Design of an Elliptical Biopsy Punch
A Major Qualifying Project Report:
Submitted to the Faculty of the
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In partial fulfillment of the requirements for the

Degree of Bachelor of Science

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Authorship

The research and writing of this report was contributed to equally by Derek Hall, Edward Tacvorian, Matthew Wainwright and David Weiner. The Introduction, Background, Design, Testing, Results, Discussion and Conclusion were comprised equally of work from the four members of the group.

Abstract

Current skin biopsy techniques utilizing a punch biopsy device can leave raised scars that are cosmetically unappealing. With 3.8 million procedures per year, the potential marketability of a superior device is substantial. The goal of this study is to design a novel elliptical punch biopsy device that maintains the simplicity of existing products while minimizing scarring. Mechanical testing was performed on porcine skin to determine the force required to breach the dermal layer using a single #11 scalpel blade (comparable to the excision biopsy technique), the traditional biopsy punch, and a novel blade design. The force required to penetrate the skin using the novel design prototype was 4 times greater than the traditional punch biopsy (17 lbs versus 4.3 lbs). Initial force data and mathematical analysis has resulted in a final blade design that requires less force than the previous prototypes and includes fail-safes to prevent excessive depth of penetration. The resulting wound has clean edges and is of proper dimensions for superior suturing layout. A prototype was taken into the clinic where a physician tested the device on an excised abdominoplasty specimen. Initial feedback from the physician was received with constructive criticism which may lead to future improvements.

1. Introduction

The skin biopsy is the most common procedure in the United States. Abnormal growths on the skin such as moles, cysts, or birthmarks are all potential reasons to undergo this procedure in order to test for cancerous tissue. Approximately 3.7 million physician visits are directed at actinic keratoses (a lesion caused by UV radiation and sun exposure) annually [1]. These types of growths can occur in cosmetically sensitive areas such as the face, scalp, hands, and other locations on the body where favorable scar healing is an important consideration. To evaluate the nature of the lesion, one of three types of biopsies is performed. The first type of skin biopsy is the shave biopsy where a physician manually removes a thin layer of the lesion to be viewed under a microscope by a pathologist. This procedure is done using a circular punch that cuts a circle around the skin lesion and then the section is removed and stitched up. The second type of biopsy procedure is called an excision biopsy, where a physician (typically a cosmetic surgeon or dermatologist) uses a scalpel to surgically remove the area of interest, again to be viewed by a pathologist. Depending on the skill of the surgeon and the size of the lesion, this procedure can leave large and unsightly scars requiring multiple stitches to heal properly. A physician may choose to perform a punch biopsy, the final technique, where a device with a circular cutting head is pushed into the lesion and rotated, removing a core to be evaluated again by histology [4]. This last iteration of the skin biopsy has become the preferred method, as it does not require the skill of a specialist and can be done in little time and minimal discomfort during an office visit.

The simplicity of this tubular cutting blade on a modified scalpel handle makes it inexpensive to manufacture and easy to operate. A disadvantage of this device is that the

patient is left with a more noticeable scar. By removing a circular section of skin around a lesion, closing the wound becomes very difficult because there are no edges to be joined. In closing such wounds, raised edges, known as "dog-ears", appear at either edge of the closed circle.

To reduce the scarring associated with the traditional punch biopsy, the wound made by the device must have two even edges that can meet to form a straight line when stitching. To accomplish this, the device must create an ellipse around the lesion. Recently, patents have been granted for many elliptical biopsy punch devices, but none have become as successful as the traditional circular punch device. In 2006, a device known as the ElliptiPunch® (Figure 1) combined the rotational aspect of the traditional circular punch with an elliptical cutting edge. In order to allow free rotational motion, the ellipse has rounded edges where corners would be found in a true ellipse. This compromise for rotation leaves two edges that cannot be joined resulting in abbreviated "dog-ears".

The focus of this project is to design a device that lacks the rounding associated with previous designs while maintaining the cost and simplicity of previous devices.

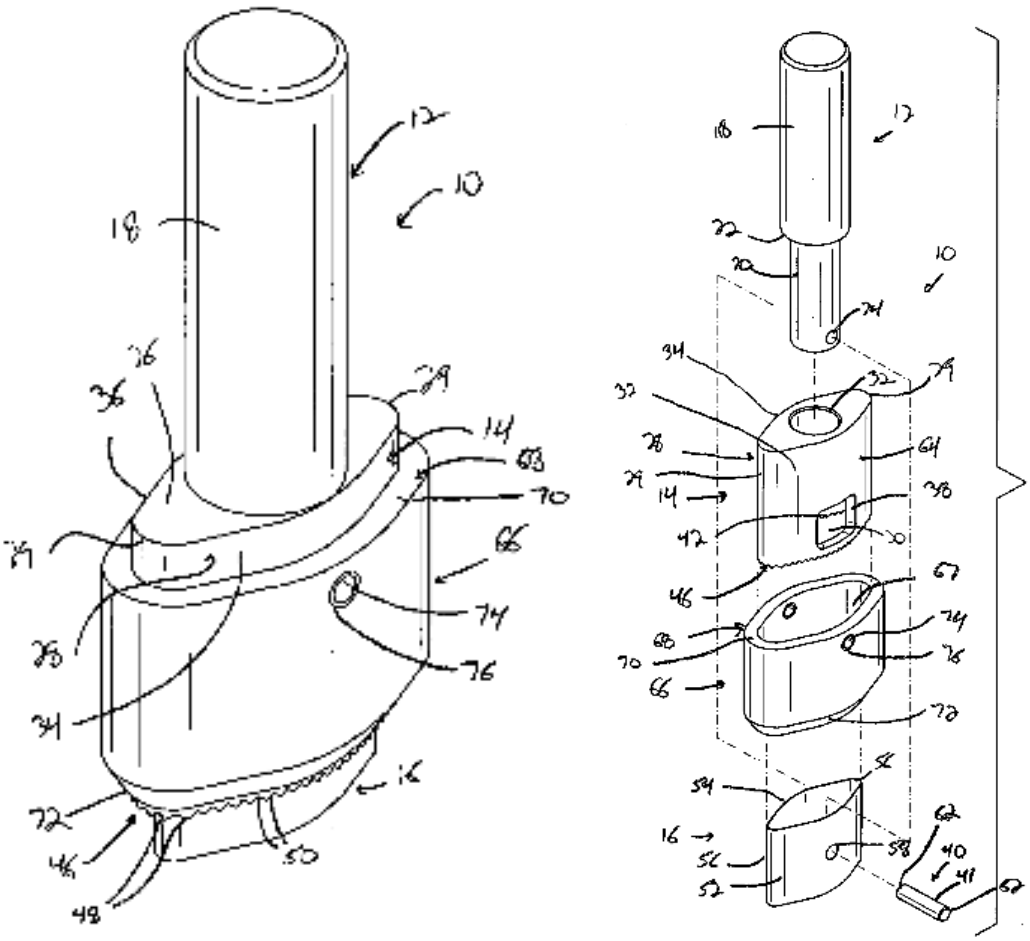

Figure 1. ElliptiPunch®, Huot Instruments

2. Literature Review

2.1 Dog-ears: A Review [10]

This article focuses on the presentation of the phenomenon known to doctors and surgeons as "dog-ears". Dog-ears can be defined as an upward formation of excess skin as a result of a suture. Dog ears are the result of the closure of a circular or asymmetric wound which causes surrounding skin to create pressure on the wound site and force the flaps of skin upward and outward. The paper identifies four main causes of dog-ears: tissue dynamics, wound geometry, surface contour, and surgical techniques.

Dog-ears can form due to the lack of elastic prosperities of the skin being closed. These properties can be affected by age, location of the wound, and the nature and extent of the wound itself. Some wounds, whether it is due to location or the severity of the wound, can cause excessive tension which can cause depression in the central region of the wound and vertical displacement in the outer corners. The geometry of the wound also plays a key role in the formation of dog-ears. The ideal shape of a wound to avoid the effect of dog-ear formation is fusiform in shape, symmetric, and has apical angles of approximately 30°. If the wound length to width ratio is below 3:1, the likelihood of dog-ear formation increases as the shape becomes more circular. When the wound become more circular in shape, the distance at the center of the wound at the center are significantly greater than the rest of the wound and cause excess tension in the center. Once the ability of the skin to tolerate these forces is surpassed, dog-ears are formed. Surface contour also plays a key role in dog-ear formation, as the will form more readily on convex surfaces. The skin in these areas seems to resist bending and distortion which extenuates the formation of the Dog ears. Surgical Techniques can play a role in Dog ear

formation. Improper surgical techniques can cause excess tissue to be present at the wound site. This often occurs due to the tendency of surgeons to defer from the 90° proper cutting angle.

2.2 Leashing the Dog ear [4]

This paper introduces a new technique used to correct the effects of Dog ears. This technique involves suturing the Dog ear down with additional sutures after the closure of the wound. A suture is inserted into the Dog ear along the axis of the wound closure. The needle must penetrate down to the subcutaneous layer as pictured below in Figure 2. The dog ear essentially is pulled down and "leashed" by anchoring it to the subcutaneous layer. While effective, this technique does not work in all instances of a standing cone and scarring still results after healing.

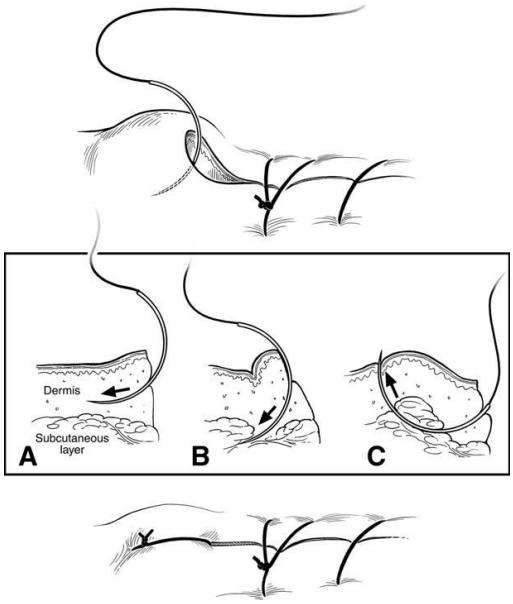

Figure 2. Leashing the Dog ear technique

2.3 Patent Search

A thorough patent search was performed to locate patents for currently marketed devices and current technology. Similar to the majority of devices on the market, patent number 3,515,128 depicts a biopsy punch with a circular blade on its tip and may be seen in Figure 3. On this syringe-shaped device the user would push down the plunger on the top portion of the device to reveal its cutting edge and then rotate it freely until the dermis of the patient is punctured. The excised portion of the dermis may then be removed with forceps.

