been optimized for hospitals in HICs that have larger budgets and more readily available resources. The meshing devices used in the United States are generally expensive to purchase and maintain; as a result, they are often used past their lifespans in developing countries. Therefore, the opportunity for improvement seen in this step for LMICs is significant; improving skin graft expansion could lower the fatality rate and mitigate the physical and emotional trauma due to burns.

1.6 Review of Existing Research for Meshing Techniques Worldwide

Understanding the current devices and techniques used for skin meshing/expansion both in LMICs and HICs is crucial to understanding why the expansion/meshing step is not optimized and how we can design a useful solution. There are many ways to mesh a partial-thickness skin graft, ranging from paper expansion, cutting, and suspension of skin pieces.

1.6.1 Current and Novel Techniques[21]

The following list will describe four current and novel techniques to mesh a skin graft.

1. **MEEK Micrografting** is a technique that relies on cutting a small skin graft horizontally and vertically, transferring it to gauze, and expanding the gauze in order to create desired expansion ratios. Ratios refer to the pattern of the serration of a single blade. This

[20]Kadam, D. (2016). Novel expansion techniques for skin grafts. *Indian Journal of Plastic Surgery : Official Publication of the Association of Plastic Surgeons of India*, *49*(1), 5–15. http://doi.org/10.4103/0970-0358.182253
[21] Kadam, D. (2016)

technique allows for true expansion, but it is labor intensive. The technique was introduced to the Red Cross War Memorial Children's Hospital in Cape Town, South Africa, in 2011 and has been used on many pediatric patients with 15-86% TBSA.[22]

2. **Meshed grafts** utilize a mechanical technique in which the skin is cut using blades, allowing the skin itself to be stretched. It is the most common and accessible technique and there are different variations on instrumentation used. In this method, true expansion may not be achieved and there can be difficulty in handling skin in larger expansion ratios.
3. **Micrografting (Xpansion® System)** is a technique that uses micro grafts (0.8mm x 0.8mm), applies them to the burn, and then dresses the burn with gauze. The small grafts can be achieved with a handheld blade and can also yield high expansion ratios, but this technique requires specific instrumentation and may take multiple sessions for large burns.
4. **Pixel Micrografting** is similar to the Xpansion® System micrografting technique but utilizes grafts that are 'pixel' sized; a special mincing device cuts the skin graft 5 times in each direction in order to achieve grafts that are 0.3mm x 0.3mm. This technique has yielded even higher expansion ratios than previous micrografting techniques, but is still undergoing research.

Due to the time and resource limitations on our project, as well as the resource and skill limitations in LMICs, we decided to focus on technique #2: meshed grafts. This technique would address the established need and be most readily available and applicable because doctors would be able to simply mesh the grafts using a machine to make cuts. Therefore, we examined the current market for these types of devices.

1.6.2 Current Meshing Devices

The following section will describe five current meshing devices.

[22] Rode, H., Martinez, R., Potgieter, D., Adams, S., & Rogers, A. (2017). Experience and outcomes of micrografting for major paediatric burns. *Burns*, *43*(5), 1103-1110. http://dx.doi.org/10.1016/j.burns.2017.02.008

1. **The Humeca MEEK Micrografting**[23] device utilizes pieces of skin cut to the size of a square cork plate, which is fed through the device twice using a crank. An external motor is attached to the machine to make the cuts, creating small, 4mm x 4mm square grafts. The resulting grafts are then sprayed with glue while still on the cork plate and transferred to pre-folded gauze; the gauze is then expanded by pulling and is then placed and fixated on the burn area. This technique requires many tools (motor, blades, cork plates, glue, pre-folded gauze, etc.) and contains numerous consumables. The device can be autoclaved (sanitized) if disassembled.
2. The **Brennen Skin Graft Mesher**[24] is a device that uses a crank system in order to mesh the skin graft as it is fed through. Each device has a fixed ratio, with 1:1, 1:2, 1:3, and 1:4 expansion ratio meshers available. It will mesh both thin and thick grafts, and it does not require any carrier or other consumable to lay the graft on while it is fed through the mesher. This is beneficial because there is no risk of carriers being lost or unavailable. The mechanism used in this mesher is pinching the graft instead of cutting. Additionally, the device is autoclavable.
3. The **Zimmer Biomet Skin Graft Mesher**[25] also utilizes a crank system in order to feed the graft through the device; however, this mesher uses different cutters to achieve different expansion ratios (1.5:1, 2:1, 3:1, 4:1) that can be switched between use. It also has smooth, disposable carriers to place the skin graft on when feeding it through the mesher, which are designed for single use, creating more consumables. The device comes with an autoclave case and can be autoclaved if disassembled.
4. The **Aesculap Power Systems Skin Graft Mesher**[26] only has a single cutter, and the graft expansion ratios are determined by the patterned carrier that the graft is placed on, with 1:1.5, 1:3, and 1:6 expansion options available. This device also takes advantage of the crank mechanism in order to feed the carrier and graft through the mesher. It contains

[23] BV Humeca, The surgical procedure of MEEK micrografting (2011) from https://www.youtube.com/watch?v=6TDpQ2Qu2ys
[24] Taghizadeh, R. & Gilbert, P. M. (2008). Comparison of commonly used mesher types in burns surgery revisited. Burns 34, 109-110.
[25] The Zimmer® Skin Graft Mesher (2012) from https://zimmerbiomet.tv/videos/406
[26] The Aesculap Power Systems Skin Graft Mesher pamphlet https://www.aesculapusa.com/assets/base/doc/doc107_rev-skin_mesher.pdf

a cutter adjustment to accommodate different graft thicknesses and has a continuous feed carrier guide to make it easier to create long, uniform grafts. The carriers are disposable and are a consumable associated with this device.

5. The **Humeca SOBER Mesher**[27] is Humeca's cost-effective mesher design: the compact mesher has a maximum graft width of 45mm and uses a snipping mechanism to mesh the graft to avoid the need for blade sharpening or replacement. It has a fixed ratio of 1:2.5, and the graft must be fed through the mesher carefully as the snipping mechanism utilizes two rollers on top of one another, with the skin graft fed between them. A knob on the side of the machine is turned in order to move the graft through the device. It does not contain any consumables.

1.6.3 Critiques and Drawbacks of Current Devices

1. **Humeca MEEK Micrografting:** According to Rode et al., "there is a considerable 'learning curve' associated with this technique."[28] Thus, it is not a viable solution for settings in which there is not a well-trained interdisciplinary team with a great deal of experience. Furthermore, the use of many consumables make this method less than ideal for resource-constrained settings and those where last-mile distribution is an issue. Finally, the need for disassembly of the micrografting device for autoclaving can lead to loss of parts which will limit the treatment center's ability to treat patients.
2. **Brennen Skin Graft Mesher:** While the Brennen mesher does not require carriers for its use (reducing long-term cost), each device can only achieve a single meshing ratio. The size of each graft is limited only by the width of the mesher, which is 10cm, and can mesh any length of graft. If more than one meshing ratio is desired, which is the norm for most burn treatment centers, multiple Brennen meshers must be purchased. This poses an issue because a single Brennen mesher costs approximately $7,800.[29] This is a large investment that may not be feasible for many resource-constrained treatment centers.

[27] Humeca: Cost Effective Devices from http://www.humeca.com/cost-effective-devices/
[28] Ibid.
[29] Ibid.

3. **Zimmer Biomet Skin Graft Mesher:** The standard Zimmer mesher is one of the most widely used throughout the world because it is modular and can achieve numerous expansion ratios. The device must be disassembled to be autoclaved, potentially leading to loss of parts. The use of consumable graft carriers may pose an issue for resource-constrained treatment centers because each carrier costs approximately $20[30]. Furthermore, the size of graft is limited by the size of the carrier, which is only 7.6 cm wide and 20.3 cm long. Some clinicians have described grafts folding on the carrier, which reduces the quality of the graft. While Zimmer recommends using each carrier once, they are used two to three times per operative case, even in HIC treatment centers. Overused carriers can compromise the graft quality. Clinicians have described difficulty peeling thin grafts from the carrier, and thick grafts sliding on the carrier as they advance through the mesher. These challenges can lead to tearing of the graft and, ultimately, reduced viability. Zimmer meshers are an expensive investment at approximately $6,900.[31]

4. **Aesculap Power Systems Skin Graft Mesher:** The Aesculap skin mesher also uses consumable graft carriers, which can limit clinicians' ability to treat patients if they are lost or unavailable. There is an added cost due to the need for different carriers for different expansion ratios. The mesher can be autoclaved if it is disassembled, possibly leading to loss of parts. Aesculap claims its mesher can achieve a 1:6 ratio with the largest carriers, but Vandeput et al. determined that the actual expansion ratio was 1:2.93. This large of a difference between claimed expansion ratio and actual ratio is undesirable as a surgeon using it has a certain expectation for particular ratios of meshing, and not achieving the correct one may result in a burn not being completely covered by a graft.[32]
5. **Humeca SOBER Mesher:** The SOBER mesher was designed for use in LMIC hospital settings. Thus, it does not require disposable graft carriers, whose cost accumulates over time and limits graft length. However, the SOBER mesher only has one expansion ratio (1:25), which may limit clinicians' ability to treat patients with very large TBSA injuries.

[30] 00-2195-013-00: ZIMMER DERMACARRIERS II SKIN GRAFT CARRIER from https://www.esutures.com/
[31] Ibid.
[32] Ibid.

Furthermore, the width of grafts is limited to 4.5 cm. For all of the aforementioned roller-type graft meshers, if the skin gets dislodged to one side while moving through, the quality of the mesh is significantly reduced.

1.7 Project Goals, Objectives, and Results

Our goal, first and foremost, was to demonstrate proof of concept for our idea; our device needed to make cuts in the skin graft that lead to a greater surface area of the graft when stretched. In addition, we needed to achieve a meshing pattern while keeping the skin taut for an even cut without crushing the graft. After that had been established, we aimed to optimize different meshing ratios while keeping the device manually-powered, autoclavable, and comprised of a limited number of parts. Production and maintenance costs of the device also needed to be low.

We were able to validate our proof of concept for our unique rolling device style. Through our prototyping, testing of the blade cartridge subsystem, and iteration on our designs, we created a device that could achieve different meshing ratios while being manually-powered, autoclavable, and a low number of parts. The only aspect of the device we did not achieve by the end of our time frame on this project was implementing a fixation method to keep the graft in place while the meshing occurs.

CHAPTER 2: Systems Level

The following section will identify and describe the various subsystems involved in our device design.

2.1 Systems Level Overview

The device that we proposed as a solution contained various parts that could be separated into three main subsystems: the handle & stabilization mechanism, the cartridge bar with blades, and the cutting board & skin-fixation-while-meshing mechanism. These three subsystems interact to create a useful meshing device. Although the handle, stabilization mechanism, and blades were the three components that would be integrated into a single device, the cutting board and skin-fixation mechanism were also vital for the efficacy of the proposed device. Figure 6 illustrates our final physical integration of these parts.

