Right-Angle Dissector Scissors Hybrid Surgical Instrument

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Abstract

This report describes a right-angle hybrid surgical instrument for use during deep hole surgeries such as breast reconstructive surgery. During latissimus dorsi flap breast reconstructive surgery, careful dissection around vascular and neurological structures requires precise instruments. The right-angle forceps is a common surgical instrument often utilized to tease away or present soft tissue for an assistant to cut or cauterize. However, if the surgeon is operating in a deep hole where the assistant cannot reach, the surgeon has to use the non-dominant hand to cut or cauterize, but the non-dominant hand is often occupied with another forceps or other instruments. To address this issue, three designs are described to incorporate scissors into the right-angle forceps, and a final design chosen after analysis using a weight design matrix. The final trigger scissors design remains blunt-tipped to allow delicate dissections and incorporates the ability of surgical scissors to cut desired tissue without damaging surrounding regions. The design was prototyped and tested to evaluate its performance as a proof of concept, and exhibits potential to be developed into a functional surgical instrument. Finally, additional future steps of the project, including modifications, testing, and prototyping methods, are discussed.

Background

Anatomy of latissimus dorsi muscle

The latissimus dorsi is a broad, flat triangular muscle of the lower back (see fig. 1). It contributes to the posterior wall of the axilla and is covered by the trapezius superiorly. It originates indirectly via thoracolumbar fascia into the spines of the lower six thoracic vertebrae, lumbar vertebrae, lower 3 to 4 ribs, and iliac crest and inserts into the floor of the intertubercular sulcus of the humerus[1].

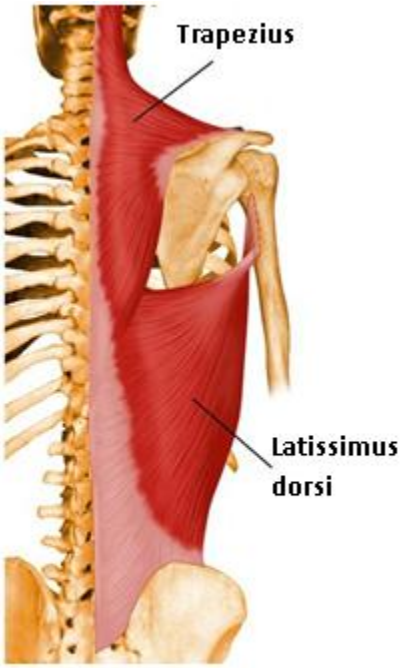


Figure 1: Latissimus dorsi muscle[2]

Latissimus dorsi flap breast reconstruction surgery

Latissimus dorsi flap breast reconstruction is commonly performed following a mastectomy of a patient due to breast cancer[3]. The latissimus dorsi flap is utilized to provide the surgeon better control of the appearance of the reconstructed breast compared to using a tissue expander or implant alone, as the soft tissue can create a more natural appearance. The flap can sometimes replace the implant entirely for patients with a small breast volume. During the procedure, the surgeon removes the latissimus dorsi muscle from the origin sites (see *anatomy of latissimus dorsi muscle* above) and elevates the muscle flap off the back (see fig. 2, left). Next, the flap is rotated about the insertion site to the front of the chest wall (see fig. 2, center). The flap is still attached to its insertion site and to the thoracodorsal artery, the main source of blood supply to the muscle[4]. Once the flap is properly placed in its new location and a breast implant is

inserted, the surgeon closes the wound. Finally, the surgeon reconstructs the nipple and areola in a separate later procedure[5] (see fig. 2, right).

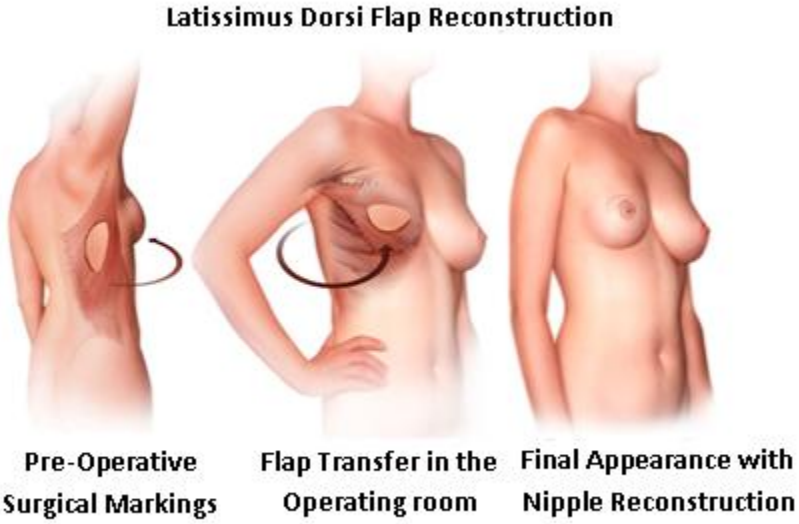


Figure 2: Overview of latissimus dorsi flap reconstruction[4].

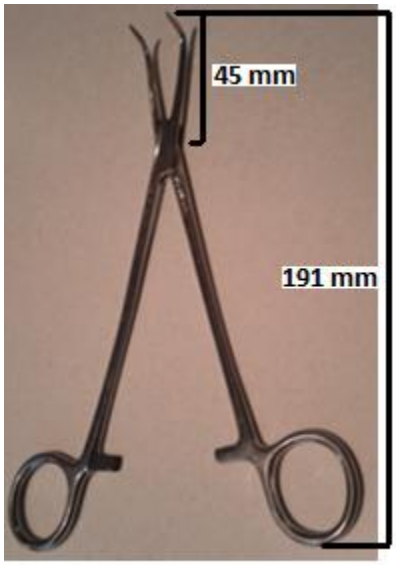


Figure 3: Right-angle forceps.

Motivation

During latissimus dorsi flap breast reconstructive surgery and other deep-hole surgeries, the surgeon is sometimes required to dissect and sever connective tissue between sensitive structures. Dissection in these deep holes is currently performed using the right-angle forceps (see fig. 3), but subsequent cutting or dissecting has to be performed by an assistant as the surgeon's other hand is often already occupied with additional instruments. The assistant usually cannot see into the deep hole, making the dissecting or cauterizing extremely challenging. The right-angle dissector scissors hybrid surgical instrument is intended to allow the surgeon to dissect and cut using the same instrument, minimizing the chances of accidentally damaging other tissue during surgery.

Problem Statement

During latissimus dorsi flap breast reconstructive surgery, careful dissection around vascular and neurological structures requires precise instruments and the right-angle forceps is often utilized to tease away or present soft tissue for an assistant to cut or cauterize. However, if the surgeon is operating in a deep hole where the assistant cannot reach, the surgeon has to use the non-dominant hand to cut or cauterize, which is a challenge since the non-dominant hand is often occupied with another forceps or other instruments. A hybrid instrument incorporating scissors in the right-angle forceps has to be developed. It has to remain blunt-tipped in order to perform delicate dissection and incorporate the ability of surgical scissors to cut desired tissue without damaging surrounding regions.

Client Requirements

The device has to incorporate a surgical cutting scissors function in the existing right-angle forceps, maintaining the dissector function of the forceps while adding the cutting function of the scissors. The device has to remain blunt on the outside edges while being sharp on the inside edges, where cutting is performed. While cutting, the device should allow the surgeon to see the deep region and not obstruct the surgeon's sight. It has to be compatible with current surgical protocols, be fashioned out of surgical-grade stainless steel, autoclavable, and having sharpenable blades. It should be operational under normal operating theater conditions of temperature approximately 20°C and relative humidity of approximately 50%. Furthermore, it should be ambidextrous and adaptable for different forceps sizes. Finally, it should be priced under $200.