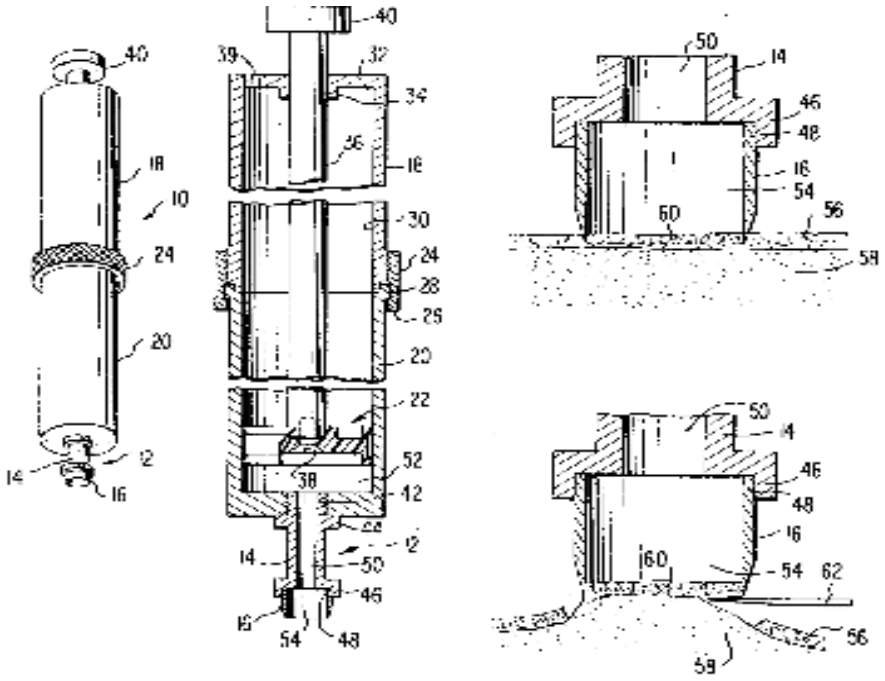

Figure 3. U.S. Patent #3,515,128

A smaller version of a similar device is illustrated in patent number 5,827,199 and may be seen below in Figure 4. This device utilizes a circular blade which is tapered inside then outside towards the tip for depth control. The tubular blade has a short and hollow handle, allowing the user to accurately place device on the portion of the patient's

dermis to be excised. The user would then rotate the device on the patient's dermis until the incision reaches the required depth.

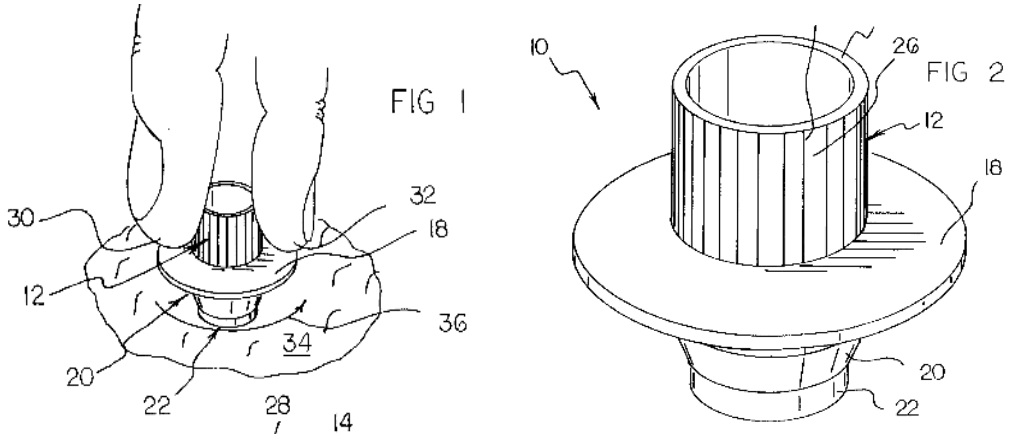

Figure 4. U.S. Patent #5,827,199

Patent number 5,325,857 combines a syringe and a biopsy punch into one mechanism. This device allows for the user to fill the syringe with an anesthetic, thus allowing the user to use one less device in performing a skin biopsy. After the user has properly administered the anesthetic, the tip of the syringe which houses the needle may be unscrewed. With the plunger fully pressed, the circular punch is exposed and the user may excise the necessary dermal area and lift it by depressing the plunger.

Figure 5 depicts patent number 5,183,053 which is a biopsy punch utilizing an elliptical blade. This device is most similar to the currently marketed punches however incorporates an elliptical blade rather than a circular one to achieve an optimal cut. Patent number 5,507,765 depicted in Figure 6 is similar to this device in terms of cut shape, however allows the handle of the device to utilize interchangeable tips. This blade on this device calls for two pieces welded together to create the final cutting shape.

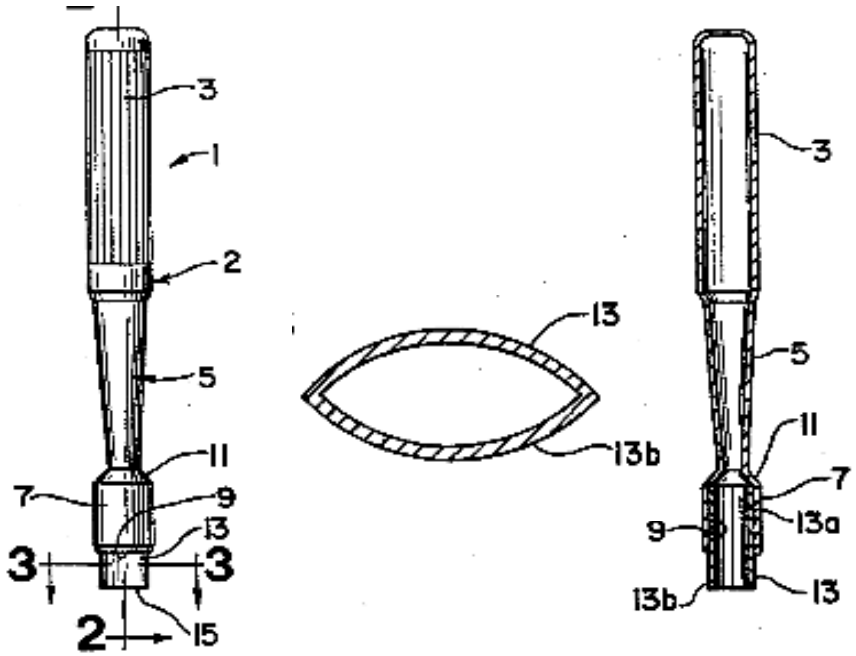

Figure 5. U.S. Patent #5,183,053

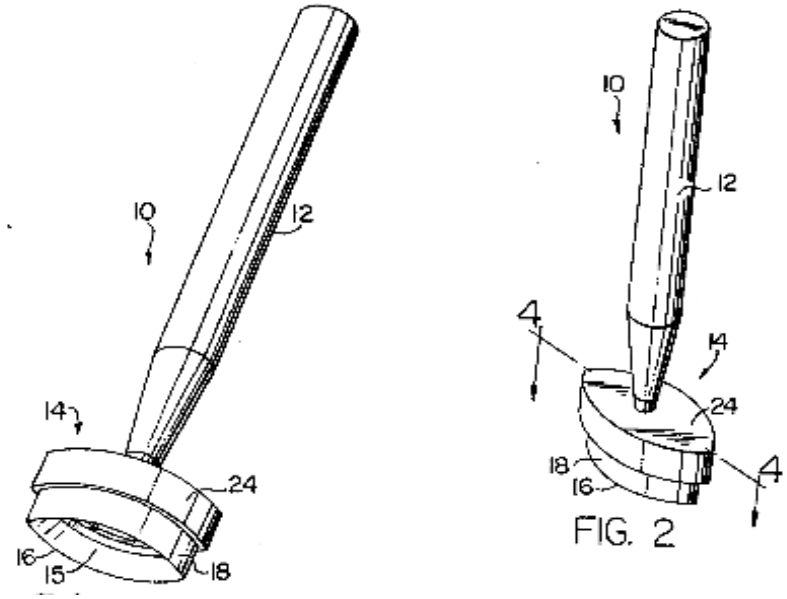

Figure 6. U.S. Patent #5,507,765

Dr. Raymond Dunn from the University of Massachusetts School of Medicine has filed a patent (application number D518178) for a dermal punch device utilizing an elliptical cutting surface. The elliptical shaped blade is depicted with numerous

serrations of various depth, geometry, and cutting angle for optimal incision. Further, the geometry of the blade allows the device to puncture the skin comparably to a scalpel blade and with similar ease in regards to the required force applied by the user to breach the skin.

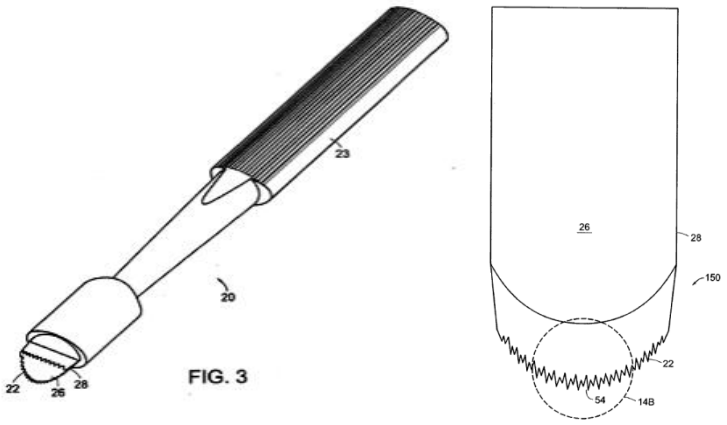

Figure 7. Dr. Dunn's elliptical punch biopsy device

2.3 Existing Products

Given the many iterations of the skin biopsy procedure, a surgeon must select the appropriate device for the type of lesion to be excised. A scalpel is a very common tool for excision skin biopsies. The circular punch is another commonly used device that is available to the surgeon. Several skin biopsy punches will be identified and described in this section.

Currently, there are a number of companies that create punch biopsy devices. These devices range in cutting surface size from about 1.5 mm to 8 mm in diameter, and most create circular incisions in the skin. Numerous companies which make punch biopsy devices include: Stiefel Labs, Acuderm Inc., Medexsupply, Miltex, and Keye's, These devices, which make a simple circular incision made, are seldom sold beyond $2.00 per device.

Innovation is the interest of one company, Huot Instruments, who sells two unique products— the VisiPunch® and the ElliptiPunch®. The Visipunch® is a device similar to other circular punches however part of the metal tube is cut so that the surgeon can better see the incision being made. The ElliptiPunch® is a device that has a cutting surface shape similar to an oval that can be rotated slightly by the surgeon in order to break the skin and attempts to reduce the "dog ears" at the ends of the incision. Neither of these devices exceed a cost of $5.00 per unit.

