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Redesigning and Prototyping a Micro Scissor for Micro-Anastomosis Post-Mastectomy

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Abstract

Breast reconstruction surgeries post-mastectomy are standard procedures aiming to restore the shape, appearance, and size of the breast. Autologous tissue flap reconstruction, a technique involving transplanting harvested tissue from the patient's body to the breast cavity through micro-anastomosis, presents advantages such as reduced infection rates but is hindered by the risk of thrombosis and necrosis. This study focuses on redesigning straight blade micro scissors used in autologous procedures to mitigate these risks. Using CAD software, 3D printing, and stereolithography (SLA) additive manufacturing, prototypes with sinusoidal blades were developed as an alternative to straight blades to improve cutting ability and maximize usable tissue of the vein. The sinusoidal blade was tested on cooked pasta and analyzed using ImageJ software and statistical analysis. The ImageJ and statistical analysis showed the sinusoidal blade's cutting ability to be comparable to the straight blade, with improved available area through reduced ridges. Clinical testing using cadaverous veins was proposed to validate the design's efficacy further. This novel and innovative approach addresses a critical need in microsurgery, potentially enhancing patient safety, expanding the landscape of current surgical tools, and improving surgical outcomes.

Keywords: Micro Scissor, Computer-Aided Design, Micro-Anastomosis

Introduction

Breast Reconstruction is a plastic surgical procedure that attempts to restore a breast to standard shape, appearance, and size following a mastectomy. The procedure can be performed using saline or silicone implants or autologous tissue flap reconstruction. An autologous procedure involves harvesting a tissue flap from the abdomen or back containing skin, fat, blood vessels, and sometimes muscle to the empty breast cavity to rebuild the breast shape [2]. The procedure typically costs over $29,226 and is often chosen due to a 23% decreased likelihood of infection post-operation [1,10]. However, according to a statistics report conducted by the American Society of Plastic Surgeons, more than 40% of women in the United States who undergo mastectomy pursue breast reconstruction, amounting to 107,000 women in 2019, with only 19% choosing to pursue autologous reconstruction [9]. Thrombosis, or blood clotting, from poor attachment of the veins during surgery is the leading cause of a failed autologous surgery [6,7]. This results in skin or flap necrosis, where an inadequate blood supply to the harvested tissue leads to the tissue not getting enough oxygen to survive and dies [6,7].

Micro scissors, a minor surgical instrument with fine blades designed for tissue manipulation, are often used in autologous surgery. The tool dissects and shapes the harvested tissue flap by cleaving small blood vessels. After cleaving the harvested blood vessels, they are attached to the host vessels using a coupler. A coupler contains pins for

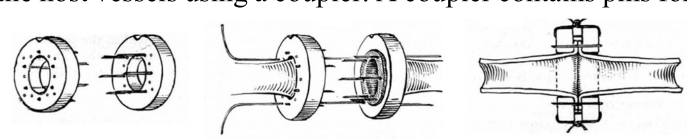

Fig. 1. Coupler Device. The device shown above is a coupler, a tool used by surgeons in anastomosis. As shown in the middle, the cleaved veins are inserted into the coupler and stretched over the pins. The coupler is closed and then sutured shut to ensure successful reconnection of the veins.

the vessels to be stretched and secured, then folds to secure them together while stitched (Figure 1). If the harvested tissue's vein diameter is less than 2.5 mm, there is a significant increase in risk for venous insufficiency [3]. In addition, when the venous anastomosis is cleaved and ragged due to dull scissor blades, the venous area increases this insufficiency and risk for necrosis. Hence, this research aims to redesign and prototype a micro scissor with a sinusoidal blade to maximize the available tissue around the coupler pins and cleaves better than current straight blades. This will improve the security of the vessels once they are stitched, which decreases the risk of thrombosis and necrosis. To ensure the successful completion of this project, a list of specific aims was generated.