Existing Devices

Right-angle forceps

Breast reconstruction surgery currently utilizes the right-angle forceps of length 191mm (7.5 inches), otherwise known as a 90-degree curved Kantrowitz forceps (see fig. 3). While the majority of surgical forceps are curved to approximately 45 degrees, this angle is ineffective for structures which are either too deep or in an awkward position, as is the case in the axilla during surgery[6]. Because of the unique angle of the right-angle forceps, it can reach around blood vessels and other important structures that are impossible with other devices. It can be used to occlude blood vessels and other structures or in dissection, where it can effectively expose hidden structures that may be blocked on all sides. However, the current device is limited by its lack of cutting capability. As a result, it must be used in conjunction with surgical scissors or a bovie-tip cautery device, creating a problem as outlined above.

Right-angle Harmonic Scalpel

A physician associated with the Nebraska Surgical Research Center, Mark A. Carlson, MD, has proposed a design for a right-angle harmonic scalpel which would combine a right-angle forceps and scalpel into one device[7]. The device would make use of a right-angle dissector and Harmonic Scalpel® (Ethicon Endo-Surgery, Blue Ash, OH) to create a tool for minimally invasive surgery. The device grasps tissue with the jaws of the shears, after which an ultrasonic vibration cauterizes the tissue and seals off blood vessels by denaturing, dehydrating, and coagulating the proteins. At that point, the jaws slice through the grasped tissue, ending the process in a quick and clean fashion. The device is currently theoretical, with no prototype constructed yet. In addition, the cost of manufacturing the device would considerably exceed the budget, as the cost of the shears alone can range from a few hundred to a few thousand dollars[8].

Endoscopic Instrument

Although the device is not used in breast reconstruction surgery, US Patent 5,281,220 describes an endoscopic instrument that utilizes technology related to the desired final product (see fig. 4)[9]. This

device is used to perform internal procedures through a trocar in which the instrument handle rotates the instrument by a control mechanism. The handle is connected to the end tube by a slide member, which allows the surgeon to rotate the tube using one hand.

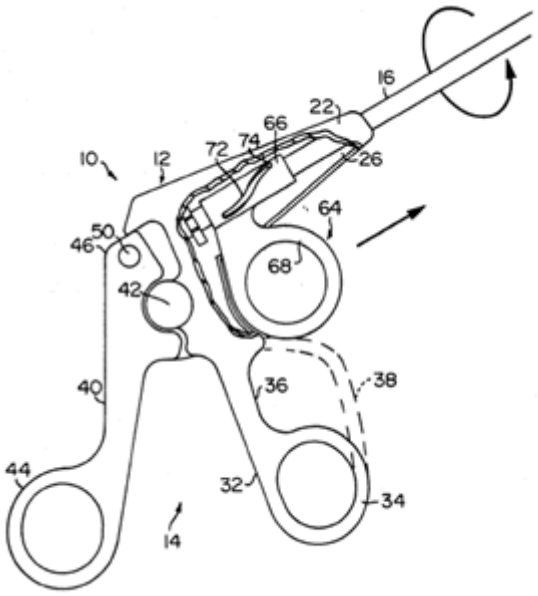


Figure 4: One-handed rotating tube endoscopic surgical device[9].

Ethics

As the device will be used to directly interact with human patients, it is important to understand the ethical issues which may be of concern. Beauchamp and Childress have proposed four ethical principles relating to plastic surgery, shown in table 1[10]. From these, it appears that the biggest ethical concern is ensuring the device does no harm to the patient while also improving care for the patient. Consideration must also be given to performing adequate testing and collecting enough data to support the use of the device and allowing patients to make informed decisions about the device being used during surgery.

Table 1: Beauchamp and Childress' four ethical principles[10]	
Autonomy	Acknowledge and respect a patient's right to self-choice and self-governance free from interference of others and from limitations towards making informed decisions
Nonmaleficence	"First, do no harm." Obligation not to inflict harm or adverse effects to patient due to absence of care
Beneficence	Obligation to prevent or remove harm while also promoting good by contributing to the welfare and acting in the best interest of the patient
Distributed Justice	Distributing benefits, risks, and costs fairly, equitably, and appropriately; treating patients with similar cases in a similar manner

Ergonomics

Hand Kinetics

Manipulating the right-angle forceps requires the use of all the fingers to properly open, close, and stabilize the instrument during surgery. A surgeon usually inserts digits 1 and 4 into the handles of the right-angle forceps. In order to open the device, digit 1 undergoes lateral rotation of the carpometacarpal joint and extension of the interphalangeal as well as the metacarpophalangeal joint while digit 4 undergoes extension of the distal interphalangeal joint, the proximal interphalangeal joint, and the metacarpophalangeal joint (see fig. 5). In order to close the device, digit 1 undergoes medial rotation of the carpometacarpal joint and flexion of the interphalangeal as well as the metacarpal phalangeal joint while digit 4 undergoes flexion of the distal interphalangeal joint, the proximal interphalangeal joint, and the metacarpophalangeal joint. Digits 2, 3, and 5 are used to stabilize the device when opening and closing the instrument. However, digits 2 and 3 are feasibly available to undertake additional tasks. Both digits 2 and 3 can undergo flexion and extension at the distal interphalangeal joint, proximal interphalangeal joint, and metacarpophalangeal joint[12]. These motions, as well as the positions of digits 2 and 3 on the device allow a trigger mechanism attachment to the instrument. The trigger mechanism attachment must either be on the arm closer to digit 1 for digit 2 to be used, or on the arm closer to digit 4 for digit 3 to be used. These will be taken into consideration while designing the device.

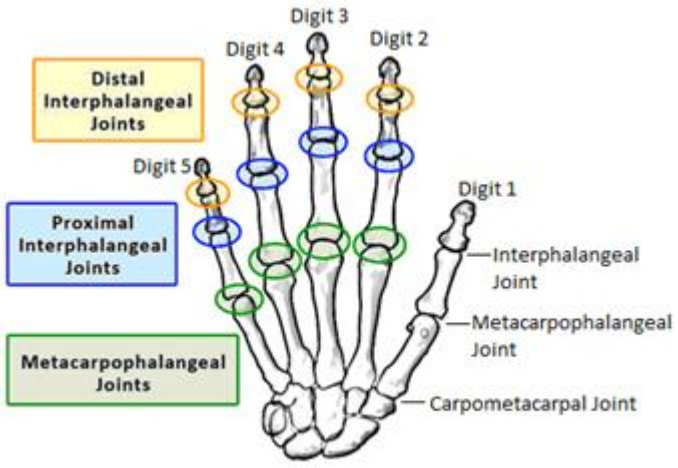


Figure 5: Joints of the hand[11].

Index Finger Physiology

Consideration must be given to the forces generated by, and range of motion of, the index finger (digit 2), since it is most likely used to activate the trigger mechanism. A previous studies on the directional forces generated by the index finger determined the maximum flexion force generated by the index finger[13]. An experimental apparatus (see fig. 6) was designed to measure the maximum voluntary isometric contraction (MVIC) forces of the index finger at various points along the digit. Eight subjects performed three sets of MVIC forces in 16 randomized directions. A trial consisted of the subject aligning a cable on the force transducer with a pre-designated direction on the direction guide, allowing for accurate direction of force application. From the results (see fig 7), the maximum force generated by the finger is (110.7 ± 9.0) N by flexing. As a comparison, extension can generate 37.6% of the maximum force, abduction 97.9% of it, and adduction 79.3% of it. With regards to range of motion, three different joints must be considered: the metacarpophalangeal joint, proximal interphalangeal

joint, and distal interphalangeal joint (see fig. 5). The expected range of motion for flexion-extension and abduction-adduction at each of these joints can be seen in Table 2[14].