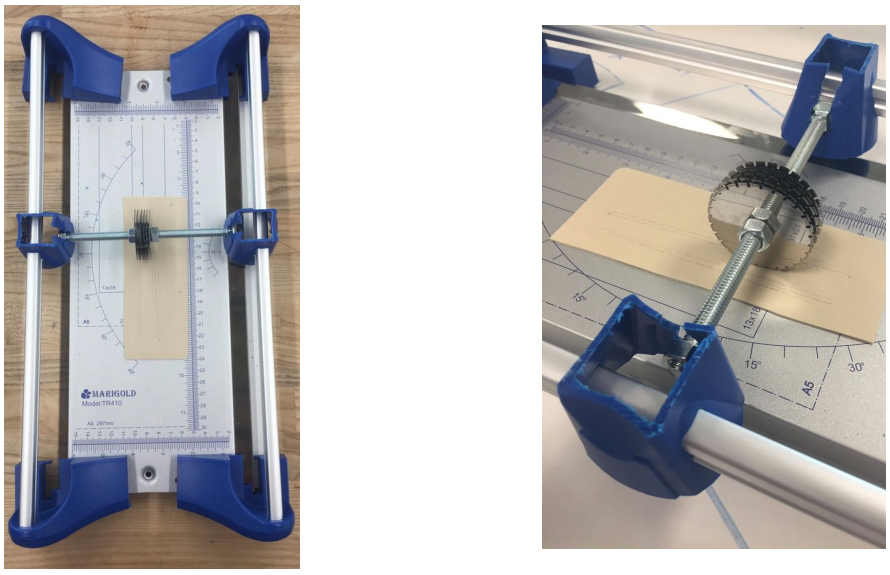

Figure 4. Final Device

As shown in the figure, the cartridge bar is connected to the sliding bars on each side in a manner that will allow the rolling of the blades while the user moves the handles forward. Here, the handles were not implemented, but would be placed on the outside of the blue sliding plastic pieces. In this device, the sliding bars on each side of the blade cartridge serve as the stabilization mechanism to ensure predictability. All of the parts are singular and attached by

screws, nuts, or pre-cut holes; the bars and sliding mechanism are directly attached to the cutting board but are removable, and there is no fixation mechanism in place here. The cutting board is long and about the width of the cartridge bar with blades to accommodate the stabilization sliders; the width of of the blade section in Figure 6 is about one fifth of the actual width of a blade cartridge.

The integration of these parts would allow the use of the device following these steps:

1. The blade cartridge is inserted into the device.
2. The skin graft is placed on the cutting board.
3. Using the two handles, the blade cartridge is rolled over the skin graft to achieve correct cutting.
4. The skin graft is removed from the cutting board and placed on the patient.

2.2 Customer Needs and System Level Requirements

Based on customer reviews of current devices, conversations with our industry advisor, and interviews with contacts in South Africa, we identified our customer needs and system level requirements. We calculated the opportunity of each by rating the importance and current satisfaction of each, utilizing the opportunity equation:

$$Opportunity = Importance + (Importance - Current\ Satisfaction)$$

Through the opportunity equation, we identified the areas with the most opportunity for improvement: creating a less expensive and less time-consuming meshing device, followed by making sure the device is reliable and autoclavable. With these customer needs in mind, we formulated our design requirements, outlined in Table 1.

Table 1. Design Requirements

Feature	**Reason**
Cuts meshing pattern	The meshing pattern is essential for covering a larger surface area, encouraging better graft take, better healing, and relevance of the device.
Autoclavable	All surgical equipment must be sanitized to eliminate cross-contamination. Autoclaving is a common sanitization method in low-resource settings.
Man-powered	It can be used in burn centers with any level of resources.
Minimum number of parts	Reduces manufacturing costs and also makes disassembly easy for cleaning.

We aimed to pay particular attention to material selection (for cost) and ease of use of the device in our system level. A detailed calculation of the opportunity for the customer needs can be found in Appendix I.

2.3 Benchmarking Results

The current mark of "success" of a meshing device is (1) the ability to make cuts in the skin, (2) the ability of the graft to expand to a larger surface area, and (3) the maintenance of the integrity of the graft. The actual quantitative measurement of how much the graft is expanding is not commented on in literature; using a 2:1 or 4:1 ratio guarantees the amount of expansion because it is consistently used on a very thin piece of skin. Current device manufacturers do not report quantitative results that we can use as a benchmark, which made it difficult for us to compare our results.

That said, we focused both on the quantitative measurement of the expansion and on the qualitative aspects we could observe to prove the efficacy of our device.

2.4 Functional Analysis

This section serves as an introduction to the system broken down into the main subsystems; please refer to the subsequent chapters for additional detail.

2.4.1 Functional Decomposition

Our device performs two main functions: to cut the skin and to do so in a rolling manner.

The main function of the device is to cut the skin in a specific pattern to be able to expand the skin graft. The cutting function relies on many different aspects including the sharpness of the blades, the number of blades, the placement of the blades, the thickness of the graft, the pressure applied to the blades during meshing, the movement of the skin during meshing, and the material surface that the blades are being used on.

A sub function, though equally important to the cutting of the skin, is the rolling aspect of the device. This function differentiates our solution from other solutions on the market (see Chapter 1) because our cutting mechanism is moving instead of the skin moving. This function relies on the stabilization of the device, the friction from the skin and cutting board material, and the amount of force put behind the device.

2.4.2 Subsystems

Our device can be broken down into three main subsystems:

1. **Handle & Stabilization Mechanism:** This subsystem is paramount because it addresses the utility of the device and the ease of use. The handle(s) needs to be easily and comfortably gripped by the user and allow for even and firm pressure of the cartridge across the skin graft. The challenge for this subsystem was providing even and strong pressure by the user across the entirety of the graft as it rolled without compromising the simplicity of the design.
2. **Cartridge Bar with Blades:** This subsystem is the most complex of the three subsystems because it contains the most individual parts and is essential to the utility of the device. It must offer the surgeon at least two options of meshing ratios, accurately produce a mesh ratio, and remain simple enough to use and clean. For maintenance, blades need to be easily cleaned and repaired and inexpensive to replace. Most of the budget was allotted to this subsystem for purchasing blades and materials to model and test the cartridge.
3. **Cutting Board & Skin Fixation while Meshing:** This subsystem is crucial because if the graft is not held in place or the cartridge is not held even, the meshing of the graft

could be unsuccessful and ruin the graft for use. This cutting surface needs to allow for the rolling cartridge to lock in place and guide the user. It also needs to ensure the graft is kept in place rather than rolled upwards with the rolling motion of the cartridge. Additionally, the cutting board needs to be a stiff material to provide resistance against the blades, but preferably not as stiff as metal so the blades have a backing material to cut into and do not dull quickly.

2.5 Key System Level Tradeoffs

In order to combat any integration issues with the various subsystems, we prioritized certain criteria and goals that helped us determine what aspects were most crucial to optimize. Please refer to Appendix I to find a detailed calculation of the opportunity of the desired customer needs.

The two customer needs with the highest opportunity are creating a less expensive and less time-consuming device. With these in mind, we took great care in the complexity of the device, focusing on the cartridge bar with blades to make sure that use and blade replacement are intuitive and less time consuming than the current options. The cartridge bar design was essential to the device's success and took most of the time and focus. As a result, the handle and cutting board did not receive as much design consideration.

A tradeoff we made throughout our design process was the size of the device; as we realized the various changes we wanted to make--using two handles instead of one, having a larger cutting board surface, implementing the sliding bar stabilizing mechanism--we were forced to make our device larger. Although we were hesitant to do this because we wanted to keep the device easily portable, we realized that getting a uniform, even, and accurate meshing pattern every time was the most important aspect of our device.

In addition, while researching possible materials we realized we had to make cost tradeoffs concerning the material selection because we wanted it to be robust and reliable (another customer need) but not too expensive. Even with this tradeoff, we believe we can manufacture our final design for less than $500.

2.6 Team and Project Management

This section will discuss the various challenges and constraints we dealt with: managing our budget and timeline, addressing the different aspects of the design process and the risks that came with it, and our own team management.

2.6.1 Project Challenges and Constraints

A significant challenge that we dealt with throughout our work was getting customer feedback in a timely manner, especially from our contacts in South Africa. Since we needed to move forward and make progress on the project, it was possible that the information we asked our contact to evaluate was outdated and the feedback provided not wholly relevant to our current design. We dealt with this constraint by relying on our US contacts, from whom we could get feedback more quickly.

Additionally, we found the time constraint to be difficult to deal with: it took time to formulate ideas, draw sketches, order materials, and plan lab time; although we were on track with our timeline, we faced numerous setbacks due to other school obligations we could not control. We addressed this by splitting up the responsibilities and relying on finding times when at least two of the members can meet.

Furthermore, we realized that the ideal prototypes that we wanted to create were not feasible with the time, money, skills, and resources we had available. We decided to create the prototypes we could to test the different subsystems and iterate based on these tests, but focused on creating a SolidWorks mockup of our final design as we were not able to manufacture a tangible prototype.

2.6.2 Budget

Table 2 outlines our proposed budget for the project as a whole; we were allocated $2,000 by the Santa Clara University School of Engineering to use for our project expenses. We expected to spend most of the funding we received on getting adequate materials to prototype our designs and to test on skin substitutes. Since one of our goals was to create a frugal device, we planned to prototype with frugal materials and did not expect to run into issues with the

budget. At the end of the project, we found that we were significantly under-budget and did not spend more than $1000.

Table 2. Budget

Activity/Product	Items	Estimated Amount	Amount Spent
Artificial Skin/Skin Substitutes	● Artificial skin or skin substitutes ○ Nitrile gloves ○ Tattoo skin ○ Plastic seat covers ○ Pig skin	$750	$10
Prototype Materials	● Metals and plastics for frame, handles ● Additional nuts, bolts, blades	$1000	$253
Sourcing Existing Solutions	● Pie crust rollers (x3) ● Dermatome	$250	$96
	Total:	$2,000	$360

2.6.3 Timeline

Table 3 outlines the timeline we followed for our project; Santa Clara University follows the quarter system, so our timeline is split into three sections. Fall quarter (September-December) was research, winter quarter (January-March) was prototyping and testing, and spring quarter (April-June) was finalizing the design and writing up our results. Throughout the project, we stayed on schedule pretty well due to regular meetings with the team and our advisor. A couple of times our prototype materials were on backorder, which slowed down the prototyping process slightly. Through these challenges, we were still able to achieve all of our goals.

Table 3. Project Timeline

Fall Quarter	**Winter Quarter**	**Spring Quarter**
Research	Prototyping	Further Testing and Iteration
Problem Identification	Testing	Final Design
Needs Finding	Iteration	Presentation
Preliminary Design	Customer Feedback	Results Write-up & Thesis

2.6.4 Design Process

With the suggestion from our SCU advisor, we utilized the Stanford Biodesign Process for our project (see Figure 7). It provided us with overarching guidelines to follow.

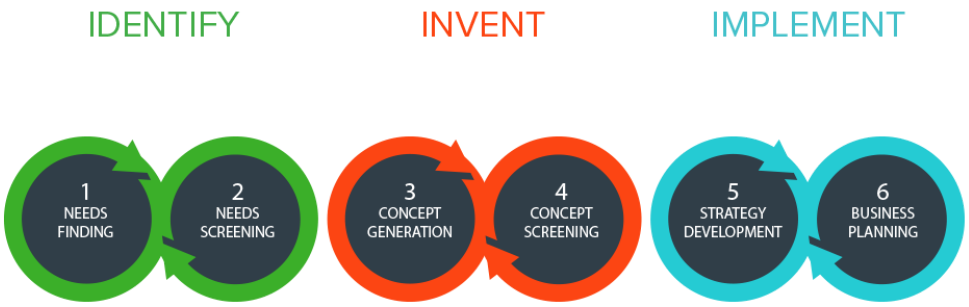

Figure 5. Stanford Biodesign Process[33]

After establishing some acceptance criteria for the project by deciding our personal goals, we used literature searches and advice from our industry advisor, Dr. Nathan Kemalyan, to help us identify the needs of burn victims in low-income countries. Next, we screened the identified needs and settled on improving the burn treatment process. We then further narrowed our focus to the skin graft meshing step (see Section 1.5). Before starting our concept generation,

[33] Stanford Biodesign Process, from http://biodesign.stanford.edu/about-us/process.html

we ran through the needs-finding process again, focusing on skin graft meshing. After establishing our design requirements (see Section 2.2), we started the concept generation step.