The first aim was to research prior art and literature and develop prototypes of numerous micro scissors using computer-aided design (CAD) software. Before beginning a new design, the researchers felt it was important to understand previous art to identify critical components and errors of the micro scissors and how previous scissors were constructed. The researchers also obtained a stainless-steel straight blade micro scissor, which was observed and measured for dimensions. They intended to use this information to CAD in Autodesk Fusion 360 multiple micro scissor designs with a sinusoidal blade. The designs would then be assembled using 3D printed polylactic acid (PLA) plastic filament, and the designs would be narrowed down to two for testing.

The second aim was to print the prototypes using an SLA resin printer and test the efficacy of the micro scissor prototypes by conducting experimental trials with each micro scissor design on multiple materials. The researchers aimed to print the prototypes for testing using resin instead of PLA, as the SLA printer consists of a smoother additive manufacturing process that is better suited for picking up precise details. The blades were then tested using multiple criteria, such as ease of use, ease of manufacturing, clean cleave of vein, and surface area of usable tissue. The resin prototypes and straight blade were tested on cooked pasta and Play-Doh; then, the materials were observed and analyzed. The analysis consisted of measuring the amplitude of the microscopic ridges in the tissue after cutting using ImageJ software. Data collected from the trials was then used in a statistical analysis comparing the straight blade to the sinusoidal blade. Based on the data collected, the final prototype was printed using an SLA titanium printer.

While current micro scissors used in surgery are generally effective, continuous improvement in surgical devices remains essential. Currently, there are no commercialized sinusoidal micro scissor blades, making this design innovative and unique as historically, no significant changes have been made to micro scissor blades. Improving current micro scissor blades by implementing and experimenting with new iterations of blade designs could decrease flaws caused by micro scissors, leading to an increased risk of thrombosis. Introducing new designs or expanding the range of blade designs tailored for specific surgeries can enhance the versatility of micro scissors and mitigate specific risks associated with each surgical procedure, optimizing their utility and safety in diverse clinical settings.

Successfully prototyping this device, as proposed in the specific aims, will allow for a cleaner cut, and maximized tissue around the coupler pins. This device would be a more efficient and precise alternative to the straight blade and can aid surgeons in any microsurgical procedures. Improving this micro scissor design allows for better preservation of tissue integrity, decreasing the risk of tissue necrosis and contributing to the success of autologous procedures.

Results

Device Iterations

To begin the iterative design process to develop and test a working prototype, measurements were first taken of current models of micro scissors. Using two different straight blade models with different handle attachments, drawings of prototype designs were iterated in Autodesk Fusion 360, a CAD software program. While preliminary designs were produced on this software, various methods of initial prototyping were brainstormed. These methods included increasing the scale of the 3D printed model to obtain a more successfully printed prototype that allowed for the examination of assembly and design details. The first iterations were based purely on the measurements of the current straight blade model and focused on a slight sinusoidal curve to not completely disrupt the ability of the blade to cut. The following iterations modified the design to emphasize the sinusoidal curve of the blade so that this design would not be lost when prototyped to scale. The final iterations were modified based on the fit of the blades together. Minor changes were made to ensure that when the blades closed to cut, they seamlessly fit together to eliminate the chances of a jagged, unclean incision.

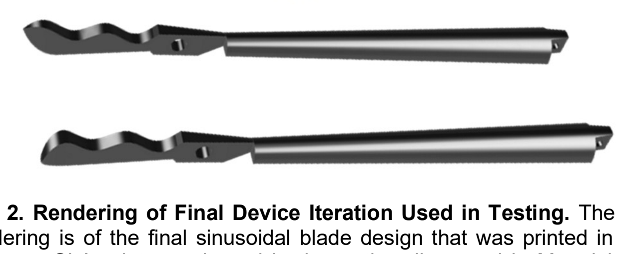

Fig. 2. Rendering of Final Device Iteration Used in Testing. The CAD rendering is of the final sinusoidal blade design that was printed in resin using an SLA printer and used in dry testing discussed in Materials and Methods.