The products described above are all inexpensive as well as disposable. The more unique products are sold at a significantly lower price relative to the basic scalpel or circular punch device. There is a premium attached to these products due to their development costs, increased material costs (in some situations), and their benefits over standard devices. Despite this fact, there is no existing product that carries a cost of greater than $5.00 per device. One could gather from this that a novel device would need to significantly improve the surgery or cosmetic results in order for the consumer to purchase a device in excess of $5.00

2.4 Manufacturing Techniques

2.4.1 Current Techniques

Almost all current disposable scalpels, circular and elliptical dermal punch devices are constructed using a two-piece design. The handle is usually made of an injection molded plastic. Injection molding is a process where molten plastic is injected into a die of the desired shape at high temperatures and pressure. Molds are mostly constructed through CNC machining which allows for very precise products. This technique, although requiring an initial investment for the fabrication of the mold, offers

an inexpensive production cost per product made. The blades are primarily one-piece carbon steel formed in the desired shape. The current dermal punch techniques involve a sharp edged blade which must be twisted to excise the tissue. These blades are tempered at high temperatures to make them harder and then sharpened under a diamond-grinding wheel. The blades are usually fixed to the handles with a slot that affixes to the bayonet of the scalpel handle. These devices set the blade in the handle of the punch while molding.

2.4.2 Elliptical Punch Manufacturing Technique

For this project, the ultimate goal is to design a die for injection molding. The design techniques, to remain cost effective, will resemble current techniques on many levels. Specifically, an over-molding technique will be used where the completed blade will be fixed inside the die and set, hardening around the blade. Similar plastic manufacturing considerations for shape and quality of plastics will be used while attempting to make improvements wherever possible. Blade design for the device will require alternative techniques. It is proposed that a two-piece blade be created with a serrated edge to connect in a perfect elliptical shape.

2.5 Materials

2.5.1 Plastics

Polyethylene is the plastic used in current elliptical punches as well as some disposable scalpels. Polyethylene is very common plastic used in many applications because it is inexpensive, recyclable and easily manufactured. Products that deviate too far from existing products sometimes do not succeed in the market because users are not

familiar with the materials used, so it would be wise for a novel device to use the same plastic that is most widely used.

2.5.2 Metals

The choice metal used for most medical grade blades is high-grade carbon steel. Other materials that would fulfill the specifications required for the blade would be ceramic, titanium, diamond or obsidian. Although high carbon steel currently is used for scalpel blades, 420 Stainless Steel is stronger and corrosion resistant. The cost of carbon steel is roughly $12 per pound while stainless steel is about $18 per pound. The benefits of stainless steel come at a price, but it may not be significantly high for a firm that is mass producing a device.

2.5.3 Sterilization Techniques

There are a number of techniques used in order to sterilize a medical device before it is delivered to the consumer. The primary techniques are ethylene oxide, gamma irradiation, and electron beam irradiation. Ethylene oxide is a process in which the device is placed in a gas chamber for a period of time. After this time, the device must undergo a quarantine period where the level of ethylene oxide is beyond that which is safe for humans. Ethylene oxide is an effective way to sterilize, but its quarantine time adds significantly to the manufacturing process time.

Irradiation is another sterilization technique that has been gaining popularity in the biomedical industry. The more common form of irradiation is gamma. During gamma irradiation, the device is placed within a shielded area, and Cobalt-60 is raised up around it. The device receives the irradiation for a period of time that is usually several hours. Electron beam irradiation involves an electron gun which shoots electrons at the

product as it moves by the gun on a conveyor belt. In both processes, the irradiation damages the DNA chains, killing microorganisms or damaging their ability to reproduce. Of all existing skin biopsy products, gamma is by far the most common of the three most often used sterilization techniques.

Another difference between techniques is in-house sterilization versus contract sterilization. Larger companies may have one or several techniques in-house. The easier option for smaller companies is contract sterilization. There are many companies across the country that have contracts with medical device companies where the company drops off their devices and picks up at a later date when their products have been fully sterilized.

3. Statement of Design Problem

3.1 Initial Client Statement

The goal of this project is to build, design and bring to market a novel skin biopsy punch device. The device will be used to excise suspicious growths on the skin surface. The device will create sharp corners at the edge of the biopsy allowing for a direct edge-to-edge skin closure and minimized healing times. The device must be easily manufactured, cost effective, disposable, ergonomically sound, and safe, and have a vertical cut component, controlled depth.

3.2 Revised Client Statement

The goal of this project is to design, build, and validate a marketable and potentially versatile skin biopsy punch device. The device will create sharp corners at the edge of the biopsy allowing for a direct edge-to-edge skin closure and minimized scarring. The device must be easily manufactured, cost effective, disposable, ergonomically sound, safe, and have a vertical cut component with controlled depth.

3.3 Objectives, Functions and Specifications

Based on the revised client statement, a set of objectives were created which can be seen below in Figure 8. The first objective was that device must be easy to use so as to be competitive with products currently on the market. The next objective was that the device must be safe for both the user and the patient. The next objective was that the device must be manufacturable so it could be easily brought to market. The next object

was that the device must be marketable, as the goal was to design for market. Lastly, the device must be ergonomically sound for user comfort.

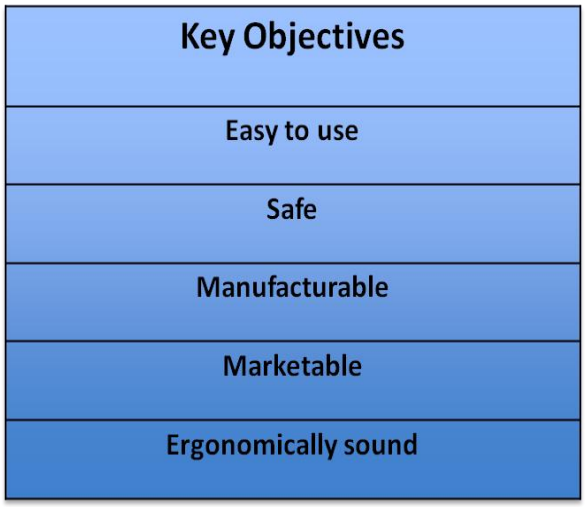

Figure 8. Key objectives

The device's functions are listed in Figure 9 below. The first basic function was to create an elliptical shaped incision with corners at each end for a superior layout for closure and to eliminate dog ears. The device's blade needed to be sharp enough to penetrate the epidermis and dermis of human skin. Also, the device needed to have some means of control the depth of penetration so as to be safe for the patient.

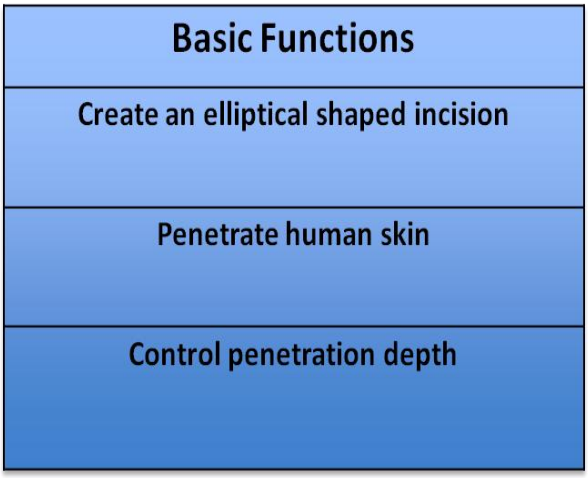

Figure 9. Basic functions

Specifications were stemmed from the revised client statement and are summarized below in Figure 10. The first specification stated that the device must cut an ellipse with a length to width ratio of 3 to 1, which was determined from literature [10]. Next, the device had to cut the skin to a depth of at least 2.5mm to penetrate the full thickness of the dermis, this was based off a personal interview with Dr. Raymond Dunn [12]. Lastly, the device had to be produced for a final cost of no more than $4.50 in order to be competitive with current products.

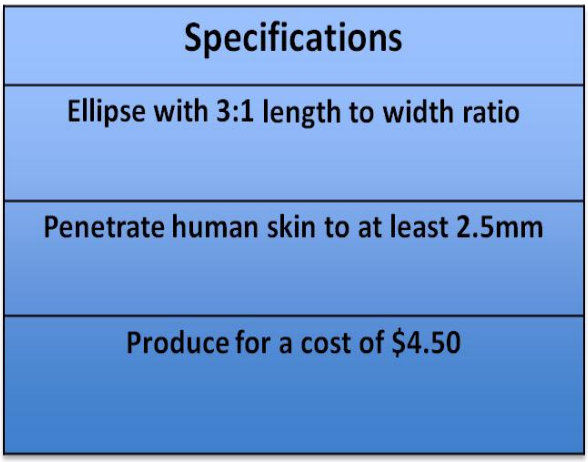

Figure 10. Specifications

4. Design Process

4.1 Design Alternatives

Design alternatives were created utilizing and adapting the claims made from patent application #10/943,051 – invented by advisor Dr. Raymond Dunn.

4.1.1 Preliminary Designs

Features of the blades were adjusted leading to the various conceptual designs. Features of the serrations were adjusted including their quantity, lengths, angles, shapes, and symmetry for optimal penetration of the skin. Furthermore, a viewing window was added to the blades for proper alignment of the punch on the patient's skin. Figure 11 below depicts the preliminary designs created. On the left is a flat bade with a single serration length and angle in addition to a viewing window. A second design was created incorporating a flat blade with serrations of multiple lengths and shape. A final design was created incorporating the features of the second design on a crowned blade.

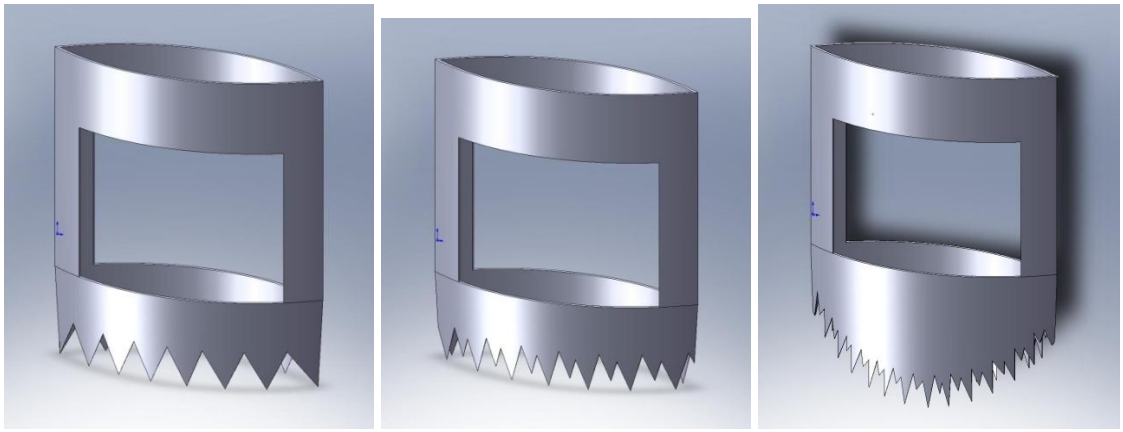

Figure 11. Conceptual Designs (from left to right: flat, staggered serrations, and crowned designs)

4.1.2 Conceptual Designs

After presenting the preliminary designs to advisors, alterations were made to the blades to accommodate the needs of the client. The viewing window was removed from the

blade designs and the alternative incorporating a flat blade with a single serration length and angle was removed. Below are designs which were updated and sent to manufacturers for quoting. Two blades were created, one flat and one crowned, incorporating similar features. The blades had serrations of two different heights, angles, shapes, and were symmetrical across the length of the blade. Figure 12 below depict the flat and crowned blade, from left to right.