We began our concept generation by using bisociation and identifying the pie crust roller as a starting point for our solution, as it created the desired meshing patten we wanted for our skin mesher. By building different prototypes and iterating our designs, we continued concept generation and concept screening for the remainder of our project. Near the end of our project, we began to look at strategy development and business planning. We submitted IP to an independent consultant to identify the commercialization potential of our design, and investigated the approval process for medical devices in South Africa.

2.6.5 Risks and Mitigations

The risks of our project were relatively low; although we were working with pig skin, the lab safety precautions (long pants, closed-toed shoes, gloves) were easy to follow in order to mitigate risk. All of the team members passed lab training and followed the safety precautions in the lab.

2.6.6 Team Management

Our team had a flat structure: we had no specific leader, and we were not delegated to specific roles. The most important quality of our team management was our communication. Through keeping each other updated at weekly meetings and through text messaging, we were able to avoid issues of miscommunication and confusion.

We met with our advisor bi-weekly to update him and get feedback; we also used email as an avenue of communication. Although we looked to him as a source of guidance, we understood that we were ultimately responsible for the success of the project which helped us maintain accountability.

Furthermore, we kept an open line of communication with our Engineering World Health (EWH) collaborators as they were helpful in giving us feedback on our designs and finding contacts both in and outside of the United States.

CHAPTER 3: Subsystem: Handle & Stabilization Mechanism

This section will discuss the handle & stabilization mechanism subsystem of our device.

3.1 Evolution of Design

Our initial design for this subsystem was similar to that of a pie crust cutter with a single handle at the center of the blade cartridge (Figure 6). It would connect to the blade cartridge on each side by a metal piece.

Figure 6. Pie Crust Cutter Tool[34]

After our preliminary, unofficial testing with the pie cutter, we determined it was difficult to apply the correct and even amount of pressure necessary to make the cuts through the material samples. Thus, we decided to design stabilizing arms in order to standardize the angle at which the roller would sit, which would create a more uniform cut and pressure across the blade cartridge (Figure 7).

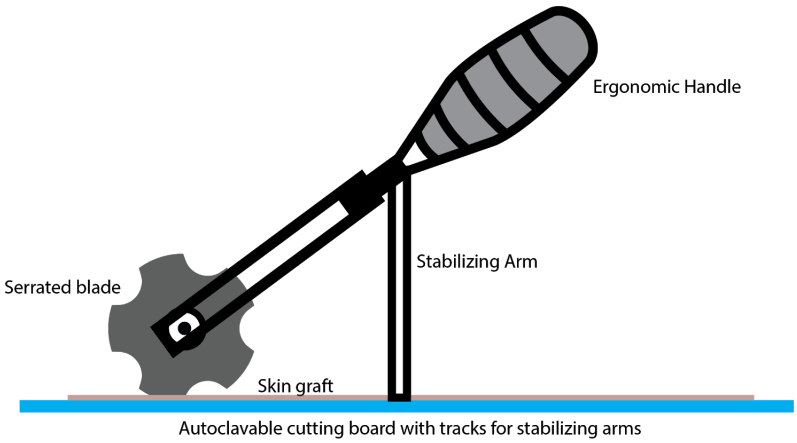

Figure 7. Initial Design with Stabilizing Arms

[34] K-Steel Roller Cutter, from www.Amazon.com

When we modeled and tested our blade cartridge, we were forced to use two handles to roll the cartridge over the sample as we did not have a single handle implemented. This opened our minds to the possibility of implementing two handles instead of just one. We decided to redesign the device to have two handles on either side of the blade cartridge similar to a rolling pin (Figure 8). We reasoned that this would be more friendly to left and right handed individuals, and also remove the issue of trying to keep the tool at a specific angle.

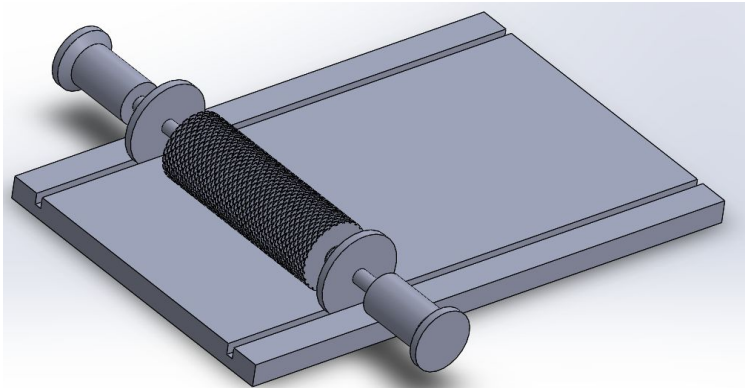

Figure 8. Rolling Pin Handle Design

Additionally, we changed the stabilizing arms to be rolling wheels in this design. This would allow the roller to move in the same path every time, allowing the surgeon to be able to place the graft on an adequate portion of the cutting board.

3.2 Final Subsystem Description

We were still worried about getting adequate pressure across the blade cartridge by just putting force on the two handles, so we investigated other possible solutions to get uniform pressure. We decided to explore the pressure mechanism in a paper cutter; by having a rubber wheel against the cutting surface, the paper cutter creates high pressure when sliding and cutting paper but does not put the pressure on the blade. Using two paper cutters blended together, we created a rough prototype of this flat design (Figure 9).

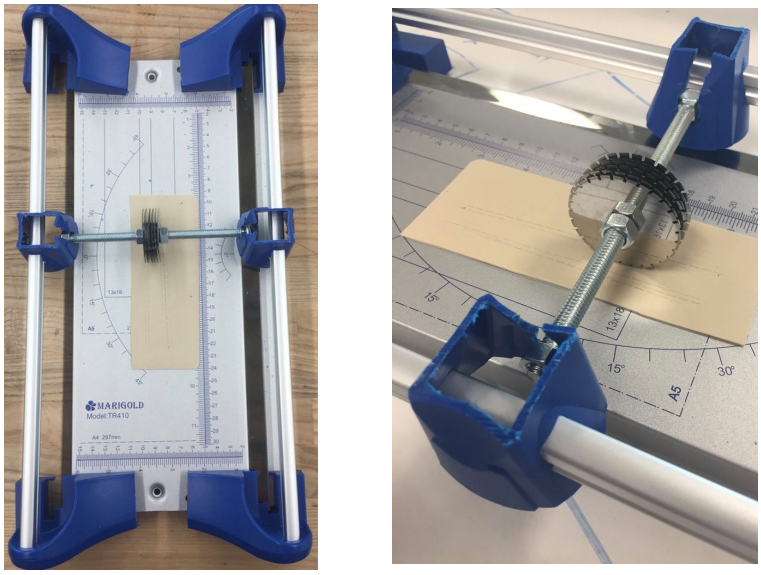

Figure 9. Final Device with Alternating Blade Cartridge

Although we did not have handles implemented in this prototype, we were able to show how the sliding bars would increase stability in rolling the blade cartridge, creating a uniform and user-friendly subsystem that would integrate well in the complete design.

3.3 Mechanics of Design

The mechanics of the handle & stabilization mechanism in this final device focus on the sliding of the plastic pieces along the bars in a manner that would allow a straight, uniform cut. The sliding would occur because the hole in the plastic piece is slightly larger than the rod, but is the same shape so it would not move around too much (see Figure 10).

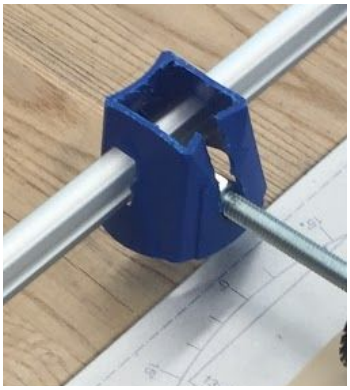

Figure 10. Lock-in and Sliding Mechanism

In addition, the blade cartridge would connect to the sliding pieces by locking into them through a downward motion, also shown in Figure 10.

3.4 Subsystem Testing

We found that testing the subsystem alone was not useful or applicable to the project; it was tested in conjunction with the other subsystems. Please refer to Chapter 6 for further elaboration on integration and testing.

CHAPTER 4: Subsystem: Cartridge Bar with Blades

The effectiveness of the cartridge bar subsystem is critical to the meshing process because it contains the blades used to cut the skin graft. Key design constraints for the cartridge bar are insurance of even cuts that produce a mesh pattern, the ability to interchange different cartridges for different meshing ratios, and durability that will last several uses before the blade need to be replaced. The cartridge bar subsystem will be the only consumable subsystem of the entire device. While the blades will be produced with durable metals designed to last for thousands of operations, they may eventually dull and require replacement. The modular design of the cutting subsystem allows users to purchase new cartridges rather than replacing the entire device.

4.1 Evolution of Design

Generally, the cutting subsystem in our designs was modeled after those found in pie crust rollers. The bar is approximately the same length as the width of the cutting board and slightly longer than the width of the standard dermatome used by surgeons in low-resource settings. The Humeca SOBER dermatome, developed for low-resource settings, is 30mm in width.[35] Our final cartridge bar is 45mm in width to accommodate grafts harvested using the SOBER dermatome, as well as larger grafts harvested using larger dermatomes.

The blades on the cartridge bar have regular serrations along the circumference. The distance between serrations varies based on the expansion ratio of each cartridge bar; hospitals will be able to purchase cartridge bars with both 2:1 and 4:1 expansion ratios (see Appendix II).

Our first design used 4:1 expansion ratio blades on a bolt, separated by washers and held together with nuts on each side (see Figure 11).

[35] Vandeput, J., Nelissen, M., Tanner, J., & Boswick, J. (1995). A review of skin meshers. *Burns*, *21*(5), 364-370. http://dx.doi.org/10.1016/0305-4179(94)00008-5.

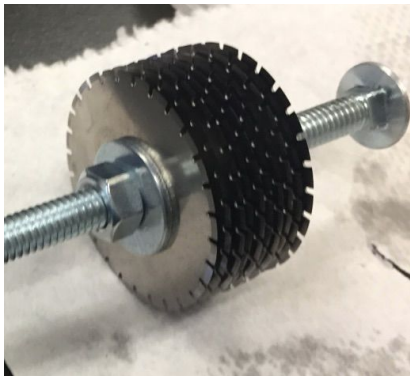

Figure 11. Initial Blade Cartridge Prototype

We found that since we weren't able to lock the blades into place, we were not getting an even, uniform pattern on our tattoo skin samples (see Appendix III). The blades should be alternating in a manner so the two blades sitting next to each other are offset. Our solution to this issue was to create a blade-locking mechanism that would keep the blades in an alternating pattern (see Figure 12).

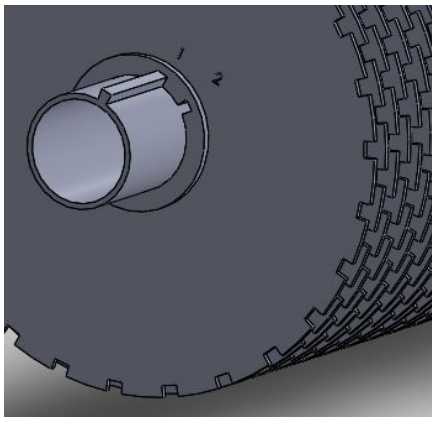

Figure 12. Blade-locking Mechanism

Although we were not able to implement this mechanism in our final prototype, we kept it in mind for our final design.