This final iteration was printed using resin stereolithography (SLA) which allowed for a sturdy and detailed at-scale prototype of the blade design (Figure 2). This blade was attached to a 3D printed shaft as the polylactic acid plastic (PLA) allowed for the flexibility needed to connect the handles. In the future, this final prototype would be produced using either titanium or stainless steel as they are both biocompatible. Due to limitations in time and availability of resources, this metal prototype was not able to be produced. To continue to conduct validation testing of the blades' ability to cut, a softer, more pliable material - cooked wide noodles - was used during testing.

Dry Run Testing Quantitative Results

Wide noodles were cooked for eight minutes and completely cooled to be used for testing. Incisions were made with both the final sinusoidal blade prototype and the current straight blade model. These incisions were given overnight to dry out for more accurate analysis. The next day, close-up images were taken of each noodle incision. A total of three cuts - six sides were analyzed for each type of blade. For the straight blade incisions, a straight line was drawn along the incision, and the amplitude of ridges in each cut side was measured and averaged in millimeters using ImageJ, an image processing program (Figure 3).

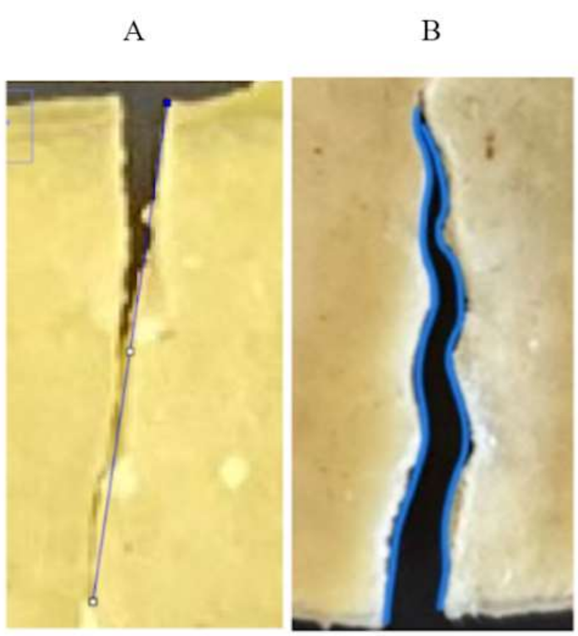

Fig. 3. Cut Pasta Analyzed with ImageJ. This depicts two of the incisions made with the straight blade (A) and the sinusoidal blade (B). Overlaying each image is the ideal cut line with a straight line being the reference for the straight blade and a periodic curved line being the reference for the sinusoidal blade.

For the sinusoidal blade incisions, a sinusoidal curve was drawn along the incision and the amplitude of ridges along the curve was measured and averaged in millimeters using ImageJ. The averages from each cut were then analyzed using an ANOVA statistical analysis (Figure 4). A p-value of 0.01 was obtained, indicating that the cutting ability of the sinusoidal blade was statistically comparable to the cutting ability of the current straight blade model at $\alpha = 0.05$ significance level.

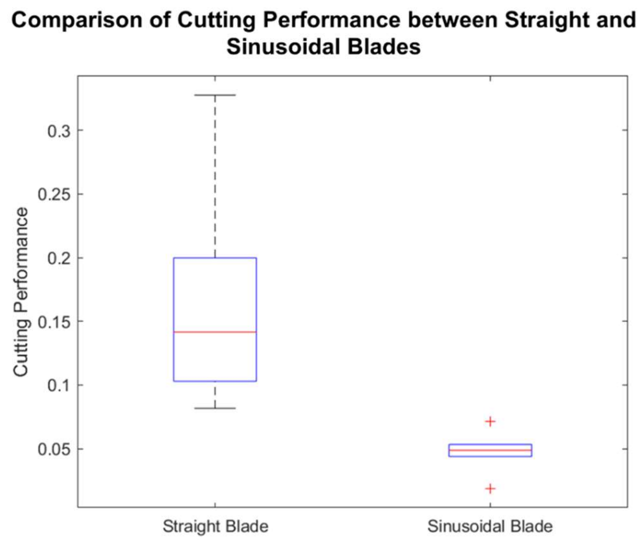

Fig. 4. Box and Whisker Plot Comparing Cutting Performance of Straight versus Sinusoidal Blades. This plot shows the average ridge amplitude measured between the ideal cut line drawn in Figure 3 and the actual cut.