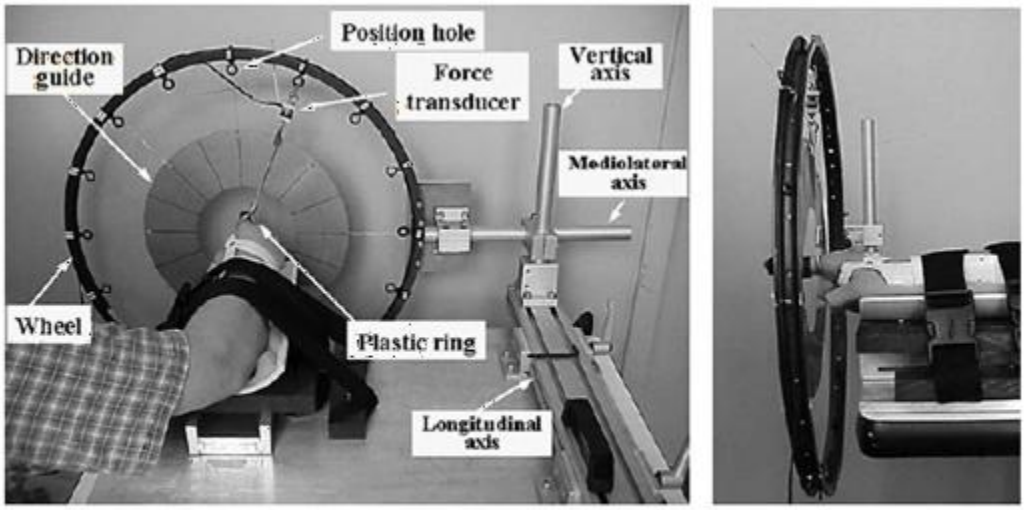


Figure 6: Experimental apparatus for force measurement of the index finger[13].

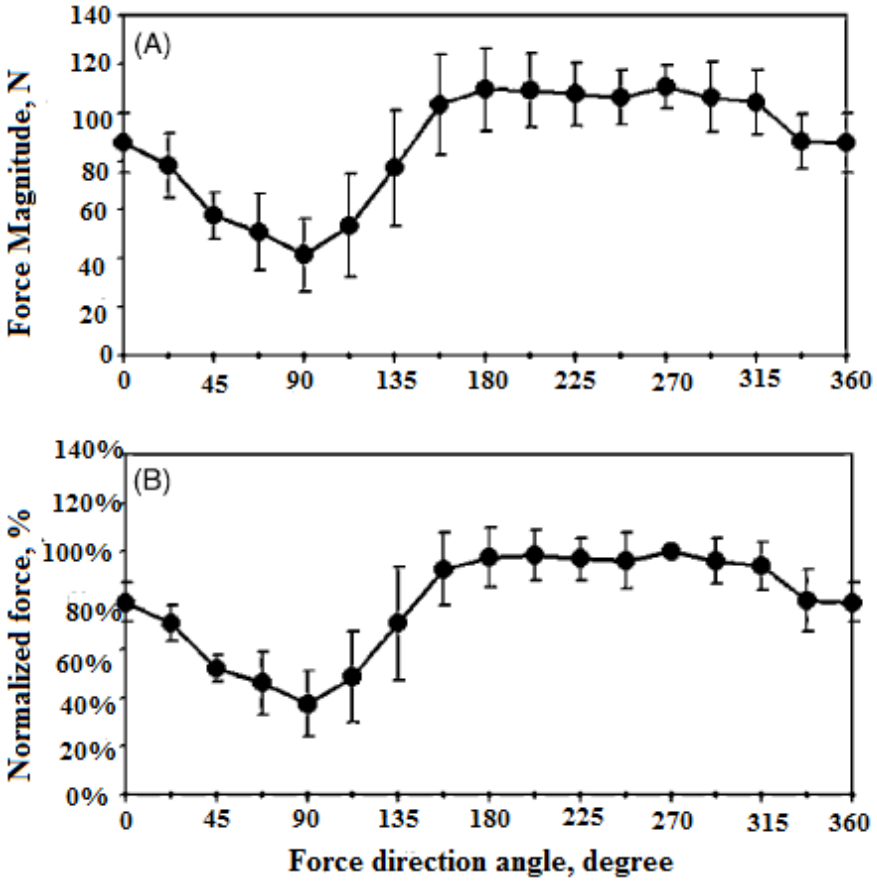


Figure 7: (A) Force magnitude in N and (B) normalized forces in percent of maximum force in the possible range of motion, given as mean ± SD. Zero degrees correspond to abduction, 90° to extension, 180° to adduction, and 270° to flexion[13].

Table 2: Range of motion values for each joint of interest of the index finger[14].		
Joint	**Direction of Movement**	**Expected range of motion (°)**
Metacarpophalangeal	Flexion-Extension	30-0-90°
	Abduction-Adduction	20-0-20°
Proximal Interphalangeal	Flexion-Extension	0-100°
Distal Interphalangeal	Flexion-Extension	0-70°

Design Proposal Overview

The device will be used during surgery by the client and therefore has to meet her standards and requirements. As mentioned before, it should combine the right-angle forceps and surgical scissors in one device, allowing the surgeon to dissect and cut using the same hand. It has to maintain the surgeon's range of sight in the region and not obstruct any other instrument. The function of the original right-angle forceps in picking up tissue or clamping is optional and need not be considered in the design process.

Design 1: Built-In Scissors

The first design is a straightforward combination of the right-angle forceps and surgical scissors (see fig. 8), measuring 191mm from tips to handles, just like the current right-angle forceps. The inside edges of the right-angle forceps are sharpened and allow the surgeon to cut simply by closing the blades. The advantage of the design is its simplicity, making it relatively cheap to produce and maintain. It can be easily autoclaved and sharpened, similar to current surgical equipment and scissors. However, it causes a problem whenever the surgeon cuts because the device has to be closed, which may obstruct the range of sight of the surgeon because the tissues are no longer spread apart. Furthermore, it provides little flexibility during surgery because the surgeon can only cut in a specific region between the blades and has to be vigilant about not accidentally damaging tissue whenever the blades are opened and closed.

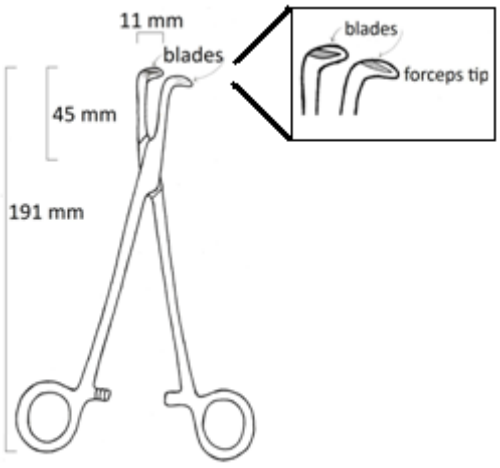


Figure 9: Built-in Scissors design.

Design 2: Guarded Scissors

The second design involves a pair of right-angle scissors enclosed by protective shell guards, which act as the dissector (see fig. 9). As before, the device measures the identical length to the right-angle forceps currently used in surgery. The blades are supported at the joint hinge and function similar to a regular pair of scissors. The shell guards allow the surgeon to dissect and spread tissue as though using the right-angle forceps, after which the guards can be locked in position. Next, the surgeon can utilize the scissors independent of the guards and cut as desired while the guards protect the spread tissue from the blades. One concern regarding this design is that the shells have to be locked and unlocked every time the surgeon has to cut tissue, which can slow the surgery down by cascade. Additionally, the possibility of accidentally damaging tissue while maneuvering the blade, though greatly reduced, is not completely eliminated.

Figure 9: Guarded Scissors design

Design 3: Trigger Scissors

The third design incorporates a trigger mechanism to activate the cutting motion of a blade into the right-angle forceps (see fig. 10). The device operates and enters the deep hole like regular right-angle forceps, with the blade protected in a shaft in order to prevent accidental injury to the patient.

Once the device is in place and opened to spread tissue, the cutting blade can be operated. The surgeon pulls the trigger (1) with the index finger, which is met by some resistance from a spring attached to the blade shaft in order to control the swinging motion of the blade. The pulling force is transmitted by a cable through the hinge joint (2), and finally to the cutting blades (3), which rotates out of the shaft and swings into a notch on the opposite forceps arm to cut the desired tissue.