4.2 Final Subsystem Description

In addition to the alternating blade issue discussed above, we found that the threading on the bolt caused the blades to sit unevenly, which led to issues with even cutting. Thus, we decided to change the blade to a wooden dowel so the blades would sit evenly (Figure 13). We used rubber cylinders and rubber bands to keep the blades in place. We tried to glue the blades in an alternating pattern, but it did not work. In this design, we still used the 4:1 blade ratio.

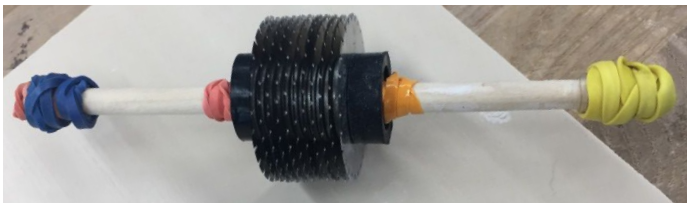

Figure 13. Blade Cartridge with Wooden Dowel

4.3 Mechanics of Design

By rolling the optimized blade cartridge on a skin sample, it will make the cuts in each graft offset from one another, ensuring a mesh pattern with maximal expansion. Each individual blade in the cartridge is evenly spaced along the bar using washers (the spacing will depend on the expansion ratio) but will cut an even, uniform pattern throughout the graft.

4.4 Subsystem Testing

Before testing our final subsystem design, we tested the actual pie roller on pig skin, along with single blades to mimic a blade cartridge (see Appendix IV). Next, we used our initial prototype (see Figure 11) and was used to create a standard mesh pattern on both tattoo skin and nitrile gloves; the tattoo skin allowed us to see the meshing pattern but the nitrile gloves did not expand significantly (see Appendix III & V). Refer to Chapter 6 for an in-depth explanation and analysis of the testing of the final subsystem design.

CHAPTER 5: Subsystem: Cutting Board & Skin Fixation while Meshing

This subsystem aims to provide an adequate cutting surface to mesh on while fixating the graft in place during meshing. It will also act as a guide for the rolling of the cartridge bar to ensure straight and accurate meshing. This is a crucial part of the overall system design because if the graft moves or the cartridge bar is not securely in place while meshing, the graft can be destroyed. Based on Dr. Kemalyan's advice, adequate material for this cutting surface could be cork or plastic. This quarter we have focused on the design of such a surface to incorporate the need of fixating the graft and guiding the cartridge.

5.1 Evolution of Design

The initial cutting board design was drawn from a standard plastic cutting board, per the suggestion of our industry advisor. In testing we used a small, flat, rectangular plastic cutting board underneath the skin substitutes. We found it to be quite difficult to cut the mesh pattern in a straight line manually and without any guiding element. Thus, we determined that we should incorporate some sort of guide to ensure that straight cuts could be made every time the device was used.

In the single-handled design, we designed longitudinal, indented tracks on both sides of the cutting board that would line up with the stabilizing bar on the handle of the device (Figure 14). The stabilizing bar would slide along these tracks to guide the movement of the user so that straight, even cuts could be made every time.

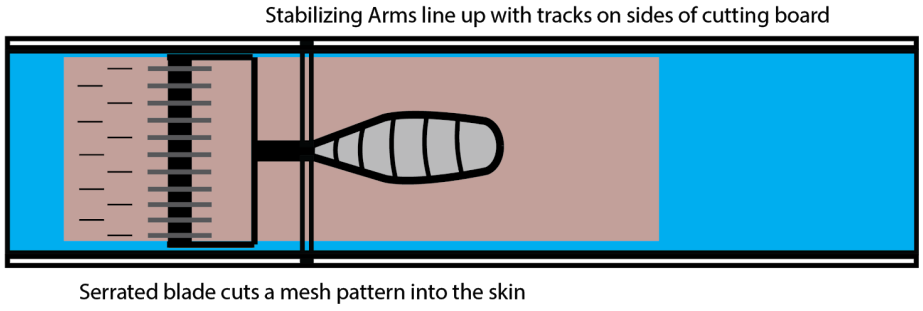

Figure 14. Single-handled design with indented tracks.

When we moved to a dual-handled design, we kept the indented tracks in the cutting board from the previous design. On the dual-handled design, raised portions of the handles would roll along the tracks to ensure a straight cutting motion (Figure 8).

In our final design, the guiding mechanism is slightly more robust. The design for these tracks was inspired by the track on the side of a paper cutter that guides a round blade across the sheet of paper, creating consistently straight, even cuts. In the paper cutter-inspired design, rectangular plastic bars run along either side of the cutting surface. Rectangular plastic carriers slide along each track and attach to the handles and blade cartridge (Figure 15).

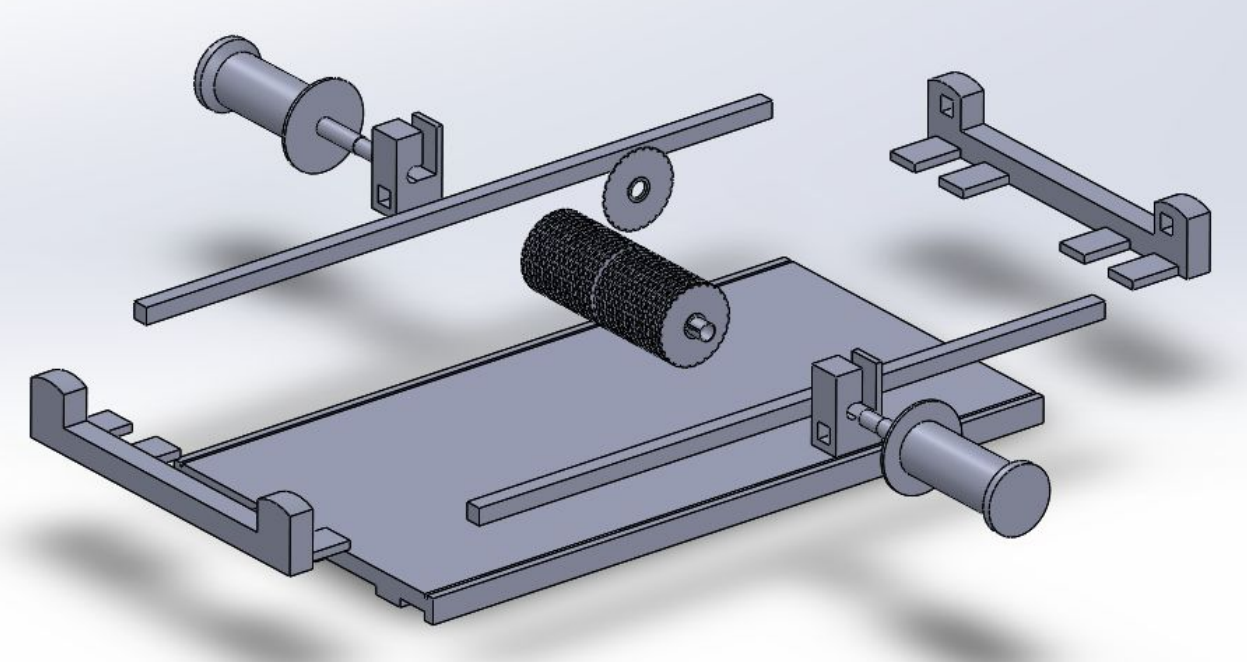

Figure 15. Exploded view of dual-handled design with raised tracks.

5.2 Final Subsystem Description

This subsystem includes two main components: the flat cutting surface and the raised tracks. Both components will be made of the same hard autoclavable plastic, which will allow them to be manufactured simultaneously via a singular pour-in molding process.

The flat cutting surface is 15 cm wide and 30 cm long to accommodate grafts harvested with any size dermatome. On either end of the cutting surface there will be raised portions to where the tracks attach. These tracks are rectangular in shape and run the full length of the cutting surface, 2 cm above the cutting surface.

We have not yet designed a fixation mechanism to keep the skin taut while it is being cut. During testing, the skin would roll up into the blade cartridge. This required a second user to hold the skin down to keep it from getting stuck in the blades. In future iterations, we will implement a clip-like mechanism on the end of the cutting surface to hold the skin taut as it is being cut.

5.3 Mechanics of Design

The plastic cutting surface is textured to allow the graft to "cling" to it via capillary action. When the skin is placed dermis-side down on the cutting surface, water molecules on the cutting board "pull" water within the skin to help it cling to the surface[36]. This ensures that the skin is always flat before being cut, eliminating the risk of folding which causes uneven cutting an results in reduced graft integrity.

We have not modeled or tested the fixation subsystem yet and thus do not have specifics of the mechanisms other than our initial sketches and design ideas. Figure 16 illustrates the basic idea of our primary design: rolling the cartridge across the cutting board in alignment with tracks on either side. Figure 8 shows a preliminary sketch demonstrating the goals of our secondary design with a paper cutter mechanism.

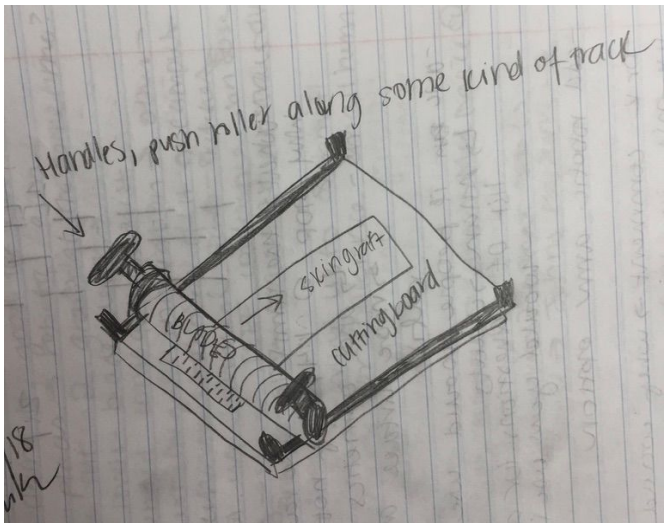

Figure 16. Secondary Cutting Surface & Skin Fixation Design

[36] Capillary Action. From https://sciencedemonstrations.fas.harvard.edu/presentations/capillary-action

5.4 Subsystem Testing

We have not fully modeled this subsystem yet, but have tested variations of cutting surfaces with the testing of the blade cartridge. For our testing we have used a plastic cutting board sent to us by Dr. Kemalyan, a metal lab tray, and layered artificial skin for a softer surface as cutting surface materials. From these materials, the plastic cutting board has proven to be the most stable while still allowing strong cutting through the skin graft.

Our prototype has a metal cutting surface taken from the paper cutters it is based on. It is a purely structural model and is not the material we would use in a final design. It does not have any means of fixating the graft in place either. The prototype simply models the integration of a cutting surface in the overall design but the properties of the cutting surface were not tested. For future testing with a prototype the cutting surface with fixation devices would need to be integrated with the overall system, and we would need to evaluate the effectiveness of keeping the graft and rolling blade cartridge in place. We will do this by placing a skin graft test sample on the surface, marking the starting position, and meshing the graft with the cartridge. After meshing the graft, we will evaluate if the graft moved, rolled, or was affected in any way, as well as if the meshing pattern is straight and even.

CHAPTER 6: System Integration

This chapter discusses the integration of our subsystems, the evolution of our device design as a whole, and the testing done with our final device.

6.1 Integration and Assembly

Due to the time constraints on the project and the time it took for parts to arrive in the mail, we decided to adopt a "test as we go" approach for our subsystem testing and prototypes; we did not wait to have a completed assembly (handle, cartridge bar, and cutting board) to begin to test. The testing that we did with skin samples has been focused on the cartridge bar with blades subsystem (see Figure 15). Although we used a cutting board in this testing, it was not of an optimized material that we would potentially use in our final device. The protocol and results of this testing are outlined in the subsequent sections.