Discussion

Final Product Considerations

The results of the dry run testing showed the statistical significance of sinusoidal blade sharpness comparable to straight blade sharpness, according to the alpha significance level of 0.05. The results also showed an increase in usable tissue for the sinusoidal blade, as the testing concluded there were smaller ridges compared to the straight blade. A obtained p-value of 0.01 suggests that the null hypothesis should be rejected, as the result received is unlikely to occur by chance under the assumption that the null hypothesis is true. Therefore, the capstone team can accept that the sinusoidal micro scissor blades are a successful alternative to straight blades.

The final design for the sinusoidal micro scissor blades successfully fulfilled the design requirements and goals set by the specific aims. Two main prototype designs were created with sinusoidal waves (Figure 5). The blades were printed with multiple materials including PLA plastic filament and resin. The prototypes were easy to assemble and were properly manufactured at scale. The prototypes were tested and maintained mechanical integrity after multiple cuts into soft material. Finally, the prototypes successfully created a cleaner cut in the soft material and therefore, maximized usable material to be stretched on coupler pins.

Fig. 5. Two Final Sinusoidal Design Iterations. The two final sinusoidal blades are shown in this image as CAD renderings. These final two blades were printed out of resin using SLA printing. They were used in the dry testing with the cooked pasta.

Impact

Breast reconstruction rates are continuing to rise as the national breast reconstruction rate increased from 12.8% in 2010 to 29% in 2019, with implant reconstruction dominating the procedure options at 79% [5]. Although there are risks associated with implant reconstruction such as a higher rate of infection, breast plant illness, and a higher risk of reconstructive failure, autologous surgery is still not considered due to the high risks of thrombosis and flap necrosis[4,8]. By targeting and improving the surgical tool directly involved with risks of thrombosis and necrosis, those risks can be minimized and autologous surgery could be considered a safer procedure for women post-mastectomy. Autologous surgery is also considered the only choice for certain patients and is a preferred method for patients expecting to receive radiation therapy or with prior irradiated breast[8]. Decreasing the risks of this surgery and making it as safe as possible for it being a certain patient's only option of breast reconstruction was also considered in the improvement of the design.

Furthermore, there are numerous risks in a multitude of microsurgeries directly associated with micro scissor design, and mitigating these risks by exploring alternative micro scissor designs can enhance safety and optimize the outcomes of each surgical procedure. Considering there haven't been many changes to the micro scissor historically, expanding on different designs of micro scissor blades would have a lasting impact on the medical industry as the ideal final product of this technical project would apply to all different types of microsurgery. Augmenting the specificity of blade designs that are adaptable to a standardized shaft could meet the demand for a tailored product while maintaining universal optimization, thereby increasing patient safety comprehensively. This innovation has the potential to reshape the landscape of existing medical device manufacturing, promoting advancements in patient care standards.

Limitations

As mentioned above, there is limited innovation in micro scissor development. Because they have stayed relatively the same, there is limited information to be found regarding specific micro scissor dimensions. Therefore, a physical device needed to be obtained from our advisor. Due to misaligning schedules, the team experienced delays in obtaining a physical device to dimension which put a delay on initial CAD development.

Additionally, the team experienced various difficulties in regard to prototyping. Initial at-scale 3D printed prototypes were unsuccessful due to the 3D printers' inability to produce the minute details required of the CAD designs. This was solved by scaling the prototypes to be much larger than what the finalized design would entail. Even with this solution, the 3D printers accessible were finicky and would not consistently print usable prototypes. A similar problem occurred when using the SLA printer to produce a resin prototype. Difficulties occurred with the printer causing the cured resin to build up on the bottom of the resin bed instead of attached to the plate. This was not noticeable until approximately 30 minutes after the print had begun as at the beginning of a print, the plate is barely lifted out of the resin bed. Incorrect prints also occurred where additional resin would be cured onto the actual prototype. This created a sloppy prototype with incorrect dimensions and noticeable deformities.