One option for creating the trigger mechanism is to adopt the trigger mechanism from the endoscopic instrument as mentioned above (see *existing devices* section). The method of force transmission through a slide member from the handle to the tip of the device can be applied to the trigger scissors design, although the trigger scissors design does not involve any rotation about the long axis.

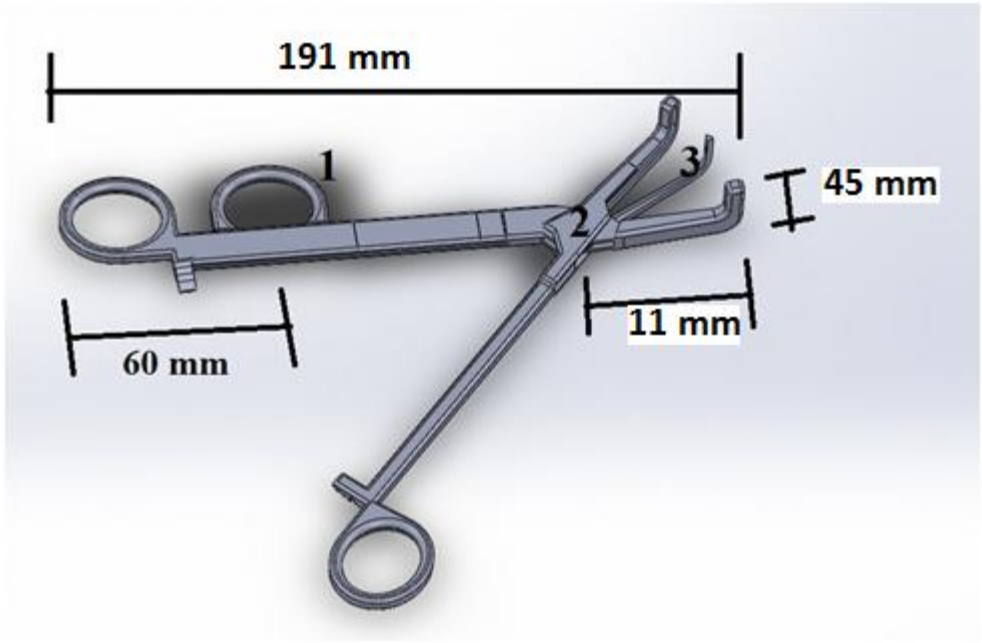


Figure 10: Trigger Scissors design. The numbered components shown are 1) trigger, 2) hinge, and 3) cutting blades**.** Dimensions shown are approximate and were refined for the final prototype design (see Prototype Construction section below).

Design Evaluation

Five categories were chosen to evaluate the 3 designs and weighted based on how critical they were to fulfilling the design and client requirements that were established previously (see table 3). Total scores were rated on a 100 point scale. For each category, the design that fulfilled a category the best was given full points, with the other designs receiving points based on how they compared to the best design in that category. This allows for assessment of the designs based on how they compare to each other rather than simply an arbitrary standard.

Table 3: Design Selection Matrix. Category weights are given in parentheses.						
Design	Patient Safety (30)	Functionality (20)	Client Preference (20)	Sterilizability (15)	Feasibility (15)	Total
Built-in Scissors	10	15	10	15	15	65
Guarded Scissors	20	20	18	10	13	81
Trigger Scissors	30	20	20	5	10	**85**

Safety

The first category was patient safety, assigned 30 total points. Patient safety is a key driving force of the project and of utmost importance. It was a desire for improved visibility and safety that first inspired the client to submit this project. The trigger scissors design is the safest of the three because it minimizes the risk of accidentally cutting tissue while in use. The guarded scissors design is the second closest to the safety standard, but is still harder to control than the trigger design. The built-in scissors designed scored the worst because it was the hardest to control and did not maintain any visibility while cutting. The trigger scissors design allows the surgeon to maintain full visibility in the deep hole while cutting, control the speed of cutting, and dynamically apply and adjust the cutting force.

Functionality

Functionality, defined as the amount of control and visibility the device allowed the surgeon while dissecting and cutting, was the next category and was assigned 20 total points. While all the designs scored similarly in this aspect, the guarded scissors design and trigger scissors designs scored better than the built-in scissors design in this respect because of their ability to maintain visibility while cutting. Furthermore, they allowed the surgeon the choice of when to cut while the built-in blades design would cut whenever the tips were closed.

Client Preference

Client preference was scored based on the client's preference for each design and was assigned 20 total points. The designs were assigned scores based on the client's comments after the mid-semester presentation. The trigger scissors design was the client's preferred choice, being the most innovative and the safest. The guarded scissors design received favorable comments due to its functionality and practicality, while the built-in scissors design was satisfactory but not ideal.

Sterilizability

The next category evaluated was the ease of sterilizing the device, given 15 total points. While an important feature of the design, it is a less rigorous criterion because all the designs are sterilizable to a certain degree. The built-in scissors design is the easiest to sterilize due to the absence of additional moving components. The trigger scissors design and guarded scissors design may need to be disassembled prior to sterilization, leaving them less ideal in this category.

Feasibility

The final category is feasibility, related to the complexity of the design, the ease of fabricating and assembling all the necessary components, as well as the practicality of completing the design within the timeframe of the project. The built-in scissors design is the simplest to accomplish, followed by the guarded scissors design and finally the trigger scissors design. However, all the designs are reasonably attainable within the time frame given.

Total

After computing the total scores for the designs, it was determined that the trigger scissors design had the highest score of 85 and was chosen as the design to pursue.

Material Selection

Due to the restrictions regarding surgical instruments, material selection is an important factor of consideration in the design process. The device will be used in surgery repeatedly and will have to be sterilized in between procedures by the standard process of autoclaving. Therefore, the device needs to be composed entirely of a material or materials that are autoclavable, biocompatible, hemocompatible, non-immunogenic, non-allergenic, and non-toxic in the surgical setting. The client also prefers a device similar in weight to the current right-angle forceps for comfort and functional reasons.

After research into stainless steels, 3 grades of surgical stainless steel meeting these criteria were found: 316, 420, and 440, referring to the different ratios of alloys in the steels. The grade of steel indicates its composition and strength as well as certain characteristics. In addition, there are autoclave-able polymers available, but they were not considered due to weight and strength concerns. Stainless steel grade 420 is the most common grade used in surgery and is commonly known as “surgical grade” and “cutlery grade”. Stainless steel grade 316 is the second most common grade of stainless used in food and surgical fields, commonly known as “marine grade” due to its anti-corrosive properties. Stainless steel grade 440 is an improved version of 420 with more carbon and better edge retention. All of these can potentially be used to fabricate the device. In order to obtain advice on the grade of stainless steel best suited for the device, local and national manufacturers working with stainless steel have been contacted to obtain their expert opinions. The final decision for the stainless steel grade to be used will be made based on cost, durability, and ease of manufacturing.

Prototype Construction

Understanding Right-angle Forceps Mechanics

Using an angle grinder and appropriate safety measures, the forceps provided by the client was dismantled to be analyzed and reassembled in order to understand the pivot mechanism (see fig. 11). To ensure the forceps were dismantled carefully, the angle grinder was first tested on scrap steel and on smaller forceps obtained by one of the team members. The photos below document the dismantling of the forceps. Unfortunately, one arm of the forceps was damaged in the process (see fig. 12).