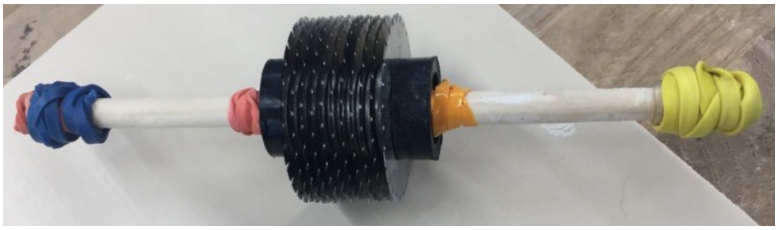

Figure 17. Blade Cartridge Prototype

After testing the blade cartridge, we wanted to model a more complete design. We looked into other ways of stabilizing the blades because we noticed in our testing that strong and even pressure every time was crucial. A paper cutter maintains even pressure on its blade by sliding it across a track rather than the user manually stabilizing the blade, so we based our next prototype on a paper cutter to implement this sliding track (see Figure 16). In this prototype, we put tracks on both sides of the cutting surface, built a cartridge of blades, and attached them to the carriers that slide along the tracks on the outside for stability and uniformity.

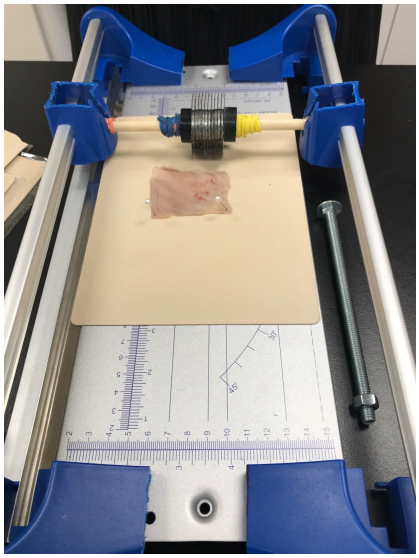

Figure 18. Final Device with Pig & Tattoo Skin

Through brief and unofficial testing of this design, we realized that we still needed to address pressure issues but make sure the cartridge and blade subsystem would be easily removable from the tracks.

6.2 Testing Protocol

The testing that we performed during this project focused on the blade cartridge subsystem of our design; due to how we manufactured the blade cartridge locking into the sliders, we could not roll within our final device. Thus, we removed the blade cartridge (see Figure 15) and tested it on a separate cutting board.

The planning and setting up of the prototype and testing protocol can be accomplished pretty quickly; it does not require extensive planning and may take around 30 minutes. The most planning that was required in this process was procuring pig skin regularly so we could test on fresh samples, more adequately simulating the surgical conditions where our device would be used.

Although we addressed in section 2.3 Benchmarking Results we did not have existing quantitative data to compare to, we decided to pursue quantitative data as well as qualitative data

to be thorough. We developed a testing protocol that gave us both types of data to help prove the efficacy of our device. An outline of this protocol is as follows:

1. Measure stretch width of unmeshed material using standard weight
2. Lay material onto cutting board/meshing surface
3. Roll blades/mesher away from body through entire piece of skin
4. Observe cuts made (or not)
5. Measure cuts made (not expanded if possible), length
6. Stretch meshed skin in direction perpendicular to rolling direction using standard weight, lay flat and measure expanded width, compare to ratio and premeshed width

A single test took about 5 minutes. We used binder clips, standardized weights, and a ruler (see Appendix VI for setup) in order to quantify the unmeshed stretching and meshed stretching widths.

6.3 Results

In the following subsections we discuss the materials used for testing and the results we achieved.

6.3.1 Skin Substitute Materials

In these tests, we used a generic cutting board, did not implement a handle, and were just focusing on the blade cartridge. Our initial prototype (Figure 11) gave us a blade cartridge width of about 1.5” and a 4:1 ratio to work with. After rolling single blades on thick pig skin samples and realizing we needed a way to cut graft samples, we decided to do initial testing on tattoo skin and nitrile gloves, utilizing the testing protocol outlined above.

We began our testing by using skin substitute materials because they were inexpensive, obtained easily, and did not create a biohazard risk. First, we ordered tattoo skin online, but found that its thickness (2 mm) was much more than a skin graft thickness for our application (0.2 mm). We decided to test our blade cartridge on this material anyway, and found that it was difficult to quantify any results with the tattoo skin because it did not contain similar elastic

properties as human skin, so it did not stretch at all, even when attempting to stretch it by hand. That said, we found it was useful for visualizing the pattern created by the blade cartridge (see Appendix III).

From here, we decided to try nitrile gloves as they were also easy to obtain, and their thickness (<0.2 mm) more closely mimicked a skin graft (see Appendix V). We created the nitrile glove strips by cutting up the palm area of the gloves. When comparing the stretch width of the unmeshed and meshed strips, we found a 5 mm difference, with the meshed strips being able to be stretched further. Although these results were exciting as they demonstrated the proof of concept of our device on a material that had similar properties to skin, we still found the thickness and elasticity of nitrile gloves to be inadequate. Thus, we did not standardize these tests to get more data. Instead, we decided to return to pig skin as our testing material, getting thinner samples by utilizing a dermatome.

Although we did not get quantitative data from this testing, we were able to gain valuable insight into multiple aspects of our initial prototype of our blade cartridge. First, the blades on the prototype were not secured to a specific position, so when rolled, they created an uneven meshing design (see Appendix III). Not having an even meshing design can detract from the aesthetic of the meshed graft and can create inconsistencies in the meshing quality. From here, we investigated different locking mechanisms that would hold the blades in place so there would be a predictable meshing pattern each time. We also found that our method was quick and inexpensive, meeting two customer needs we identified.

In addition, since our first prototype did not have a handle and we were forced to roll it by using both of our hands (see Appendix V), we began to consider creating two handles instead of one. This could allow the device to be more versatile and not catered towards left or right-handed individuals. An implementation of this idea will be seen in the next iteration of our design.

6.3.2 Pig Skin

Prior to testing our prototype on skin substitute materials, we initially believed pig skin to be an adequate material to test with. We purchased pig skin and tested a variety of blades by

simply rolling them across the skin by hand, and discovered that the pig skin was too thick to accurately model a skin graft. We managed to thin out several small pieces with a blade, and hand roll the different blades across to mimic our future prototype (see Appendix IV). However, the thinning out of the skin was very tedious and time consuming. Thus, in order to make testing on pig skin beneficial, we needed to find alternative methods to create thin samples. We ordered a dermatome and in the meantime tested on other promising skin substitute materials (see Section 6.3.1).

After receiving the dermatome, we were able to cut ~1mm thick pig skin samples to test with our blade cartridge prototype. Although 1 mm is still significantly thicker than a split thickness skin graft, using a material that has the same elastic properties as human skin was important for getting accurate and relevant results. We tested the samples using the testing protocol outlined in 6.2 with our final blade cartridge prototype (Figure 15); the table of the results is below and pictures can be seen in Appendix VII.

Table 4. Pig Skin Testing Results

Test	Starting Length (cm)	Ending Length (cm)	% Increase in length	Quality of Cuts
1	11	12.5	13.64	Uneven meshing; unclear measurement
2	7	7	0	Very few cuts went through
3	8.3	9.6	15.66	Most meshing, some rips
4	5.5	6.1	10.91	Some cuts went through
5	5.56	6.5	18.18	All cuts went through
6	5.9	7.1	20.34	Most cuts throughout center, poor/none on sides
7	6	7.1	18.33	Almost all cuts went through
8	8.4	9.7	15.48	Most cuts went through fully
9	8.3	9.0	8.43	Some cuts went through

Of nine tests, five were successful (highlighted in grey). The results of these tests in the table above outline the increase in length that is achieved when the graft was cut through fully and evenly. The remaining tests did not yield even or full cuts, causing the increase in length to be low. We did not have quantitative data to compare our results to but found that this data validated our idea of using a rolling mechanism for our device.

The main issue we found through this testing was the high probability of not getting full cuts, leading to a large amount of variance in the increase in length values. Since we found that the better the cuts were, the more expansion there was, we believe the variance came from a lack of consistent and adequate pressure. In order to increases the successful amount of tests we decided to implement a pressure mechanism in the next iteration of our device.

CHAPTER 7: Final Device Evaluation and Final Design

7.1 Final Prototype Evaluation

The prototype based off of the paper cutter was the most complete built prototype we achieved. It had slots to insert the blade cartridge into the carriers, tracks on either side, and an assembled blade cartridge of about 20 blades (see Figure 17). The carriers slid along the tracks and the blades rolled when pressured.

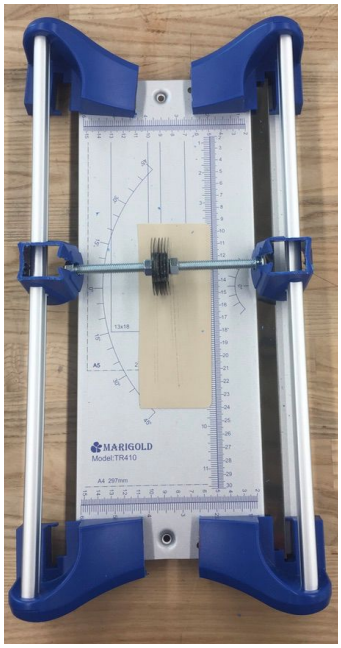

Figure 19. Final Device

After assembling this device, we evaluated it based on our design criteria (see Table 5). Two of our four design criteria were fully met, while one was partially met and a fourth was not met at all. Moving forward, we need to address the issues with cutting skin in a mesh pattern and building the device with few parts.

Table 5. Final Prototype Evaluation by Feature

Feature	**Achieved in Device?**
Cuts skin in a mesh pattern	PARTIALLY. Results from the pig skin testing validated the core functions of the device and blade cartridge design, but lack of uniform pressure is still a major issue. Graft is also not fixed which could cause poor meshing. Replaceable cartridge design allows different blade ratios and therefore different meshing ratios.
Autoclavable	YES. The design could be manufactured in many different materials such as autoclavable plastic.
Man-powered	YES. None of the functions of the device (cutting and rolling) rely on a power source.
Low number of parts	NO. Total of ten parts (two handles, one blade cartridge, two sliding arms, four plastic holders, one cutting board).

7.3 Iteration: Final Design

In order to address the features of our final device that did not meet the design criteria, we created further iterations to create our final design. This design was adapted into 3D models using Solidworks, but were not built or tested with skin samples (see Figure 18).