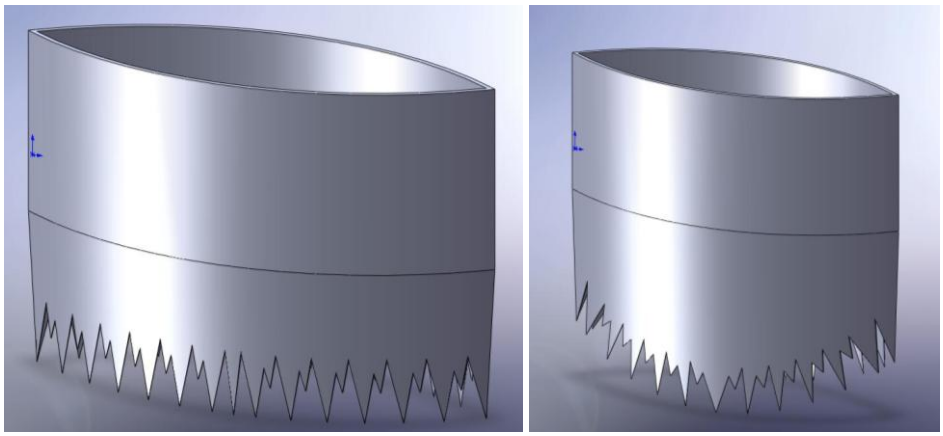

Figure 12. Flat versus crowned designs

4.1.3 Final Design

After sending the designs to manufacturers, final alterations were made to accommodate the ease of manufacture. In this final iteration, a crowned blade was designed with serrations of two different heights. Furthermore, each serration represents an isosceles triangle and has an interior angle of about 22°. Furthermore, the large serrations penetrate a depth of 2.5mm while the small ones penetrate 1.25mm. Figure 13 below shows the final design.

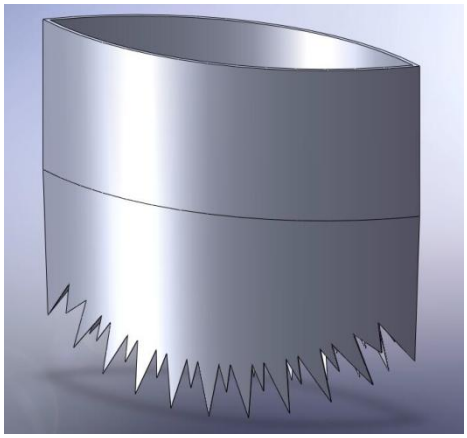

Figure 13. Final Design

4.2 Handle Design

Instrument handles were designed to meet the specifications of the client. The handle was to be ergonomic for user comfort.

4.2.1 Conceptual Design

A handle design was created from adapting handles used in previous technology. This handle incorporated vertical lines in the top portion of the handle thus allowing the client to properly grip the handle. It then tapers into the area of the handle grasping the created blade. This design may be seen below in Figure 14.

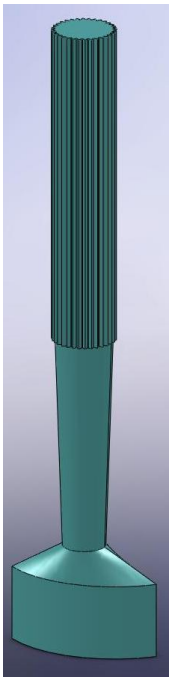

Figure 14. Initial handle design

4.2.2 Final Design

After presenting the original handle to the client, the design was modified to meet certain goals. This iteration of the blade allowed for a controlled depth of 4mm to enter the skin and may be seen in Figure 15.

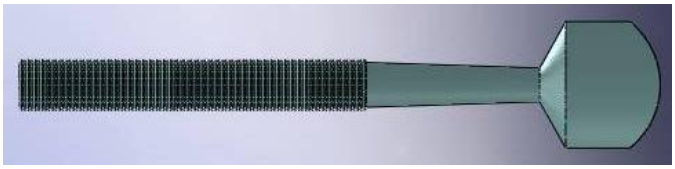

Figure 15. Final handle design

4.3 Final Assembly

A final assembly was created by combining the final blade and handle designs.

Figure 16 below depicts the final assembly from a two points of view.

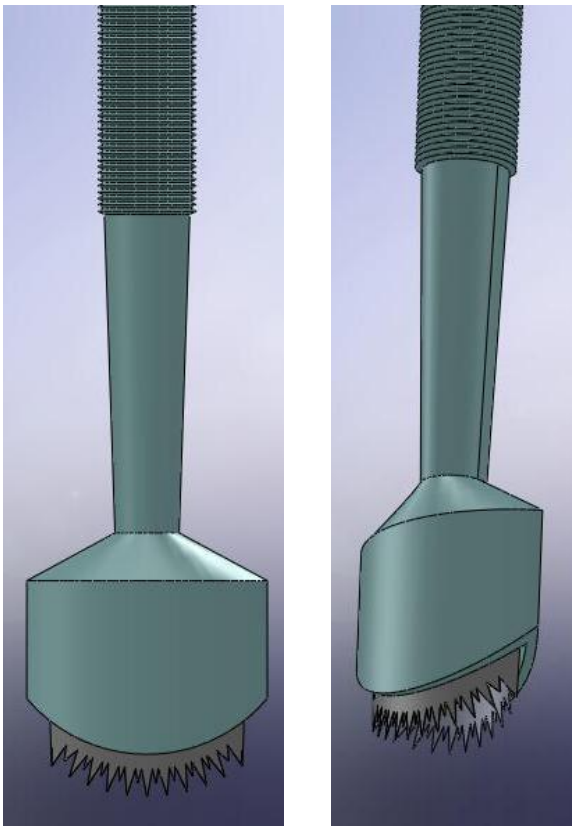

Figure 16. Final handle design with blade attached

5. Testing

5.1 Uniaxial Mechanical Testing

In order to compare the effectiveness of the proposed design with current devices, mechanical testing was performed on porcine skin obtained from a local slaughterhouse. Using a uniaxial testing device (Instron 5544), the force required to puncture skin was compared using one #11 surgical blade (Figure 17), a flat serrated prototype blade for proof of principle, and the traditional circular punch (Figure 18) in a custom machined block to allow for its rotation.

Figure 17. One #11 blade scalpel blade used for testing on porcine skin

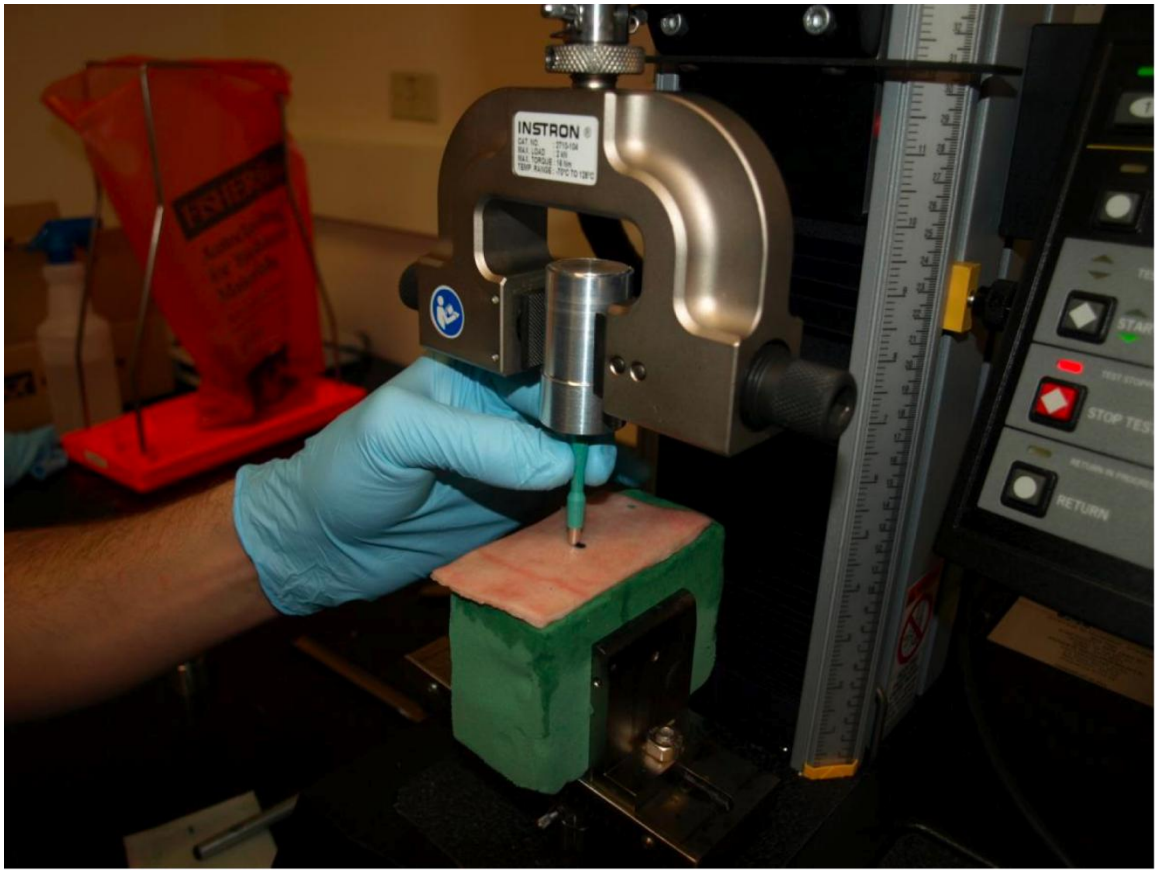

Figure 18. Circular punch used with custom machined block testing on porcine skin

5.1.1 Testing procedure

First, frozen pig skin was thawed in a bath of DI water at 37° C. The pigskin was then cut into sections measuring about 5 x 5 cm. The thickness of the skin at the location to be punctured was measured using a digital caliper. The group first attached the skin to the custom platform by using a zip-tie. This led to inconsistent results, and so the group used the base grips of the Instron to hold the skin down uniaxially. The surgical device being tested was then attached to the upper clamp of the Instron testing machine. The entry force for each device was determined as the peak force measure by the machine as

the device was compressively lowered onto the skin. For circular punch testing, the custom aluminum block was attached to the upper testing platform and the desired size biopsy punch was inserted. This allowed for the rotation of the circular punch in order to more effectively test for entry force in realistic surgical situations. In order to achieve results through this compressive testing, Bluehill2 software was opened on the testing computer. After selecting compressive testing, the descent rate was set to 0.1 mm/s. The surgical utensils were lowered to the top of the pigskin. The extension was then zeroed so that the exact deflection of the skin at puncture could be measured. The program was then run until the surgical utensil was fully through the pigskin. Results of this testing can be found in Appendix C.