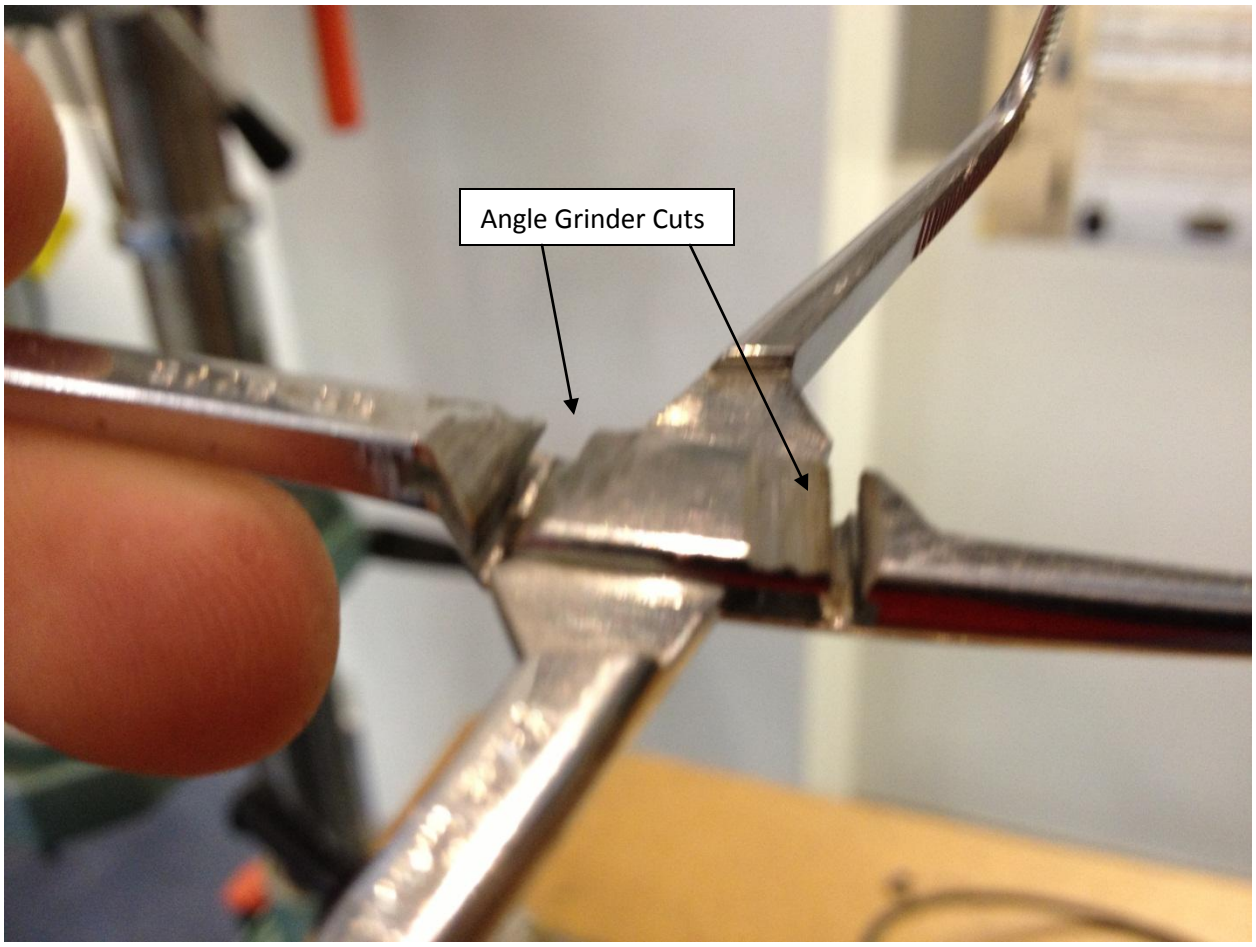


Figure 11: Forceps after being cut by angle grinder.

Figure 12: Completely dismantled right-angle forceps. The top arm was broken in the dismantling process.

Construction/Assembly of Prototype

Since the prototype should mimic the weight of an unmodified right-angle forceps, dimensions were kept as close to the original as possible. However, various components of the forceps needed to be changed and modified in the SolidWorks design to allow for easier construction. Firstly, the shape of the design was simplified by widening and thickening the middle joint and ends of the arms to accommodate the pieces being incorporated and to reduce frictional shear on all the components. Additionally, the tips were slightly modified to include the blade in the groove of one arm. The trigger mechanism, including grooves for the connecting wires, trigger, and spring, was added by hollowing out the center of the same arm as that with the blade. These modifications resulted in the entire device measuring 190.6 mm, the cutting tip of the arm measuring 19.4 mm long, and the arm measuring 46.15 mm long (see fig. 13). The trigger is able to slide a total length of 20.5 mm in the slot, which allows the blade to move through the necessary range of motion, which was defined to be a distance of 20 mm between the far ends of the tips.

The final prototype was constructed in seven parts designed in SolidWorks and constructed out of thermoplastic acrylonitrile budadiene styrene (ABS) using the fused deposition printer, 0.4 mm mm stainless steel wire, and four 2.82 mm outer diameter stainless steel springs each with a length of 6.8 mm. The seven parts were designed separately in SolidWorks (see fig. 15) and can be assembled (see fig. 13 for a closed device, fig. 14 for an open device). The springs and wires attach to the trigger and blade through a hollow channel (see fig. 16). For more descriptive drawings showing the dimensions of the seven parts in front, top, left, and right views, see Appendix B.

When entering the deep hole in surgery, the device is operated with the tips closed in an identical manner to current right-angle forceps. Once in the desired location, the surgeon can spread the forceps and henceforth use the cutting capabilities of the device. To cut, the operator pulls on the trigger, which is attached to the cutting blade with the stainless steel wire (fig. 16, colored gray). Due to the wire attachment point on the cutting arm, the arm and blade swing in an arc about the hinge point

and pulls on the stainless steel wire (fig. 16, colored white) that attaches to the spring (fig. 16, colored black). This allows the blade to swing to the groove of the opposite arm, cutting the desired tissue. The blade then returns to its original position by the resistive force provided by the springs.

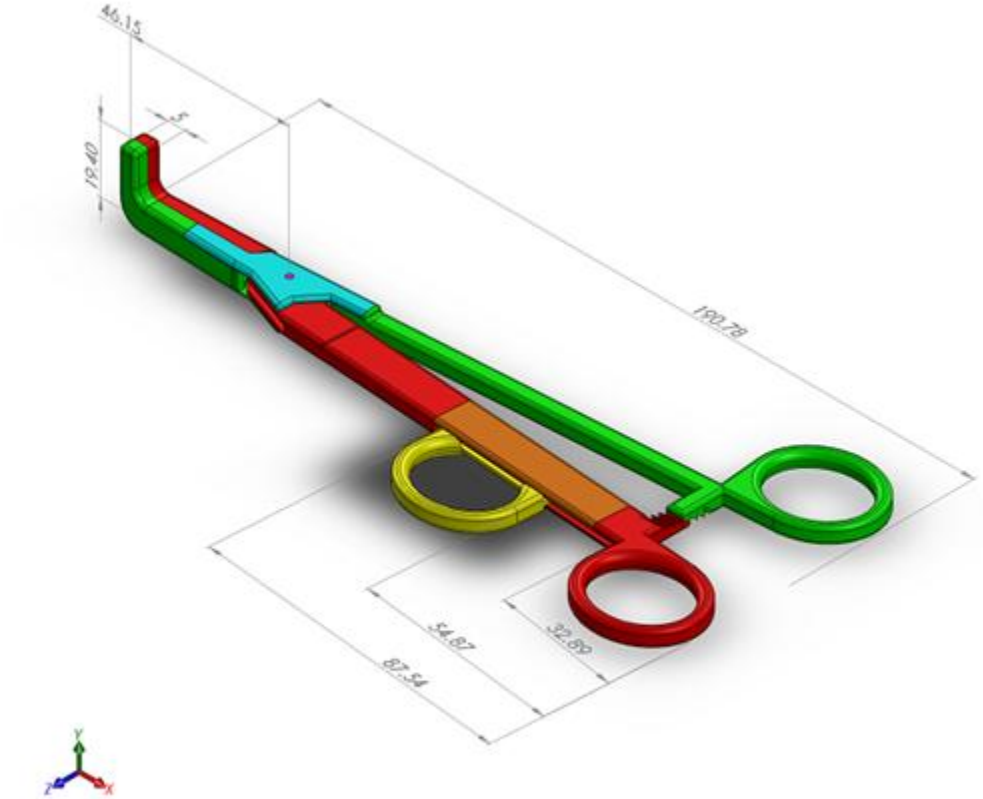


Figure 13: The seven parts of the device as assembled with the tips closed. Note: the spring and the wire are hidden. All dimensions are in mm.