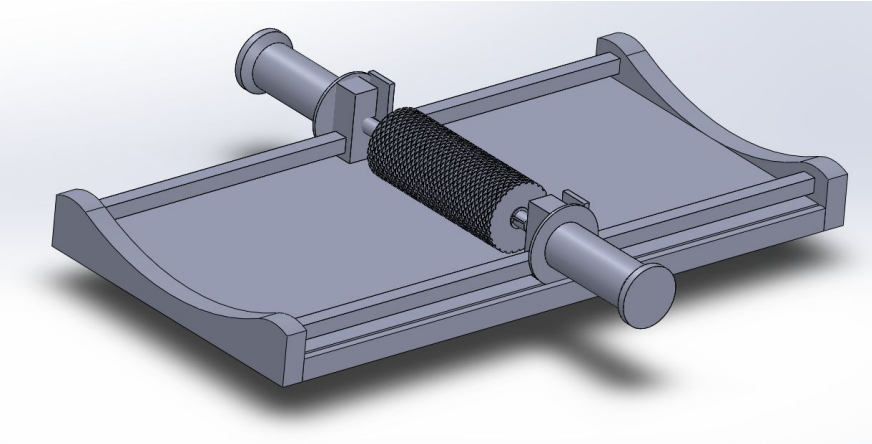

Figure 20. Final Design

Figure 11 depicts our current, final design of our prototype. From the paper cutter prototype, we have kept the cutting surface with the tracks on either side and the blade cartridge

and handle removable piece. The primary outcome of our testing was the need for stabilization of the blade cartridge in order to maintain even and strong pressure across the blades when the user slides it along the tracks. We do not want the user to have to push down to make the cuts, but rather insert the blade/handle combination and easily push it along the tracks. To achieve this stabilization we modified how the blade/handle piece is attached to the tracks. The carriers on each track has a lock-in mechanism so when inserting the handle, the user can push down and forward in an "L" motion to lock the piece in place (Figure 19). This lock-in mechanism will bring the blades flush with the cutting surface and provide the strong, even pressure needed to make cuts in the skin graft. This lock-in mechanism will address the issue of uneven pressure and incomplete cuts.

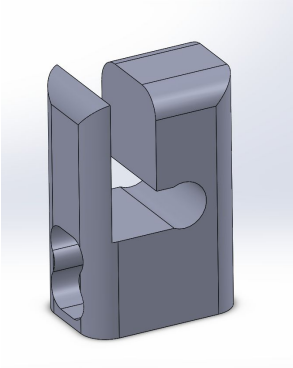

Figure 21. "L" Lock-in Mechanism

The cutting surface, the tracks on either side, and the carriers on the tracks are all one piece, and the two handles fasten into the blade cartridge to create a second piece that will allow for replacing the blade cartridge. The ends of the axle will be threaded to allow easy attachment to the handle subsystem.

Table 6 outlines issues with previous designs that must be addressed in the final design. Three of the below issues have been addressed with our final CAD model, but we did not yet design a fixation mechanism that will prevent the movement of skin during meshing. This is the highest priority design consideration moving forward, as skin must be kept taut and in place to create straight, even cuts consistently.

Table 6. Final Design Solutions

Issue to Address	**Solution in Final Design**
Uneven meshing / incomplete cuts	Two-handled design that is fixed into place using a locking mechanism for uniform and adequate pressure during cutting.
Multiple meshing ratios for location specific treatment	Replaceable blade cartridge that allows the device to easily host different blade configurations for different meshing ratios.
Movement of skin graft during meshing	Design of a graft fixation mechanism that keeps the skin taut while meshing under progress.
Reduce the number of disposable parts	All the parts (handles and cutting board) other than the replaceable blade cartridge will be reusable after autoclaving.

7.2 Success Metrics of Final Design

In order to determine if our final design (Figure 18) will fully meet the needs of low-resource burn centers, we evaluated it against our initial design constraints.

Table 7: Final Design Evaluation by Feature

Feature	**Achieved in Final Design?**
Cuts skin in a mesh pattern	PARTIALLY. Results from the pig skin testing validated the core functions of the device. Replaceable cartridge design allows different blade ratios and therefore different meshing ratios. Fixation method not yet implemented.
Autoclavable	YES. The design allows significant flexibility in the choice of materials. All parts except the blades can be fabricated from autoclavable plastic.
Man-powered	YES. None of the functions of the device (cutting and rolling) rely on a power source.
Low number of parts	YES. Total of four parts (two handles, one disposable blade cartridge, one cutting board with sliding tracks) with an estimated assembly time of less than ten minutes.

Most of the important success metrics for our device have been met by our final design. These success metrics are informed by our industry advisor and customer needs evaluation. In order to fully meet these needs we must implement a fixation mechanism in the next iteration to ensure that even cuts can be made in the skin graft consistently.

7.3 Materials and Manufacturing

While the majority of our time has been spent on the mechanics of the device design, it is crucial to consider the materials and manufacturing considerations of it, especially because of the lack of resources in our target area. All but the blades of the device will be made from autoclavable plastic. There are a variety of plastics available, and potential candidates would have to be tested to evaluate the different mechanical properties. The plastic used for the cutting surface must provide a solid base for cutting without dulling the blades too quickly. The blades will be made from surgical stainless steel, a common material used in surgical tools, and will be strong enough for the blades to cut through the skin graft.

The device would be manufactured as four parts: the blade cartridge, two handles, and the cutting surface with tracks and carriers attached. The cutting surface, tracks and carriers will need to be assembled by the manufacturer, or built as one piece. The blade cartridge will also have to be built with the blades attached to the center bar.

7.4 Cost of Device

When looking at the materials and manufacturing for the device, the cost plays an important role because of the limited resources our target users have. Current devices range from $7,000-$15,000, so our device needs to be substantially lower than this. We would like to be able to sell this price for $500 or less, which is the target price range set by our industry advisor, Dr. Kemalyan. Ideally, the device could be manufactured for less than $250. We have not selected the materials the device would be built out of yet, so we cannot propose an accurate cost of production. Our device will likely not be for profit, and can be mass produced to make it affordable for LMICs. The following list identifies what will contribute to the overall cost of the device:

- Autoclavable plastic (all parts except blades)

- Stainless steel blades
- Replacement blade cartridge
- Production/manufacturing
- Shipping

CHAPTER 8: Engineering Standards and Realistic Constraints

Because we wanted our device to be frugal and optimal for low-resource settings, we took economic, sustainability, manufacturability, ethical, and health and safety factors into great consideration; we wanted our device to reflect Santa Clara University's mission of "engineering with a mission." Our goal was to offer a functional solution to mesh and expand skin grafts.

8.1 Economic

The current cost of a commonly used mesher is over $7,000-15,000, which decreases the accessibility of this tool in low-resource settings. We wanted to reduce the price of the device as well as the replaceable blades to increase the accessibility and provide more opportunities for skin graft surgeries for burn victims. We were economically frugal and built our prototypes with materials under $400. Our overall goal for the final product is to be under $250. Through researching different materials, we believe we can have the overall cost be under $500 (see Section 7.4).

8.2 Sustainability

Another important aspect for our frugal design and device is sustainability. This device must work efficiently without breaking frequently. The only replaceable part of our device should be the blades that are interchanged for different ratios and can be replaced when they become dull. In order for our device to be sustainable, the blades should be durable to withstand multiple uses before they need to be replaced. An important quality that we wanted to achieve for our device is the ability to be autoclavable. Autoclaving our device will contribute to the sustainability of the design because it will allow our mesher to be sanitized each time it is used and contribute to the longevity of the device.

8.3 Manufacturability

Our goal was to engineer a skin graft meshing device that has a simpler design and is cheaper to manufacture than current skin graft expansion devices. Thus, manufacturability has been in the forefront of our design ideas. Specifically, one of our design criteria was to keep the

device at a minimum number of parts; we reduced the number of moving parts in order to reduce the risk of damage, breakage and loss of parts. Because of this goal, our manufacturing process in the future needs be more streamlined than the current manufacturing of the devices on the market. It also needs to be compatible with the materials we are using, hard plastics and metal blades, while not harming the environment. In addition, although we aim to keep the cost of our device low, we aim to utilize companies with fair working conditions in order to make our device. We kept these ideas in mind throughout the project, and recently started reviewing the 501(k) FDA and PMA clearances and restrictions that we will need to consider before we manufacture our final design.

8.4 Ethics

It is important that our device is ethically designed with the goal of helping solve a public health issue and improving the quality of life of burn victims. The WHO considers burns to be a public health problem, and we want to increase the accessibility of skin graft surgeries in low-income and low-resource settings. We strive to design a safe and affordable device that is usable for the operator. To ensure that our device is ethical, we have referred to the Biomedical Engineering Society Code of Ethics, which recommends that we follow regulations and industry standards.

8.5 Health and Safety

During our design and prototyping stage, we have been mindful of the health and safety the user and the skin graft recipient. Our device does have exposed blades that the user needs to handle with caution. We want our final design to have a track for the blades to move on to decrease the risk of injuring one's self with the blades because there is less opportunity for the blades to slip. We also want to consider the health and safety of the skin graft recipient. Because our device is a surgical tool, it needs to be properly sanitized in an autoclave before each use. Our device also must not compromise the integrity or crush the skin graft. The device also should be made of biocompatible material so it does not corrode or leach into the skin graft.

CHAPTER 9: Summary and Conclusions

In this chapter we will summarize our work thus far, comment on the progress of the project, and discuss our future plans.

Chapter 9.1: Summary

After identifying the problem in Fall Quarter, we focused on sketching, modeling, purchasing testing material, building a prototype, and testing our frugal skin graft expansion device during Winter and Spring Quarter. We then created further iterations of our design to more fully meet the needs of developing countries. We sketched different designs of each subsystem in order to understand how they would work as well as optimize the design according to the constraints we defined based on our interviews with burn surgeons. Modeling was also important to understanding the mechanism of each subsystem. Due to our use of the concept of bisociation, we were able to use pie crust rollers to model our design concept. The purchase of testing materials was necessary for us to prove that this method of cutting (with the blades moving across the skin graft, rather than the skin graft moving through the blades as common meshers do) is effective. Using materials purchased from a hardware store, we created a rough prototype and tested it on nitrile gloves. The prototype successfully created a mesh pattern on the gloves, and they expanded in area after meshing. The rolling mechanism proved successful, and from this testing we learned the key areas of focus for furthering our prototype. We found that strong, even pressure across the cartridge was difficult to maintain, and a method of securing the graft in place is necessary for testing. To address this we developed our second design and our prototype with tracks on either side of the cutting board to stabilize the blade cartridge.

While developing this design we continued testing with our blade cartridge. We were able to use thinned samples of pig skin and achieve a mesh pattern by rolling the blades across them. We successfully achieved a mesh pattern in the pigskin and the samples expanded when stretched. From the testing and the prototyping, we re-evaluated our design and made some adjustments to create our final design of the device. We developed the design in CAD, and included an L shaped lock in device to hold the blades tight against the cutting surface. It achieves almost all of our design criteria, though we still need to consider a method of fixing the

skin graft in place while meshing. We believe with a few more iterations, our design can be implemented and deployed, helping countless burn victims in low-resource settings.

Chapter 9.2: Future Work

We plan to continue to work on our device after graduation from various locations and maintain communication and progress. This work will consist of modeling and testing our final device design and implementing a fixation method for the skin graft. We will also be making materials selections and testing materials options. We have developed a preliminary deployment plan with the help of our EWH collaborators.

We have decided for deployment that we would still like to focus on South Africa. To be able to deploy in South Africa, our device would need to be approved for a Class B license by the Medicines Control Council (MCC); we would also need to work through the EMERGO site and with the South African Department of Health. As of now, we do not have a design we feel comfortable implementing; we still need to create a physical prototype of our final design and would like to create at least one more iteration off of that design, including a fixation method for the graft while it is being meshed. We will also be doing a more in-depth materials and manufacturing analysis in order to ensure our device stays frugal and is meeting the needs of low-resource burn centers. We would love to keep working with Dr. Allorto and the South African Burn Care Trust as a way to possibly find hospitals to implement our device in the future. That said, we are also looking at working with Doctors Without Borders or some contacts we have found at the Miller Center for Social Entrepreneurship at Santa Clara University.

Concerning the business part of our plan, we have submitted Intellectual Property to independent consultant to identify the commercialization potential of our designs, and are still waiting to hear back. We are also discussing whether we would like to pursue a for-profit or nonprofit business model.