5.2 Custom Testing Device

As previously stated, when trying to perform testing on the rotational biopsy punch the device was manually rotated. Because the force transducer has such a high sensitivity level, manual rotation led to excessive noise in the acquired data. To more accurately test the force required to puncture the skin a system was developed which would allow for user operation of the biopsy device while accurately measuring force. A 5 ml Syringe was outfitted with a strain gage (Vishay, Malvern, PA) between the 1ml and 2ml graduated markings. A three way valve was connected to the Luer-Lok® tip of the syringe to prevent the release of air when the plunger of the syringe was depressed. The three-way valve was outfitted with a plastic protrusion that fit inside the hollow handle of the rotational biopsy punch. A stand was fabricated to maintain stability of the device during testing (Figure 19).

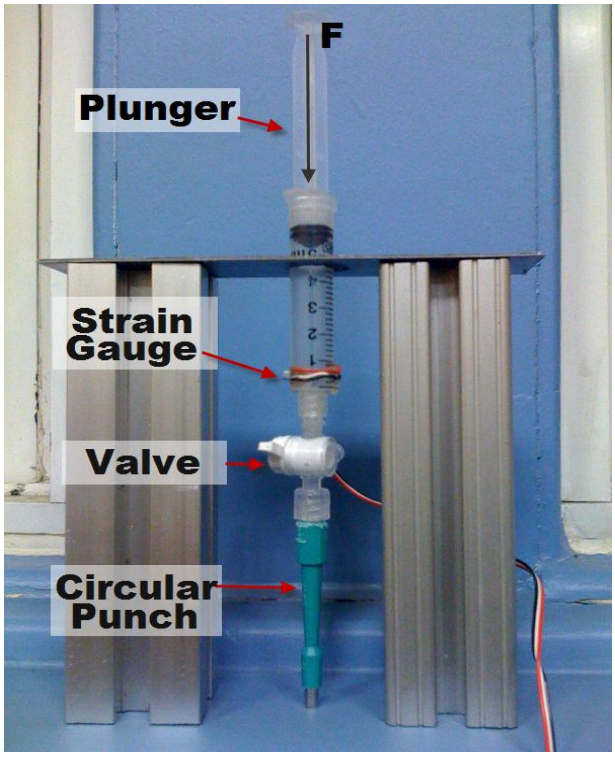

Figure 19. Syringe Force Testing System

The strain gage was connected to a hardware amplifier with an excitation voltage of 1V and gain value of 1900X. This connected to a National Instruments DAQ board (SCI-1122X). A simple LabView program (Fig. 20 and Fig. 21) was then created to acquire the strain value data. Using the following equation (Eq. 1), the recorded strain value was converted into syringe chamber internal pressure. Knowing the cross sectional area of the plunger then allows the calculation of force (Eq. 2) being applied. These equations are shown and described on the next page.

$$P = \frac{E * t * e}{r * \left(1 - \frac{nu}{2}\right)}$$

Equation 1. Internal Chamber Pressure
P=Pressure (psi), E=Elastic Modulus (psi), t=Wall Thickness (in), e=Measured Strain, r=Radius (in), nu=Poission's Ratio (psi)

$$Force = (P * \pi) * (r - t)^2$$

Equation 2. Force from Internal Pressure
Force (lbs), P=Pressure, t=Wall Thickness (in), r=Radius (in)

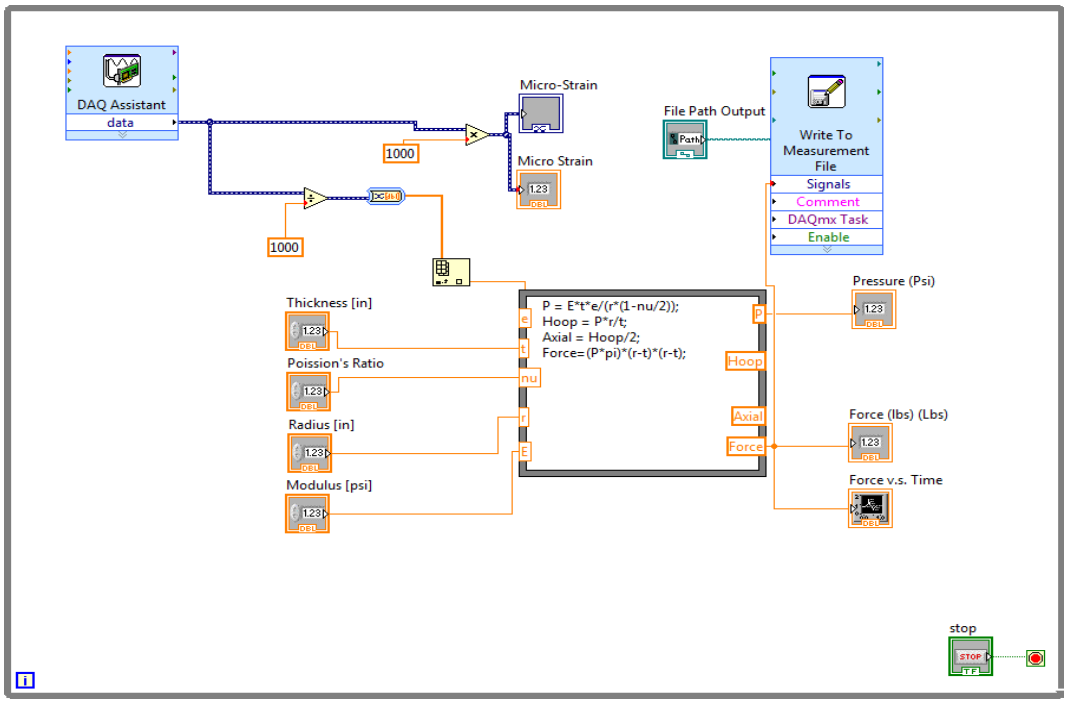

Figure 20. LabView Program Block Diagram

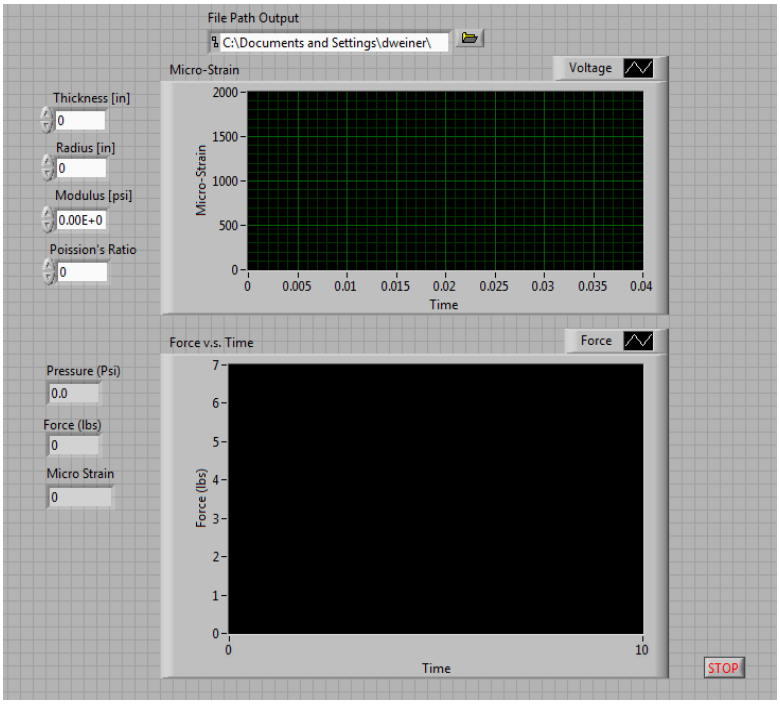

Figure 21. LabView Program Front Panel

Results using a 6mm rotational biopsy punch indicated a penetration force of 4.3 pounds (Figure 22). This was completed with approximately two full rotations, and represents the minimum force required to breach the dermis.

5.3 Skin Testing

5.3.1 Performance Testing

As mechanical testing alone will only yield data based on the penetration forces, testing was conducted on both porcine skin and human skin. This testing generated data not only on the skin penetration force, but also allowed visualization of the incision geometry and the suture characteristics of both the Miltex® circular biopsy punch and prototype created. This testing ultimately allows assessment of the performance of the device and therefore validates the overall design of the device.

5.3.2 Porcine Skin

Porcine skin was donated from Midtown Meats of Worcester, MA and Ed Stearn's Dressed Meats of Charlton, MA for performance testing. Skin from both sources which were closest to 2.5 mm thick was chosen to simulate the depth which designed the device to penetrate. Each device was then used on porcine skin and each incision was sutured to investigate the suture layout and the formation of standing cones. The resulting wound layouts were photographed and measured to quantify the results.

5.3.3 Clinical Testing

Due to the porcine skin had been stripped of all underlying tissue and did not fully replicate the characteristics of human skin, further performance testing was conducted. On April 3, 2009 Dr. Raymond Dunn, the chief of Plastic Surgery at the University of Massachusetts Medical Campus Hospital tested the prototype. After approval was received from the Institutional Review Board (IRB) at UMass Medical School, excised human skin from an abdominoplasty procedure was obtained to test the performance of the prototype. A 6 mm Miltex® circular biopsy punch was tested along with the prototype to compare the performance based on the excision procedure and the geometry of incision made. A felt tip marker was used to denote a lesion and performed a biopsy with each device. The procedure was recorded on video and Dr. Raymond Dunn's feedback was used to evaluate the performance of the device.

6. Results

6.1 Initial Uniaxial Testing Results

Due to the multidirectional forces required to operate the circular punch (a twisting motion combined with a downward force) and the prototype (a rolling motion combined with a downward force), viable data was only obtained from the testing of the #11 surgical blade in porcine skin. It was found that the minimum force required to penetrate porcine skin using a #11 surgical blade was 0.54 pounds over sample size n=3. Results from this testing can be found in Appendix A.

6.2 Custom Apparatus Testing Results

Results from the custom testing apparatus compared the forces required to penetrate porcine skin using a circular punch and the prototype. It was found that an average force of 4.3±0.1 pounds was required to penetrate skin using a circular punch while 17±1.97 pounds was required for the prototype. A students t-test was performed on the maximum recorded force of the testing trials from each group (n=3 for both groups). A *p*-value of 0.006 was recorded, indicating the use of the prototype did require a significantly higher amount of force to penetrate skin. Results from this testing can be found in Figure 22.