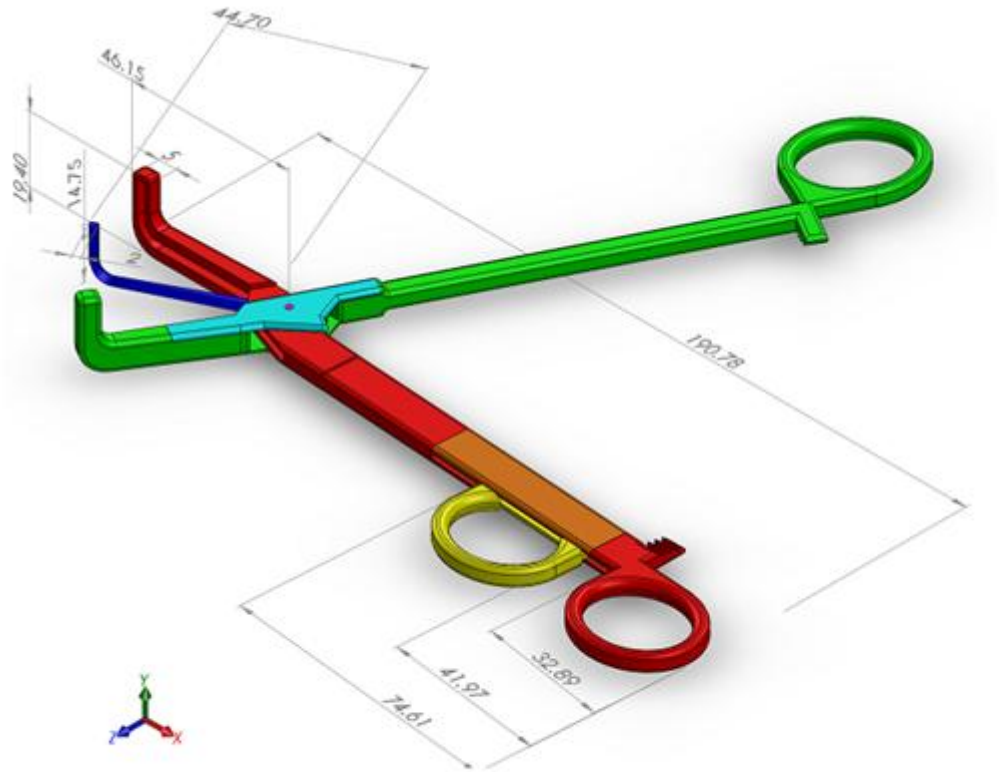
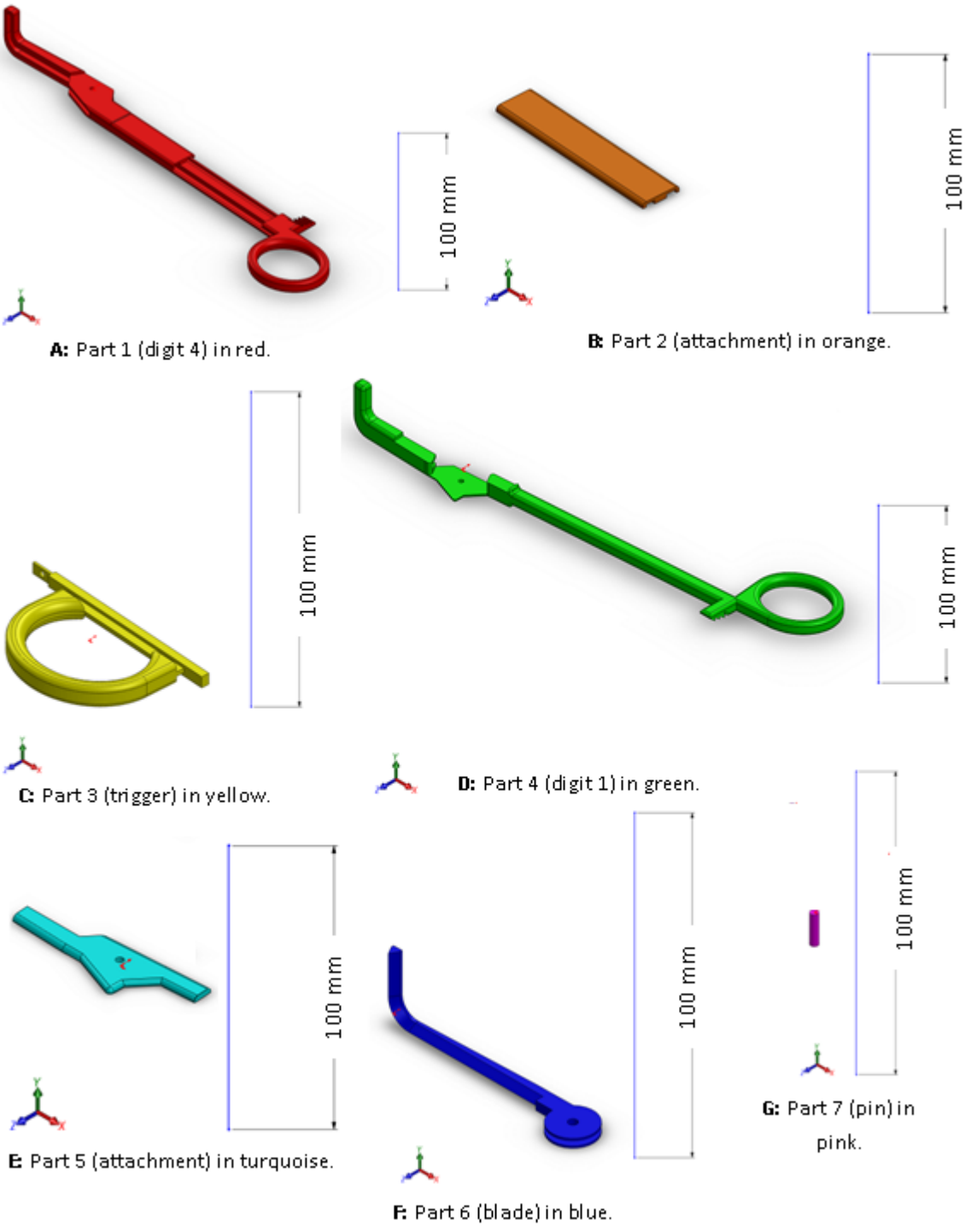


Figure 14: The seven parts of the device as assembled with the tips open and blade exposed (blue). Note: the spring and the wire are hidden. All dimensions are in mm.



A: Part 1 (digit 4) in red.

B: Part 2 (attachment) in orange.

C: Part 3 (trigger) in yellow.

D: Part 4 (digit 1) in green.

E: Part 5 (attachment) in turquoise.

F: Part 6 (blade) in blue.

G: Part 7 (pin) in pink.

Figure 15: The seven parts of the device designed in SolidWorks, each with a 100 mm scale.