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APPENDICES

Appendix I: Customer Needs Evaluation

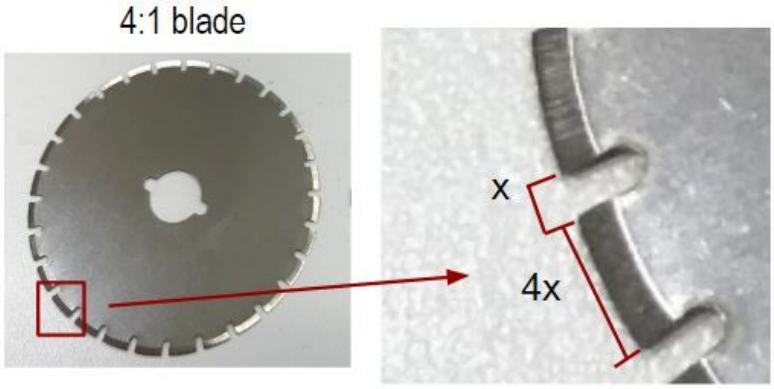
Opportunity = Importance + (Importance – Current Satisfaction)

Table 1. Customer Needs Evaluation

Customer Need	**Importance**	**Current Satisfaction**	**Calculated Opportunity**
Less expensive (up-front cost, consumables, and simpler/cheaper maintenance)	9.5	2	17
User friendly/less complex	7	4	10
Reliable (able to be used if electricity goes out/no electricity)	9	6	12
Easily transportable (can take/use to different locations to reach more patients)	7	4	11
Less time-consuming	8	2	14
Can be sanitized in an autoclave	9	6	12

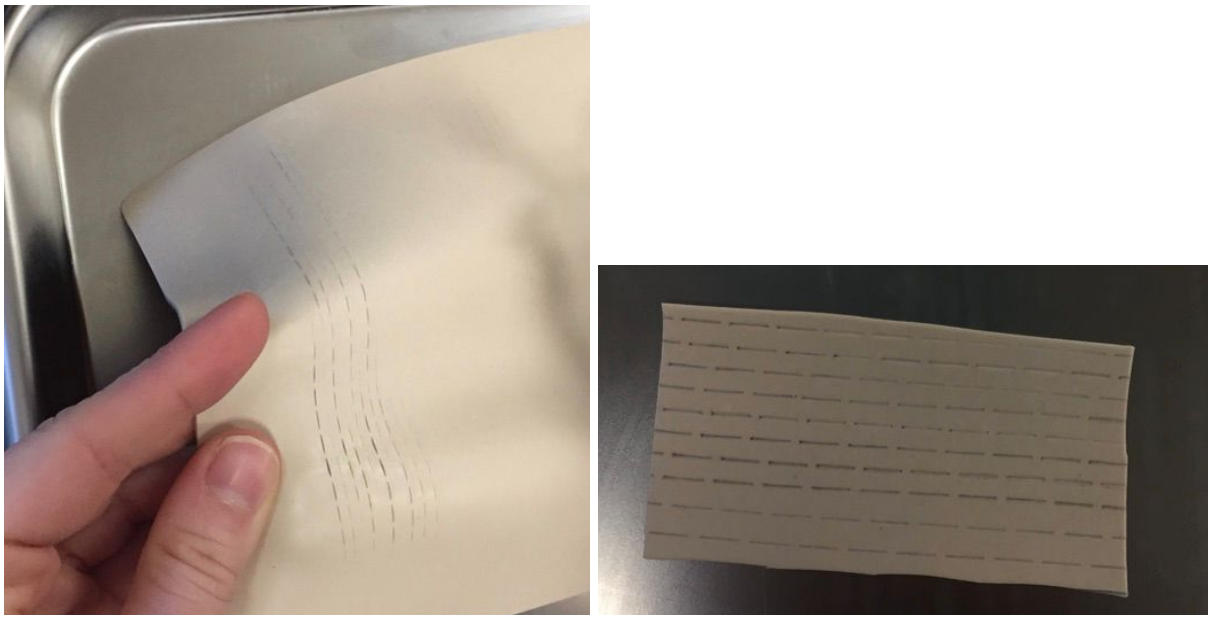
Appendix II: Expansion Ratios

The blade on the left is a 4:1 blade, the one on the right is 1:2.



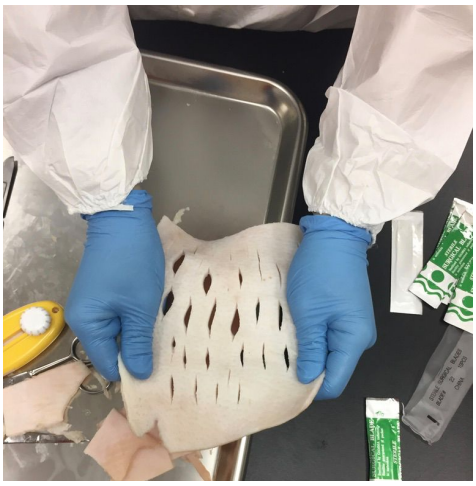
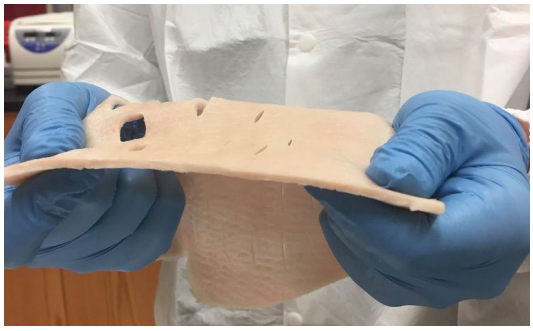
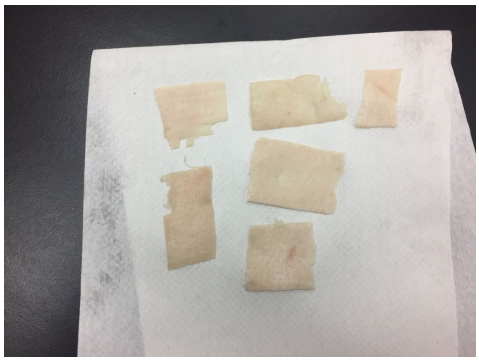
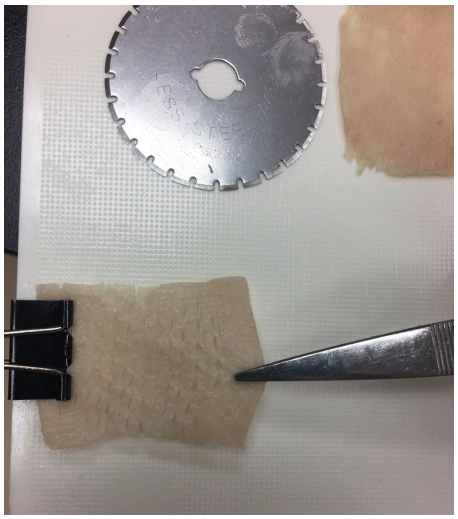
Explanation of blade ratio meaning.

Appendix III: Tattoo Skin Testing



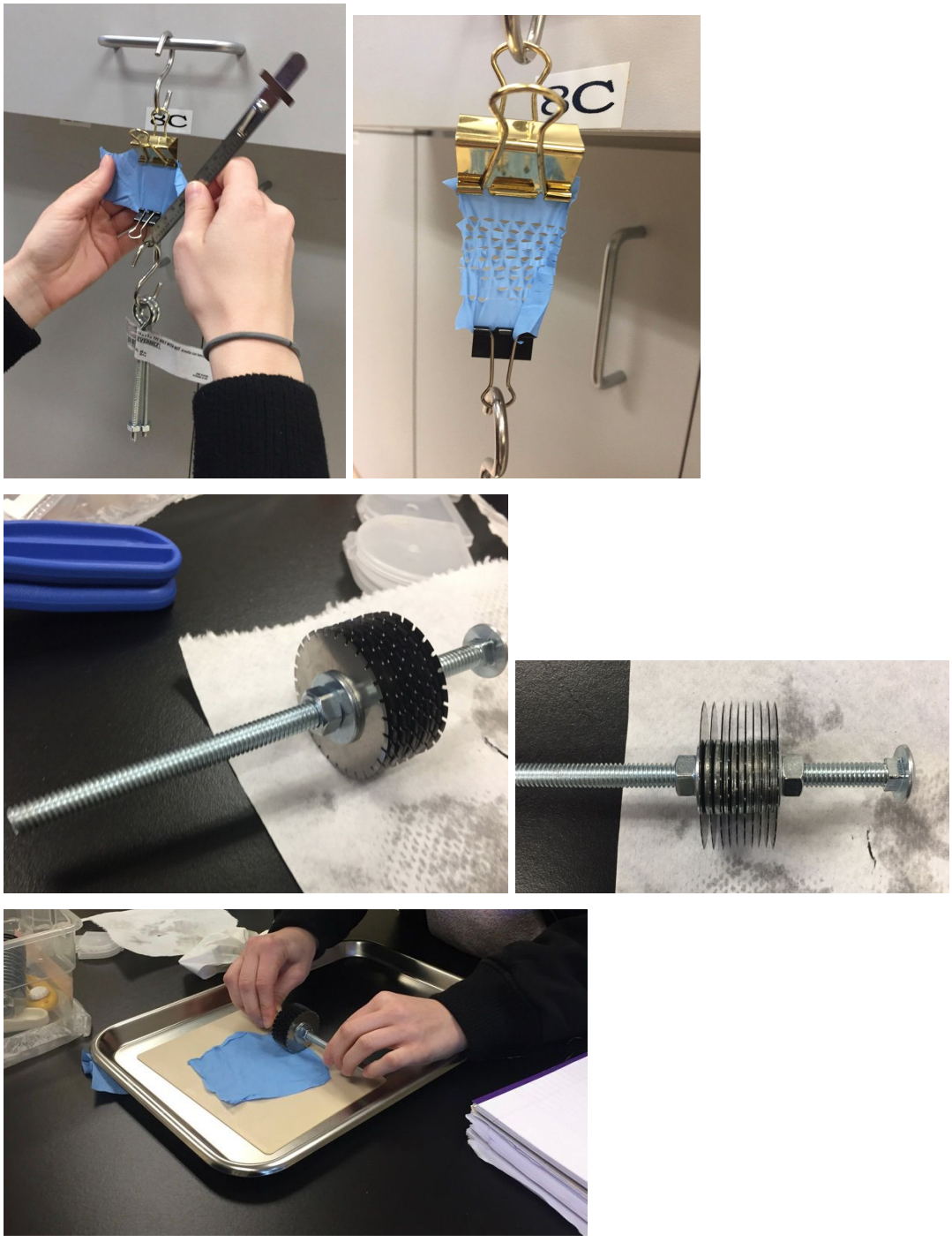
Images from left to right: 1) Demonstrating the blade cut through the artificial skin, 2) showing the uneven meshing pattern

Appendix IV: Initial Pig Skin Test

Images from left to right: 1) Various cutting materials to test including a variety of blades 2) hand cut full thickness pig skin 3) Side view of full thickness pig skin 4) Small, thinned out pieces of pig skin used to test cutting materials 5) Successfully meshed thinned pig skin. Hand rolled depicted blade in columns across skin to create mesh pattern.