Finally, there were many difficulties experienced in obtaining a metal prototype of the finalized CAD design which prevented clinical testing from occurring. Initially, a metal prototype was to be created with help from the Materials Science department. Professor Ji Ma uses an SLA printer and titanium powder to create metal devices. However, due to the nature of his research, he was not able to allocate an entire print to our capstone project. He offered to allow the printing of just the blade as he used the printer for his research but showed reservations when considering the dimensions of the blade and the orientation of which it would have to print. Ultimately, he was not able to produce a metal print for our use. In addition, research was conducted to create a list of companies that specialize in creating prototypes whether that be through additive manufacturing or milling. Of the nine companies contacted, only one response was received. Follow-up emails were sent, and companies remained unresponsive. The one company that did respond directed our team to use their "novel" quoting software on their company website which was not able to successfully process the CAD file input.

Future Work

Further implementation needs to be done to ensure that this micro scissor blade design is truly comparable to current straight blade designs. The resin SLA printed blade would need to be fully assembled with a pivot screw and undergo more trials of testing for clinical integrity before moving on to metal additive manufacturing. Due to the limitations caused by the makerspace SLA printer, exploration and use of other SLA resin printers on campus would be imperative to getting a successful prototype.

Titanium and stainless-steel prototypes would then need to be printed using SLA additive manufacturing, although other forms of manufacturing such as further research into outsourcing and casting molds should be considered in the case that the additive manufacturing does not work at scale. The design process would then be repeated, going through trial and error of different CAD designs based on the success of the metal print, dimensions of couplers used in surgery, and clinical testing. Numerous trials of clinical testing would be conducted on cadaverous veins provided by Dr. Campbell's lab and the same analysis on ImageJ software would be performed. In addition to testing blade sharpness, the cadaverous vein would then be stretched over a 6-pin coupler and compared to a vein cleaved by a straight blade to test the maximum area around the pins of the coupler. Statistical analysis would then be done to determine if the data collected is statistically significant.

One last cycle of the design process would then be performed, iterating the final blade design to accommodate all types of couplers used in surgery, along with a detachable shaft so that the proper blade can be attached based on vein diameter and the number of coupler pins. Other factors such as ergonomics, durability, sterilization, and biocompatibility would be considered through further testing and communication with surgeons performing microsurgeries.

Following the successful validation of clinical integrity and completion of the design process, filing for a patent to protect the intellectual property rights of the newly designed blade would be essential. Ensuring regulatory compliance and meeting standards for medical devices would then be explored by obtaining approval from the FDA and gaining ISO certification.

Materials and Methods

Creation of Prototype Designs

To get to the prototyping stage of the project, the product design cycle was followed. It began through background research and discussion of prior art. In this background search, it was discovered that there have not been many design changes when it comes to surgical micro scissors. Because of this, micro scissors that Dr.Campbell currently uses were given as a reference for both design and dimension analysis. Through various brainstorming, children's craft scissor blades combined with current micro scissors became the design reference used in iterating various blade designs. Designs were sketched and changes to these designs were made through team discussions until two finalized designs were created to be CAD on Autodesk Fusion 360.

After finalizing initial designs on CAD, 3D printing with PLA plastic was used as a cheap and easily accessible method of prototyping. These initial prototypes were messy and often printed with several deformities. It was therefore difficult to examine the prototype to determine what revisions to make. To solve this problem, future iterations were printed 200X to 300X larger to properly examine the blade design as well as determine how the two blades fit together. Various large-scale 3D printed designs are shown in Figure 6 for reference.

Fig. 6. Scale Comparison of Blades. The two final iterations with the larger, scaled-up 3D printed version on the left and the to-scale SLA resin printed blade on the right.