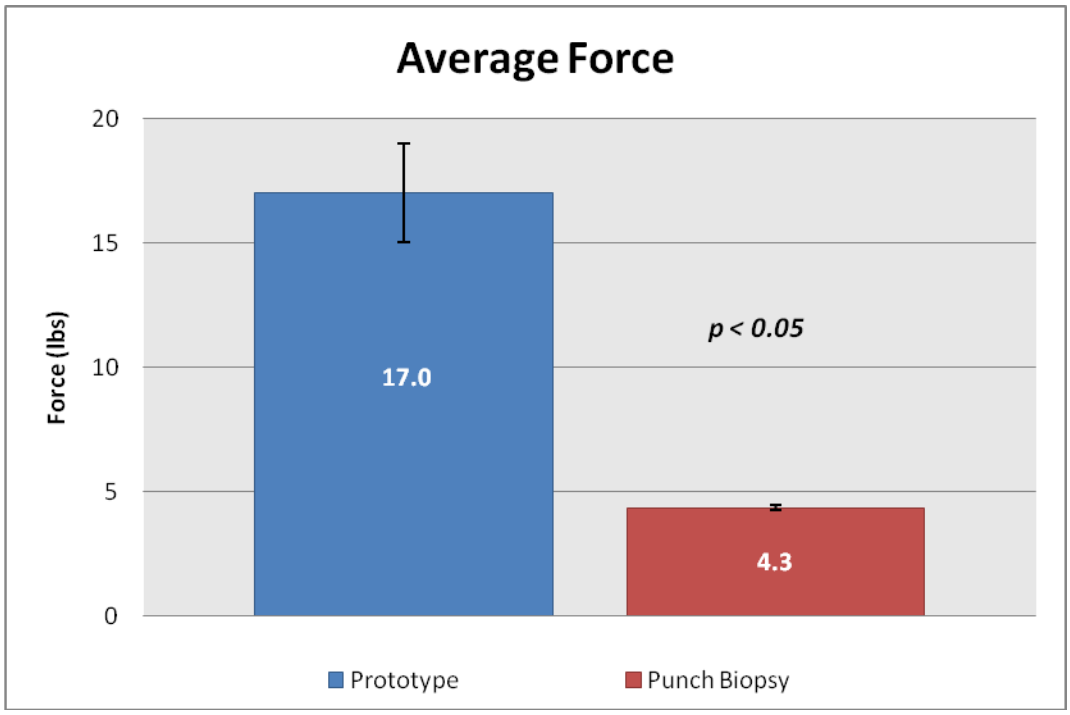

Figure 22. Comparison of Prototype Force versus Rotational Punch

6.3 Skin Testing Results

6.3.1 Porcine Skin

Both the Miltex® circular punch biopsy and the prototype were used on porcine skin to compare suture geometry. Figure 23B shows the circular punch biopsy suture from above and Figure 23D shows the circular punch biopsy suture from the lateral view. Figure 23A shows the prototype suture from above and Figure 23C shows the prototype suture from the lateral view.

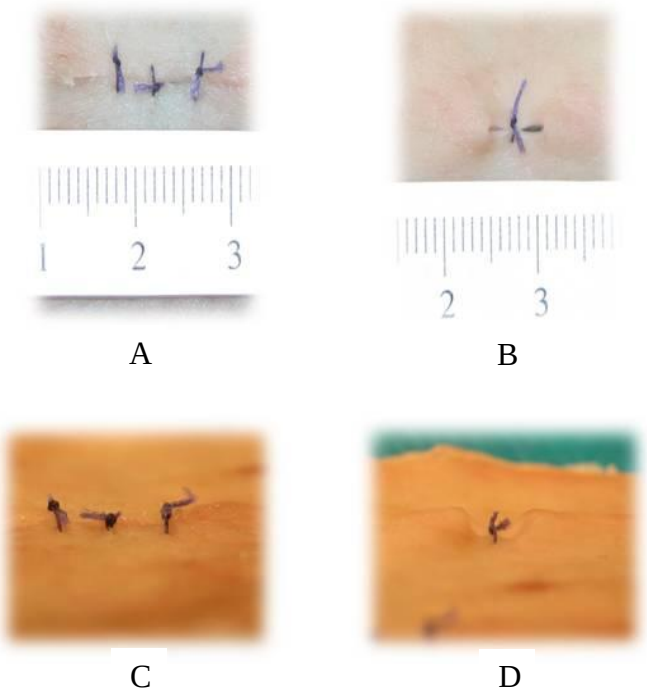

Figure 23. Porcine Skin Testing

6.3.2 Clinical Testing

A video was recorded of both the Miltex® circular punch biopsy and the prototype being used on excised human abdominoplasty skin. After conducting performance testing on human skin, Dr. Raymond Dunn's feedback was organized into Table 1 below as advantages and disadvantages of the prototype compared to the Miltex® circular punch biopsy.

Advantages	Disadvantages
Clean leading edges	Required excessive force to penetrate skin
Corner angles matched design specifications	
Superior geometry for easy suturing	

Table 1. Summary of Surgeon Feedback

7. Discussion and Analysis

7.1 Discussion

The force required to penetrate porcine skin was considerably higher than the circular punch. The circular punches ability to penetrate skin with such a low force is based on its cutting surface area. The rotation of the blade slices the skin at all possible points, creating a cut of infinite length. The infinite points of contacts can be classified as a high degree of cutting surface area. The initial design called for a cutting surface length of 172.8 mm (2.5mm long serrations and 1.25mm short serrations) as seen in Figure 24.

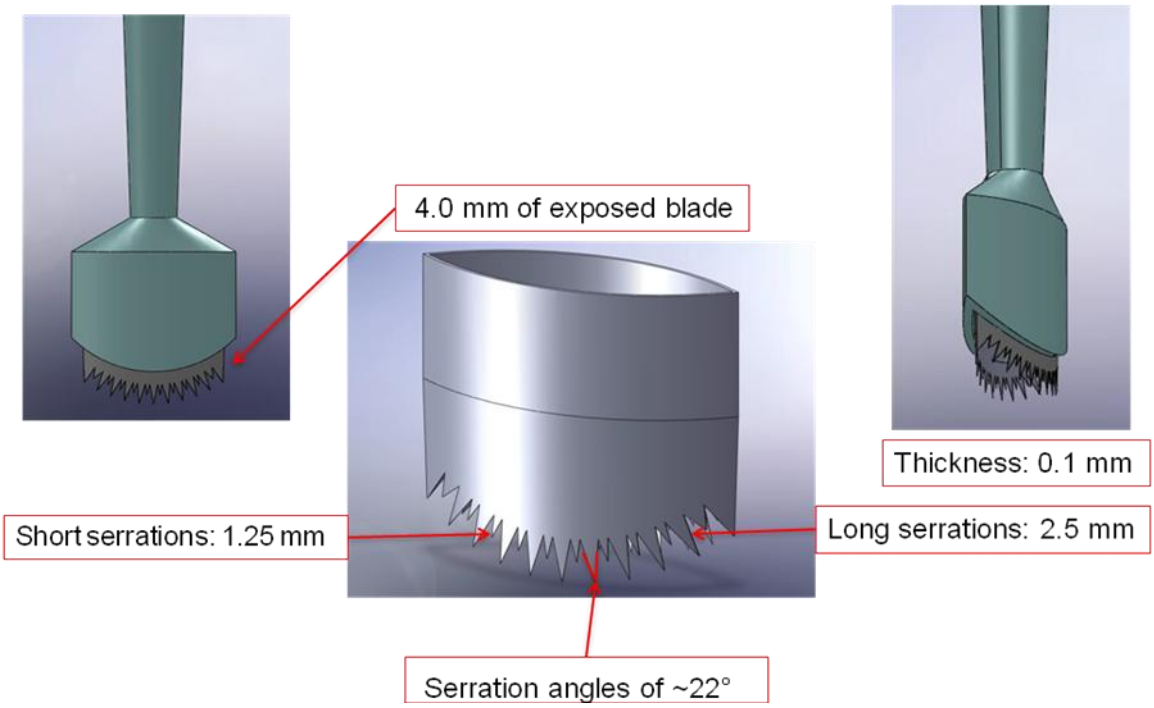

Figure 24. Blade Design Specifications

Prototypes were received from Leverwood Knifeworks of Dallastown, PA. The prototype blades received did not meet the set design specifications and had serration lengths shorter (1.4mm for the long serrations and 0.9mm for the short serrations) than

what was called for in the design (see Figure 24). This resulted in a cutting surface area of only 120.7 mm, which was only 69% of what was had planned for in the design. Because cutting surface area is directly related to the ability to penetrate skin, the prototype did not function as designed.

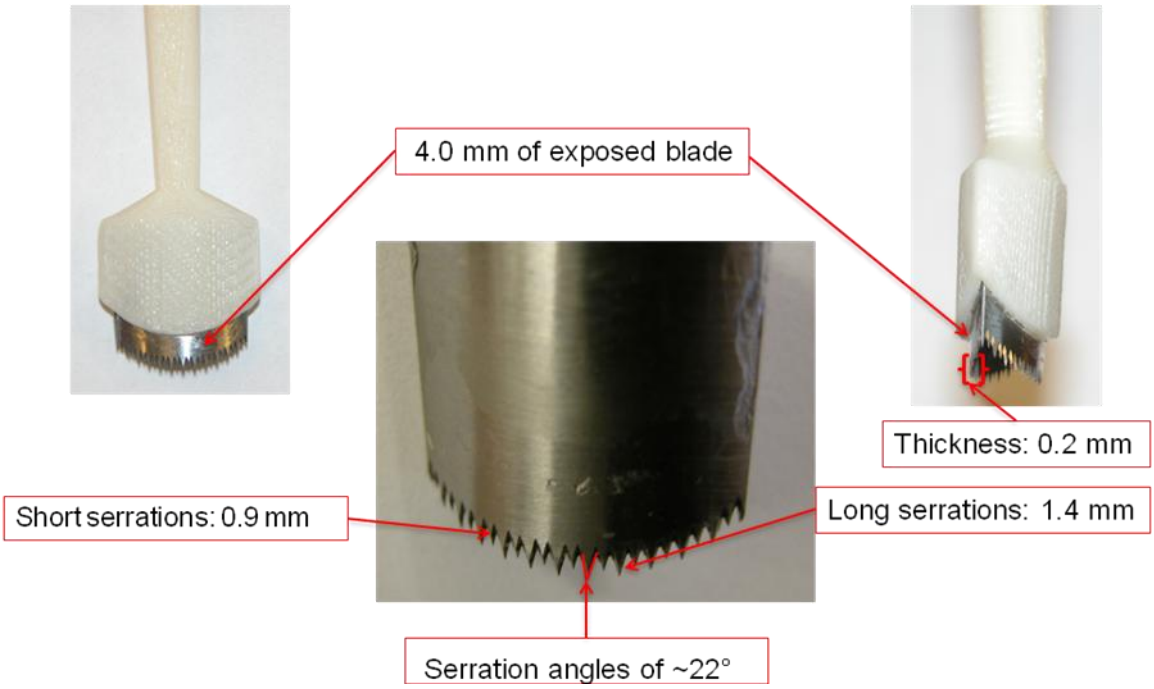

Figure 25. Prototype Blade Specifications

A second reason for the increased force required to penetrate skin was the rolling technique. To try and reduce the force required, the blade design incorporated an arc angle of 60 degrees. The rationale for this was that there would be an increased force per unit area resulting from the decreased points of contact at the surface of the skin (the same rationale was used to incorporate short serrations). The device was intended to then be rolled over the lesion, transferring the applied force to the next adjacent serration. While the theory is sound, the practice of this technique did not produce the desired results. The serrations of the prototype all point in the same direction instead of directly out from the center of the crowned edge. This would theoretically increase the force to

penetrate because each serration does not point directly into the skin while the device is rolled across the skin. Also, due to the compliance (elasticity) of the skin, more than one serration was in contact with the skin at all times, increasing the required force for penetration.