Appendix V: Nitrile Glove Testing



Images from left to right: 1) Measure of stretch before meshing, 2) Measure of stretch after meshing, 3) & 4) Initial prototype: ten 45mm diameter blades separated by washers, 5) Rolling of prototype on nitrile glove

Appendix VI: Testing Protocol Setup

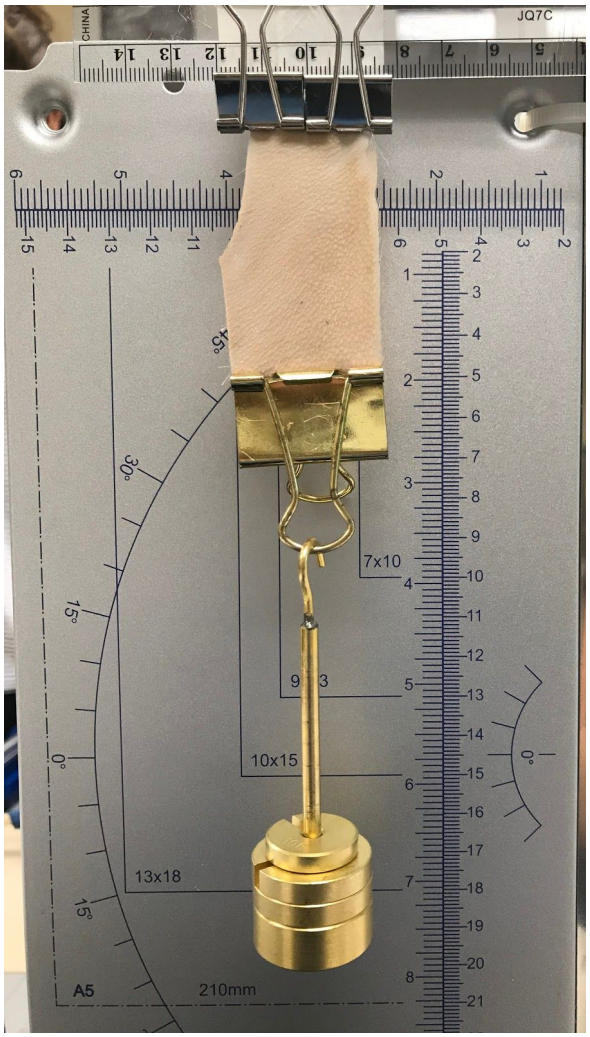
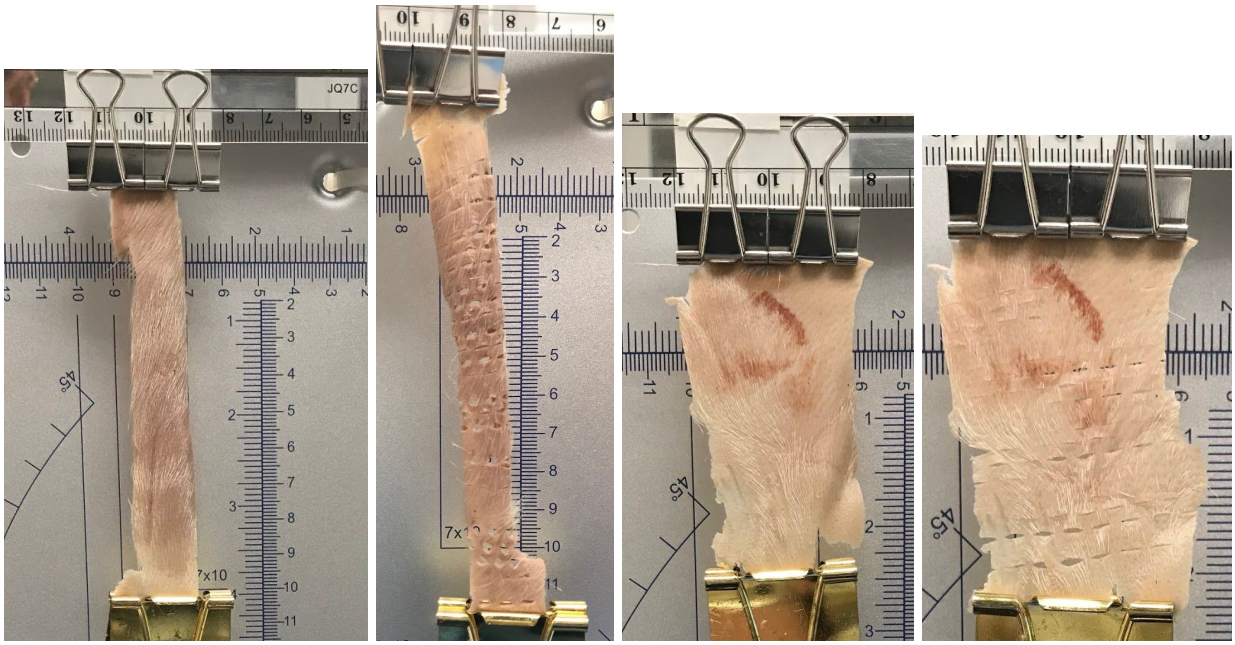
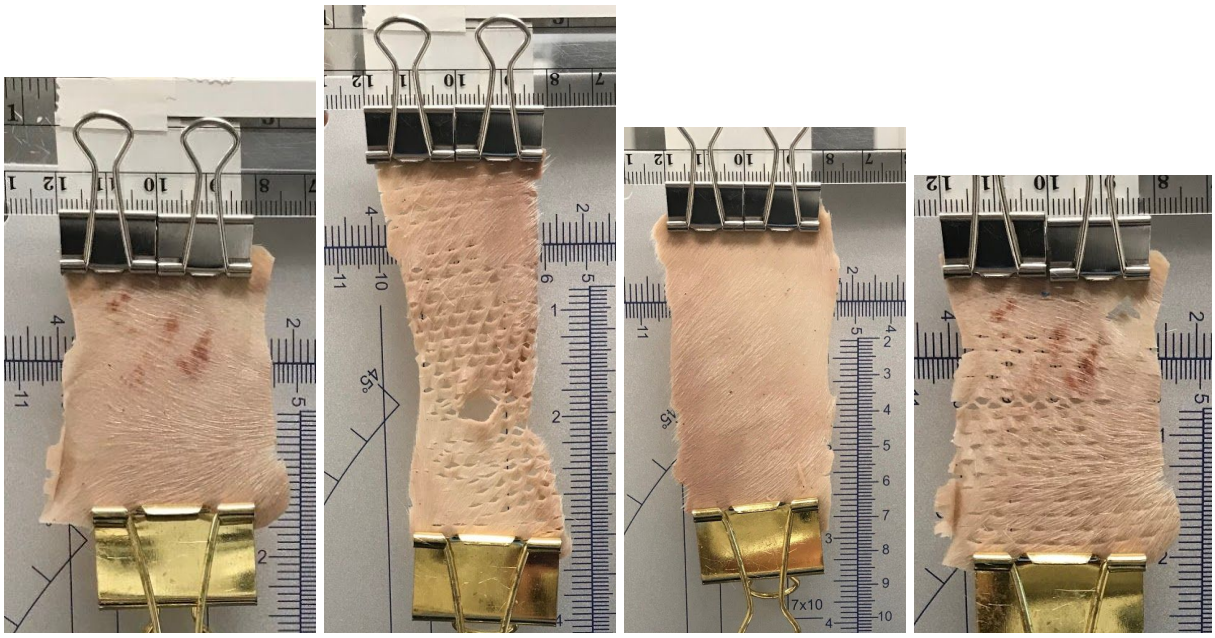


Figure demonstrate the mechanism used for measuring the stretch of the material: a binder clip on either side of the material, standard weights on the bottom.

Appendix VII: Pig Skin Testing with Final Device

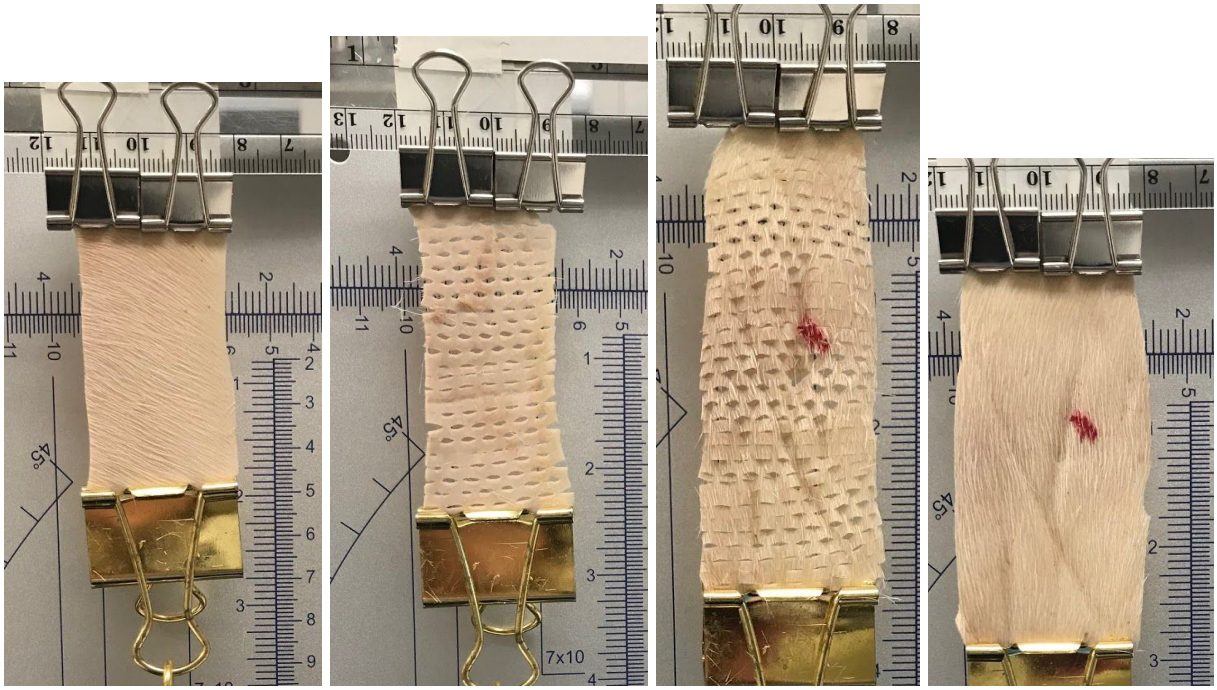


Images from left to right: 1) Test 1 unmeshed, 2) Test 1 meshed, 3) Test 2 unmeshed, 4) Test 2 meshed

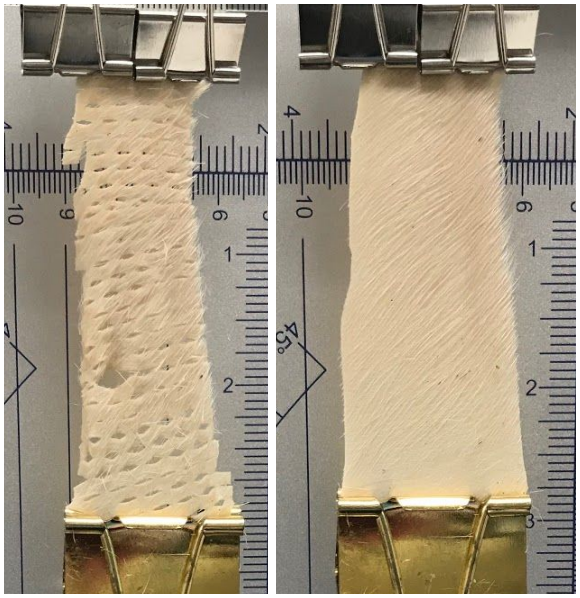


Images from left to right: 1) Test 3 unmeshed, 2) Test 3 meshed, 3) Test 4 unmeshed, 4) Test 4 meshed

Images from left to right: 1) Test 5 unmeshed, 2) Test 5 meshed, 3) Test 6 unmeshed, 4) Test 6 meshed



Images from left to right: 1) Test 7 unmeshed, 2) Test 7 meshed, 3) Test 8 unmeshed, 4) Test 8 meshed



Images from left to right: 1) Test 9 unmeshed, 2) Test 9 meshed