After editing the large-scale PLA blades to optimize fit and design, the two finalized designs were printed at scale using resin SLA printing. SLA printing utilizes a metal blade that is dipped in a pool of resin and is cured to develop a product layer by layer. This created a blade that had the strength to withstand initial testing with cooked pasta and included minute details similar to an actual micro scissor. The blades were connected to a 3D printed shaft (Figure 2) as the PLA plastic is more flexible than resin and therefore allows for the flexibility and tension required to push together the handles and open and close the blades.

Dry Run Device Testing

The cutting ability of the sinusoidal resin prototypes was determined with the use of cooked wide pasta noodles. Pasta noodles were determined to be the material for this experiment as they provide a soft and flexible interface that can be cut with a resin blade while still retaining the integrity of the incision made. The pasta noodles were submerged in boiling water
for approximately eight minutes to cook all the way through. They were then cooled until completely cold to the touch. The pasta noodle was cut five times with both sinusoidal resin prototypes as well as the typical straight bladed micro scissor. As one prototype could not successfully make incisions, these cuts were not used in the analysis. The pasta was then placed on a flat surface for it to dry for analysis. Close-up images of the noodle incisions were taken to be used for analysis. To determine what constitutes a "clean" and successful cut, a parameter was developed by measuring the amplitude of any ridges or negative space that stray from a line that represents an ideal cut. For the straight bladed micro scissor, this ideal cut would be a straight line. For the sinusoidal bladed micro scissor, this ideal cut would be a line with periodic waves. The three best incisions were determined for each blade to give a total sample of six sides that would be analyzed for the respective blade. ImageJ was used to zoom into the image and measure the amplitude of each ridge in millimeters (Figure 3). For each cut side analyzed, the ridge amplitudes were averaged (Table 1). A one-way ANOVA statistical analysis was performed, which yielded a p-value of 0.01 indicating that the cuts are statistically significant, and the performance of the sinusoidal blade is comparable to that of the straight blade.

Table. 1. Data from Cut Analysis.

Cut	Measured Cut Amplitude of Straight Blade Ridges (mm)	Measured Cut Amplitude of Sinusoidal Blade Ridges (mm)
1	0.1029	0.0185
2	0.1632	0.0492
3	0.1200	0.0438
4	0.1998	0.0483
5	0.0817	0.0533
6	0.3276	0.0716

Proposed Clinical Testing

As a prototype made of metal was not able to be obtained in time, clinical testing was not able to be conducted. Regardless, this was a consideration, and therefore proposed testing was created. Cadaverous veins would be obtained from the UVA Health Center. They would be cut and tested in the lab Dr. Campbell uses to instruct residents. The cadaverous veins would be cut with the assembled metal prototype of the sinusoidal blade as well as the typical straight blade micro scissor. Similar to the initial device testing with pasta, close-up images of the incisions would be taken. These would then be analyzed using ImageJ and the same parameter previously developed to determine a "clean" and successful cut. The amplitude of each ridge and negative space that strays from the ideal cut would be measured and then averaged. After this data has been collected, a one-way ANOVA statistical analysis would be performed to determine if the cutting performance of the sinusoidal metal prototype is comparable to the straight blade micro scissor.

Additional analysis would be conducted to analyze if the sinusoidal blade can maximize the usable tissue located around the coupler pins. Cadaverous veins would be cut using the metal sinusoidal blade and the straight blade. The vein would be stretched over the coupler pins. Using ImageJ, the area of intact tissue surrounding each pin would be measured. This would be conducted for a number of cleaved veins for a stronger sample size. This data would then be analyzed to determine if the sinusoidal blade can optimize the amount of tissue surrounding each coupler pin to improve the surgical procedure. From the results of this clinical analysis, further revisions would be made to improve the design of the sinusoidal blade.

End Matter

Author Contributions and Notes

Melton, G. and Gilpin, G. created CAD designs, constructed prototypes, conducted clinical and statistical testing, and wrote the final report. Campbell, C. advised on device design and cost analysis. The authors declare no conflict of interest. This article contains supporting information online.

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