This leads back to the group's original key objectives for the project. The problem is relative to the manufacturability of the device. The final design had several key design points that were considered to be very important for ease of penetration through the skin. Manufacturing constraints led to several alterations from the final design. The overall proof of concept has been shown through testing because the device makes an elliptical incision, and it requires forces that surgeons could feasibly administer. Industry has proven to be unable to manufacture the exact final design, but can manufacture a device that is potentially marketable and matches all key functions and specifications (with exception to the final price).

7.2 Skin Testing Analysis

Performance testing results served to validate the ability of the device to eliminate the formation of standing cones as well as yield surgeon feedback on the force required to penetrate skin. It was evident that the prototype successfully created an elliptical shaped incision which left corner angles of 30°, a length to width ratio of 3:1 and therefore left superior suturing geometry as defined through literature [10]. Human and porcine skin testing showed the same results with respect to wound geometry, with standing cones forming due to the closure of a circular wound. Penetration force feedback came only from the human skin testing because testing on porcine skin was performed by the group. Dr. Raymond Dunn cited the force was in excess when compared to the circular punch,

which can be attributed at least partially to the prototype not meeting design specifications for serration length. This failure of the prototype to meet the specified serration lengths shortened the overall cutting area of the device. This decrease in cutting area can be compared to the performance of a scalpel blade. If two scalpel blades of different length are used and their performance is assessed, the scalpel with the shorter blade would perform less favorable when compared to the larger blade. This point serves to illustrate the effect of the decrease in cutting area of the prototype.

7.3 Cost Analysis

The specification that the group certainly did not accomplish is the creation of a device whose price is competitive in the market (~ $4.50). An order for 25,000 full blades was quoted by Leverwood Knifeworks to cost about $10 per punch blade. In addition to this price, cost for assembly, handle, packaging, and sterilization must be accounted for. Given the distribution costs, the group would need a device whose cost is about $2 per punch. This indicates that the device is still significantly more expensive than what would make it viable in the marketplace.

Aside from the overall price of this device, one could say that the group did create a potentially marketable device. The process of bringing the device to market has been outlined in this report. In order for this device to be marketable, it needs to be a device that surgeons have confidence in, and be one whose benefits justify the increased cost versus the circular punch.

8. Post Design Considerations

8.1 Logo

One aspect of bringing this device to market was to create and trademark a logo. A few different designs were created, involving the word "Plastipunch" and a creative design. A few alternatives were created and these may be seen in Figure 26 below. A group decision led to picking design alternative 3. This iteration has the word "Plastipunch" embedded into an elliptical shaped figure representing the cutting area of the device, and a dashed line representing cuts made with the serrations.

Figure 26. Logo choices

8.2 Packaging

To properly bring this device to market, a label was designed to be printed on the top of an autoclave bag. This label is to have the device logo and provide dimensions for the user. Furthermore, the device's size should be accurately represented on the label to allow the user to pick the correct punch size for the lesion to be excised. Figure 27 below depicts this label.

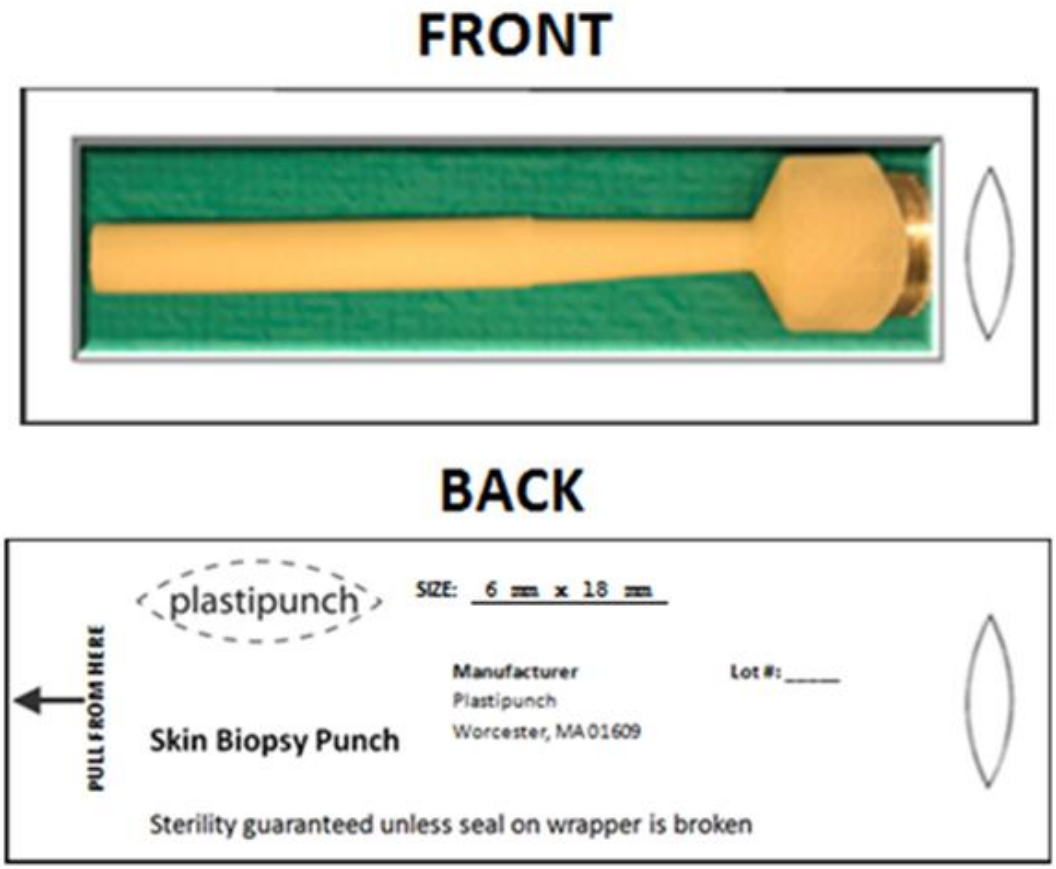

Figure 27. Product Packaging

8.3 Bringing to Market

8.3.1 FDA Approval process

Surgical punch biopsy devices are overseen by the FDA (Food and Drug Administration) under the regulation description of a manual surgical instrument for general use. These devices are considered Class I devices, which means that punch biopsies are minimally invasive and thus require minimal regulation from the FDA. In order for a corporation to begin to market a Class I device, they must be a registered manufacturer and provide a summary specifically indicating that the device is *substantially equivalent* to devices in the same product category that are presently being marketed. The form that must be submitted to the FDA is entitled a "Section 510(k)

premarket notification of intent to market" because of the section of the Food Drug and Cosmetics Act that is specifically relevant to Class I and II approval.

In order to bring the device to market, the group would need to register themselves as a corporation desiring to market a medical device. An example premarket notification would be similar to that seen in Appendix D.

9. Conclusions and Recommendations

9.1 Recommendations

There are several recommendations for the project moving forward relative to the group's prototype, the final design, and surgical incision technique. To begin, the prototype requires some revision in order to more easily cut through human epidermis and dermis. As previously stated, receiving a prototype that is accurately manufactured to the specifications of the group's final design would be necessary moving forward. This revised prototype could then undergo the multiaxial custom testing necessary for the device. Having received the results of this testing, the group would reevaluate the design based on its ease of use and force to penetrate relative to the circular punch. Acceptable penetration forces would be in the realm of about 200% the circular punch (~ 8 lbs). If the penetration force required were to be significantly greater than 8 lbs, then the group would need to redesign the final design.

The aspects of the final design that could be tailored to ease of incision are the overall cutting surface, the angle of the serrations, or more varied serration lengths. Lengthening the overall cutting surface should decrease the force necessary but would also impact the devices manufacturability. An even sharper angle for the serrations should make the device penetrate skin more easily. Varying the serration lengths further would allow less points of contact on the skin at different points during the excision process. All of these issues would make the device even more difficult to manufacture, but should impact the force required to penetrate through human dermis significantly.

Were these two attempts to fail, the group would then need to fully reevaluate the overall suggested technique for the desired device. Presently, devices in this market use a slicing motion to cut through the skin. The slicing motion associated with the #11 surgical scalpel blades requires very little force, and the twisting motion of the circular punch also gives a slicing motion along the circular incision. This surgical technique is very effective, and the group might need to return to the starting point of the project in order to try to imitate this slicing technique. Having said this, slicing would still need to be curved into the length to width ratio of approximately 3:1. Also, this device would need to accomplish the recommended 30º angles at each of the two corners. This would require some complex design alternatives, but would be necessary to create a device that can compete with the devices currently on the market relative to the ease of use.

9.2 Conclusions

In conclusion, the group believes that the objectives, functions, and specifications of the project were fully met, aside from the increased cost of manufacture. The group was able to design a device which was easy to use, safe, manufacturable, marketable and ergonomically sound. The device also created an elliptical shaped incision on skin with a ratio of 3:1 of the long axis to the short axis. In addition, it was able to penetrate skin to a controlled depth of 4.0mm, as per the handle design, and was included ergonomic features for ease of use. Though the prototypes created did not meet the project goal of $4.90 to compete with existing products, mass production of the device would result in lower costs. A quote was received from Leverwood Knifeworks, the manufacturer of the prototype, which mentioned that 25,000 full prototypes would cost about $10 a piece. Though the price received was much lower than the cost for each prototype, the group

believes that a lower price may be achieved with a larger order. In addition, it was mentioned by the manufacturer that the most efficient process would not be used to manufacture the blade, due to limitations in manufacturing equipment, thus it is believed that a better cost may be achieved through the use of a different manufacturer.