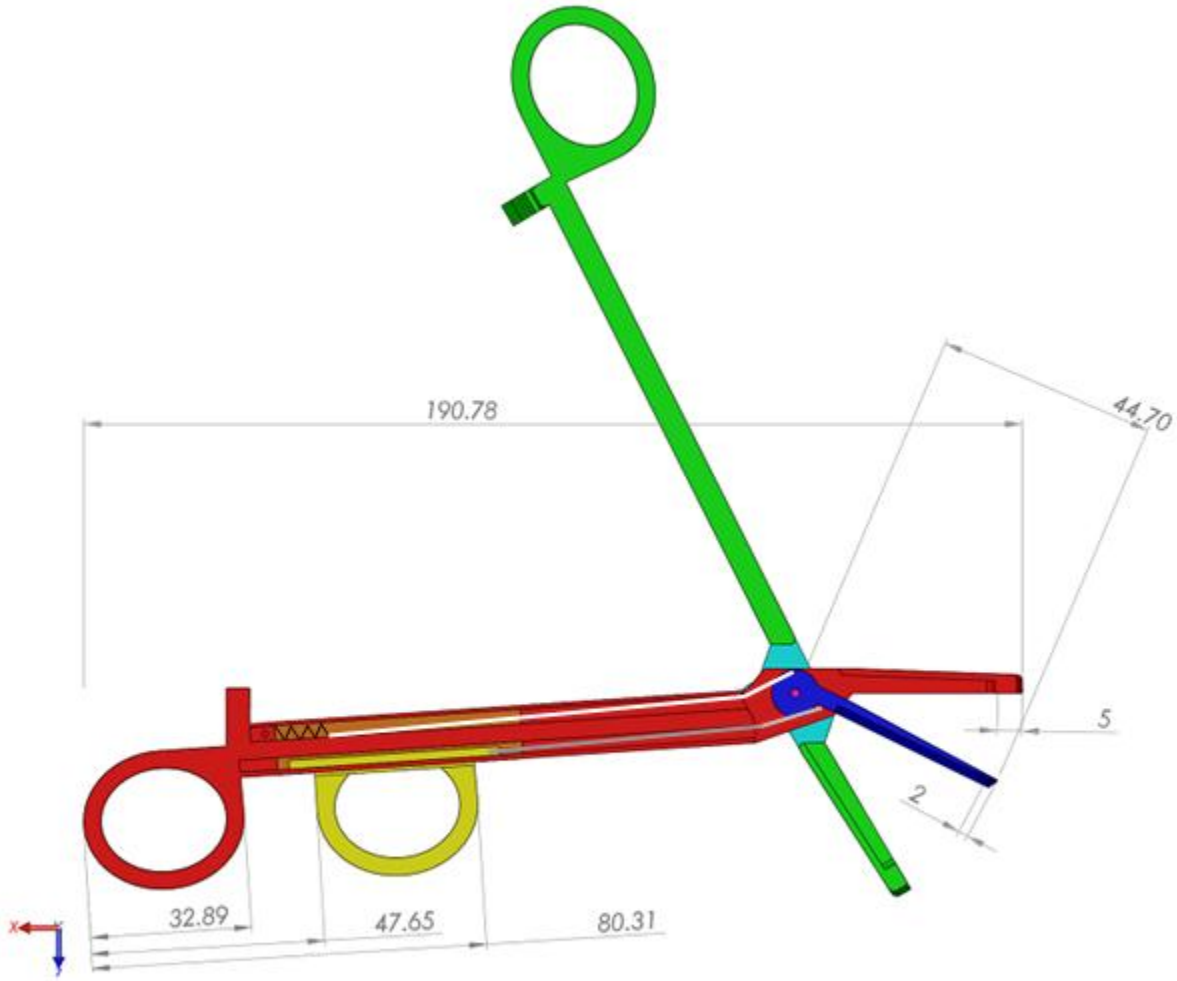


Figure 16: The bottom view of the prototype with a top sectioned plane through the device. The assembled seven parts, springs, and wires can be clearly seen clearly. All dimensions are in mm.

Testing

In order to ensure the safety and practicality of the device for use in surgery, the device was evaluated by the client and other surgical residents working at the University of Wisconsin Hospital and Clinics. The device was compared to the current surgical method of cutting in 4 categories: cutting force, precision of cut, range of motion, and ease of cutting. These criteria were selected based on recommendations by the client and are useful in determining if the device is a suitable replacement for surgical forceps and scissors. Due to the material of the prototype being ABS plastic instead of surgical-grade stainless steel, not all the actual testing procedures were not carried out, but are described in the future work section to be performed next semester.

Ergonomics

The prototype was provided to the client and two other residents at the UW Hospital and Clinics Department of Surgery to evaluate the ergonomics of the device. Each individual was allowed to handle the device and simulate any movements or tasks that they deemed relevant to using the device. After practicing with the device for a sufficient amount of time as determined by the individual (approximately 15 minutes), an ergonomics survey was provided (see Appendix C). Seven categories were evaluated on a scale of one to ten, with the resulting scores presented in table 4. In addition, room was left for each individual to write comments about what they liked and would change on the prototype, as well as any other comments they considered relevant to the project. Using these comments, future work will focus on rounding off the forceps tips to avoid damage while in use and reducing the force necessary to swing the blade.

Table 4: Results of ergonomics survey. Categories were rated on a scale of one (bad) to ten (good), with five being considered average.

	User 1	**User 2**	**User 3**	**Average ± Standard Deviation**
Trigger location	9	8	9	8.67 ± 0.58
Ability to maintain visual	9	9	9	9.00 ± 0.00
Range of motion	9	9	8	8.67 ± 0.58
Control	9	8	8	8.33 ± 0.58
Additional effort required	7	8	9	8.00 ± 1.00
Comparison to current practices	8	7	8	7.67 ± 0.58
Overall ease of use	9	8	8	8.33 ± 0.58

Range of Motion

The device is required to cut over minimum range of two centimeters separation between the forceps tips. Thus, part of the initial testing focused on confirming the prototype blades could span the desired range. The prototype was laid on a white sheet of paper, aligning the trigger and corresponding forceps half along an initial position line (see fig. 17).

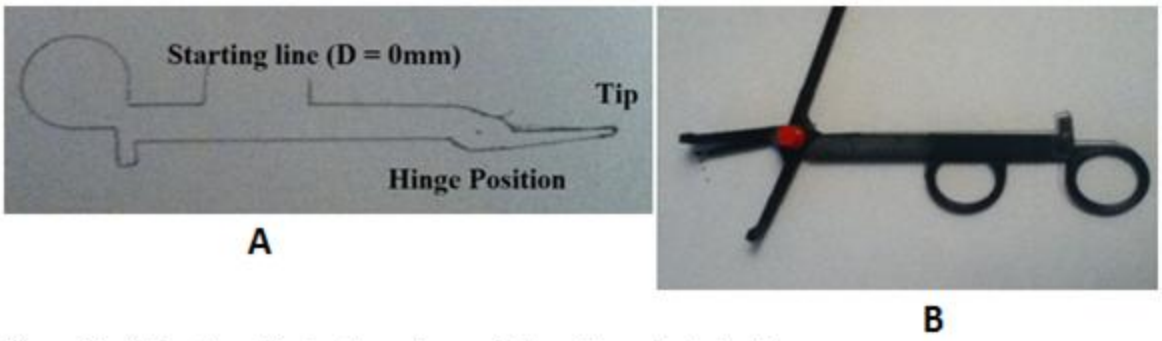


Figure 17: A) Sheet used for testing setup and B) prototype during testing.

The trigger was pulled in increments of 1 mm until its movement was obstructed by the springs. After every increment, the location of the blade tip was marked on the sheet of paper. Using the start and end locations, translational and angular ranges for each trigger displacement increment were calculated (see table 4). The measurements were used to calculate equations of best fit for range of motion as follows:

$$\text{Linear Displacement: } L = 4.1D + 0.75$$

$$\text{Angular Displacement: } A = 5.2203D + 0.9549$$

where L is the linear displacement of the blade tip (in mm), A is the angle displacement of the blade (in radians), and D is the trigger displacement (in mm). While the data indicates the prototype is slightly short of desired range of motion, the results are encouraging. To meet the desired range of 20 mm and perhaps leave more room as a potential buffer region, the track length of the trigger only needs to be extended by a minimum of 0.3 millimeters, which can be easily done in this design.

Furthermore, the equilibrium resting position of the blade was not 0 due to the channel being too narrow. Therefore, the channel should be widened to allow the blade to completely retract when not in use. Again, this is a straightforward modification for the future prototypes.

Table 5: Testing results from range of motion testing.