The group was also able to file a trademark application for the product, Plastipunch, and also create the necessary packaging label to be used when the device begins selling on the market. In addition, the group was able to develop a preliminary application for approval of the device from the FDA. The group believes that by following the recommended future improvements, the device will be able to penetrate skin with less force, become more cost efficient, and become a major competitor in the field of skin biopsy punch devices.

10. References

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Appendix A: Pairwise Comparison Chart

	Ergonomically Sound	Useful	Correct Cutting Shape	Manufacturable	Safe	Total	Percentage
Economically Sound	X	0	0	0	0	0	6.7%
Useful	1	X	0	0	0	1	13.3%
Correct Cutting Shape	1	1	X	1	0	3	26.7%
Manufacturable	1	1	0	X	0	2	20%
Safe	1	1	1	1	X	4	33.3%

Table 2. Pairwise Comparison Chart

Order: Safe, Correct Cutting Shape, Manufacturable, Useful, Ergonomically Sound

Appendix B: Gantt Chart

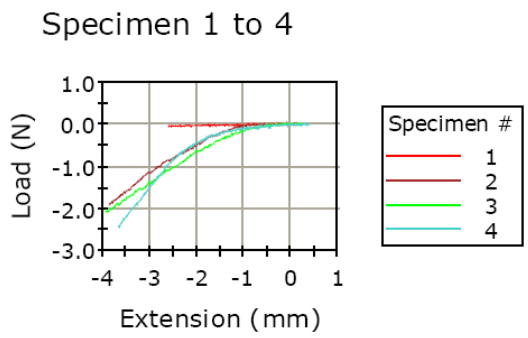
	Year	2008				2009			
	Month (1=January, 12=December)	9	10	11	12	1	2	3	4
Aim 1	1.1: Introduction, Background and Significance								
	1.2:Design and Proof of principle testing								
	Data Collection and Analysis								
Aim 2	1.3: Complete design detail, manufacturing techniques, continued experimentation, Complete Presentation and report								
	Data Collection and Analysis								

Table 3. Gantt Chart

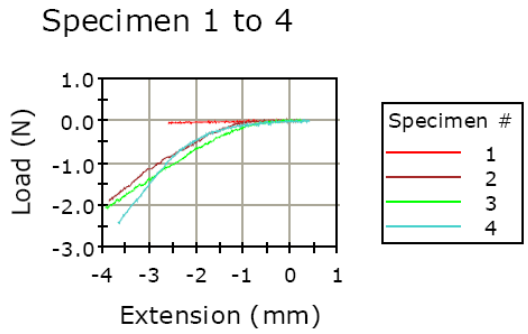
Appendix C: Preliminary Data

#11 Surgical blade

Graph 1



Graph 2



Results Table 1

	Specimen label	Extension at Maximum Compressive stress (mm)	Load at Maximum Compressive stress (N)
1	foam pilot	-2.44	-0.05
2	11 blade_1	-3.98	-1.89
3	11 blade_2	-4.15	-2.07
4	11 blade_3	-4.03	-2.42

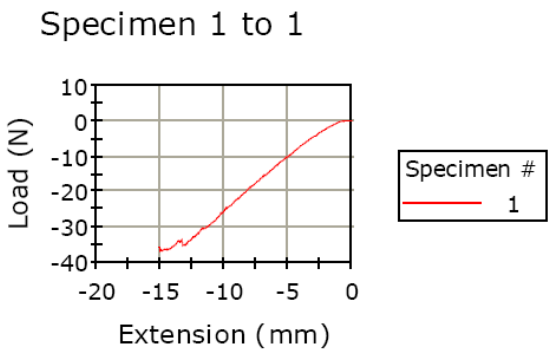
	Diameter	Length
1	n/a	45
2	2.42	45
3	2.42	45
4	2.42	45

Results Table 2

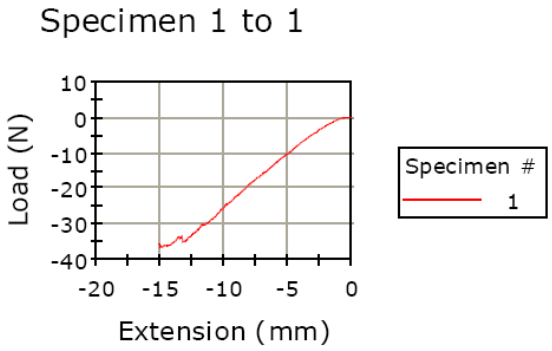
	Compressive load at Maximum Compressive stress (N)	Compressive extension at Maximum Compressive stress (mm)
1	0.05	2.44
2	1.89	3.98
3	2.07	4.15
4	2.42	4.03

4mm circular punch:

Graph 1



Graph 2



Results Table 1

	Specimen label	Extension at Maximum Compressive stress (mm)	Load at Maximum Compressive stress (N)
1	no_turning_1	-14.97	-36.55

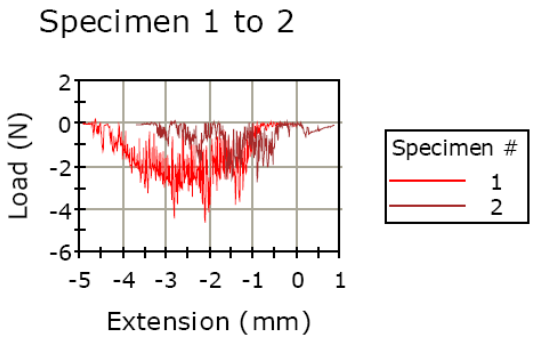
	Diameter	Length
1	2.42	45

Results Table 2

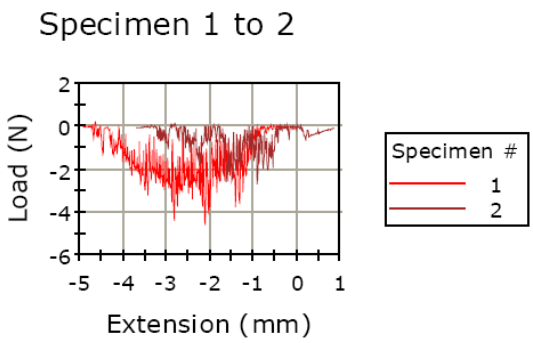
	Compressive load at Maximum Compressive stress (N)	Compressive extension at Maximum Compressive stress (mm)
1	36.55	14.97

4mm circular punch while twisting:

Graph 1



Graph 2



Results Table 1

	Specimen label	Extension at Maximum Compressive stress (mm)	Load at Maximum Compressive stress (N)
1	twisting_1	-2.11	-4.61
2	twisting_2	-1.18	-2.72

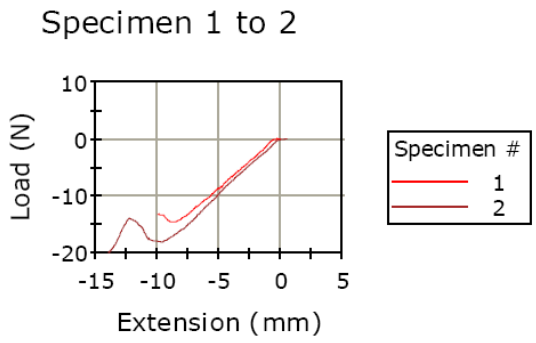
	Diameter	Length
1	2.42	
2	2.42	

Results Table 2

	Compressive load at Maximum Compressive stress (N)	Compressive extension at Maximum Compressive stress (mm)
1	4.61	2.11
2	2.72	1.18

6 #11 blades attached to each other:

Graph 1



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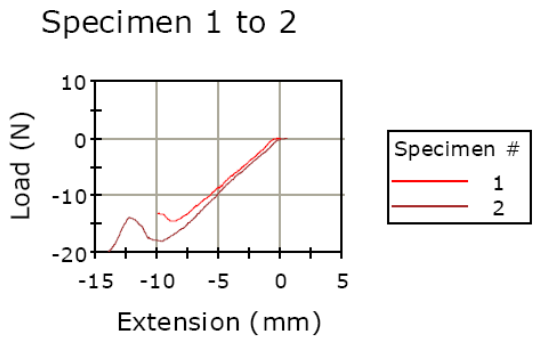

Results Table 1

	Specimen label	Extension at Maximum Compressive stress (mm)	Load at Maximum Compressive stress (N)
1	poc	-8.80	-14.47
2	poc_2	-14.36	-19.76

	Diameter	Length
1	2.42	
2	2.42	

Results Table 2

	Compressive load at Maximum Compressive stress (N)	Compressive extension at Maximum Compressive stress (mm)
1	14.47	8.80
2	19.76	14.36

Appendix D: Premarket FDA Notification

Date Prepared March 1, 2009

Sponsor
D ST MQP
100 Institute Rd.
Worcester, MA 01609
Telephone: (xxx) xxx-xxxx
Fax: (xxx) xxx-xxxx
Email: dstmqp@wpi.edu

Official Contact Person
Derek Hall
100 Institute Rd.
Worcester, MA 01609
Telephone: (xxx) xxx-xxxx
Fax: (xxx) xxx-xxxx
E-mail: der5k@wpi.edu

Common/Usual Name
Dermal Biopsy Punch Device

Proprietary Names
PlastiPunch

Classification Information

Classification Name(s):	Punch, Surgical
Medical Specialty:	General & Plastic Surgery
Device Class:	I
Classification Panel:	General & Plastic Surgery Device Panel
Product Codes:	LRY – Punch, Surgical

Identification of a Legally Marketed Predicate Device

Trade/Device Name:	ElliptiPunch, by Huot Instruments
510(k) Premarket Notification number:	NONE - Class I; 510(k) exempt
FDA Product Code:	LRY – Punch, Surgical

General Description
PlastiPunch is single use, disposable device consisting of a plastic handle molded around an elliptically shaped blade. The device is packaged and sterilized prior to delivery to the market. The blade is curved and leaves an elliptical shape when rolled on a surface. The blade also has serrations.

Indications for Use

The purpose of the device is to remove tissue in an elliptical shape in order to allow for easy stitching and thus superior wound healing. The PlastiPunch should be used by dermatologists and plastic surgeons in order to remove skin lesions or other abnormalities up to 6 mm in diameter. PlastiPunch is intended to be rolled on the skin along the skin lesion at the appropriate depth to remove dermis safely. The wound should then be stitched or otherwise bound in a straight line, one corner of the ellipse to the other.

Summary of Technological Characteristics

PlastiPunch is significantly equivalent to the Elliptipunch marketed by Huot Instruments because they are both intended to remove dermis in an elliptical shape. Both devices have a similar handle system that makes for ease of use and also accounts for a responsible depth penetration by acting as a stopper. Both devices are packaged and sterilized before entering interstate commerce. Both devices are intended for skin removal with the intention of high quality wound healing and minimal scarring.