Trigger Distance (mm)	Linear Translation (mm)	Angle (rad)
1	5	6.366198
2	9	11.45916
3	12.5	15.91549
4	17.5	22.28169

Budget Analysis

The client specified a budget of $200 for the entire project, and the total incurred in the first semester was $42.81 (see table 5 for breakdown of expenses). Surgical forceps were provided by the client, while smaller practice forceps were donated by the Department of Neurosurgery in the University of Wisconsin School of Medicine and Public Health. The SolidWorks software and machining equipment were provided free of charge, courtesy of the College of Engineering. Three-dimensional printing of the prototype out of acrylonitrile butadiene styrene (ABS) was generously funded by the Tong Family Foundation.

Table 6: Breakdown of current expenses.	
Expense	**Price ($)**
Right-angle forceps	0.00
Spray paint	8.48
3D printing	0.00
Torsional springs	22.04
Compression springs	12.29
Wires	0.00
Total	42.81

In order to get a projected expense estimate (see table 7), manufacturers are currently being contacted and supplied with the SolidWorks sketch of the device to obtain a quote of the manufacturing costs to produce the device out of surgical-grade stainless steel. Although the SolidWorks model is not finalized yet, it can provide an initial estimate of the price of manufacturing the device in the future. The companies have not yet responded, but initial estimates based on the price of machining stainless steel are in the range of $200-$500, which could be above the budget. Additionally, the price of extension springs and wires have to be considered as well. Other cheaper methods of producing the device are currently being researched as well.

Table 7: Breakdown of projected expenses.	
Expense	**Price ($)**
3D printing	0.00
Extension springs	17.00
Wires	5.00
Steel machining	200.00
Total	222.00

Future Work

For the remaining semester of the project, the prototype will be modified based on the feedback of the client and other surgical residents. The forceps tips will be sharpened to resemble the current right-angle forceps, and the blade notch will be widened to better accommodate the blade. The trigger track will be extended to allow better control of the trigger and blade. Finally, the compression springs will be replaced by extension springs.

Next, another ABS prototype will be 3D-printed to allow for more testing before the final stainless steel prototype is manufactured. This prototype will be tested on its ergonomics with $n \geq 10$ (see *testing* section), range of motion (see *testing* section), precision of cut, and smoothness of cut (see below for descriptions of tests). These tests will be performed on tissue paper, as suggested by the client.

After verifying that the design is viable as a surgical instrument, the final prototype will be machined out of surgical-grade stainless steel, and prior testing will be performed again to validate its functionality. Furthermore, force testing will be performed using two materials: latex rubber and tissue paper, because the client describes the tissue commonly encountered to be in between the thicknesses and resistance of these materials.

Cutting force

In order to verify if the force exerted by the cutting blade at normal flexion forces generated by the forefinger is sufficient to cut cleanly through the materials, the prototype will be mounted on the edge of a table and a weight of 5.10kg attached to the trigger. The maximum flexion force generated by the forefinger is reported to be approximately 110N[13], but since the finger is slightly twisted in the trigger and the device is utilized during a surgical procedure, the average force exerted by the surgeon on the trigger is estimated to be approximately 50N. In order to simulate a 50N force on the trigger, a weight of 5.10kg is chosen based on the following equation:

$$\text{weight} = \frac{\text{force}}{\text{standard gravity}}$$

$$= \frac{50\text{N}}{9.81\ \text{m s\^}-2}$$

$$= 5.10\ \text{kg}$$

The material will be placed in between the scissors blade and forceps tip, ready to be cut. At the beginning of each trial, the weight will be released to exert a force of approximately 50N on the trigger. The material will be removed after the trial to check if it is cut cleanly, and the experiment will be repeated a minimum of five times per material. Afterwards, a statistical analysis can be performed to calculate the percentage of trials in which the device generated enough force to cleanly cut through the materials.

Precision of Cut

Precision is absolutely crucial during surgery as the surgeon is operating in highly vascularized regions and any false movement can potentially result in dangerous consequences. As a result, the device will be tested to evaluate the ability of surgeons to properly learn to cut precisely using the device. The subjects will be allowed to practice using the device beforehand and later asked to cut along a material with ten markings along an edge as though cutting through tissue during a surgery. Afterwards, the maximum distances between the cuts and the lines will be measured and analyzed statistically to determine if the device is suitable for use in actual surgery.

Range of Motion

As described previously (see *testing* section), the device will be tested to verify if the blade can span the required maximum distance between the forceps tips (20 mm). After making the changes as outlined previously, the new prototype will be tested in a similar fashion.

Ease of Cutting

The ease of cutting testing is divided in 2 sections. The first category is the ability to cut cleanly. The subjects will be asked to make 10 separate incisions in the material, and the number of successful cuts will be counted. A successful cut is defined as a clean cut through the material with no visible signs of ripping or tearing. This process will be repeated with surgical scissors that are currently used in surgery. Statistical means and standard deviations will be calculated, and a t-test will be performed to determine if the prototype compares reasonably to current practices.

The second portion of the testing addresses the ability to cut through a material in a reasonable number of cuts. For this section, 5 trials will be performed with both the prototype and the current surgical scissors on the same materials as before. A trial will consist of the subjects cutting 20 cm of material in a straight line. The number of cuts required to cut the length of the material will be counted and normalized by dividing by blade length. This is necessary as the two devices may have blades of different lengths. Statistical means and standard deviations will again be calculated and a t-test used to compare the two devices.

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Appendix A: Product Design Specification (PDS)

Right-angle Dissector Scissors Hybrid Surgical Instrument

Function:

The client, Dr. Emily Hartmann, is a plastic and reconstructive surgeon at the University of Wisconsin School of Medicine and Public Health and performs regular reconstructive surgery. Careful dissection around vascular and neurological structures during surgery requires precise instruments and the right-angle forceps is often utilized to tease away or present soft tissue for an assistant to cut or cauterize. However, if the surgeon is operating in a deep hole where the assistant cannot reach, the surgeon has to use the non-dominant hand to cut or cauterize, which is a challenge since the non-dominant hand is often occupied with another forceps. A hybrid instrument incorporating scissors in the right-angle forceps is to be developed. It has to remain blunt-tipped in order to perform delicate dissection and should be applicable in various operative situations as well as available in various lengths.

Client requirements:

- Incorporate a cutting scissors in existing right-angle forceps
- Maintain dissector function while adding cutting function
    - Remain blunt-tipped on outside edges
    - Sharpened on inside edges
- Compatible with current surgical protocols
    - Surgical-grade stainless steel
    - Autoclavable
    - Sharpenable
- Ambidextrous function
- Surgeon-customizable
- Operational and storable under normal operating theater conditions
    - Temperature approximately 20°C
    - Relative humidity approximately 50%
- Adaptable for different forceps sizes
    - Currently using: Kantrowitz Forceps, delicate 90° jaw, 19.1cm
- Weight under 100g
- Under $200 budget

Function (a general statement of what the device is supposed to do): The PDS should begin with a brief, concise paragraph describing (in words) the overall function of the device. In the initial stages, this will be the problem statement, and will become more specific as you decide on a final design.

Client requirements (itemize what you have learned from the client about his / her needs): Briefly describe, in bullet form, the client needs and responses to your questions.

Design requirements: This device description should be followed by list of all relevant constraints, with the following list serving as a guideline. (Note: include only those relevant to your project):

1. Physical and Operational Characteristics

a. *Performance requirements*: The device should be able to withstand repeated surgeries and the standard autoclaving process in between. The blade should allow for regular sharpening if required.

b. *Safety*: The device should maintain blunt outside edges so as to avoid inadvertently cutting tissue. The device must be made of surgical-grade stainless steel and withstand temperatures present during the autoclaving process.

c. *Accuracy and Reliability*: In the closed position, the device should function in the same manner as an unmodified right-angle dissector forceps. Throughout the lifespan of the device, the surgeon should be able to cut with accuracy and precision and not damage any blood vessels near the surgical site.

d. *Life in Service*: The device should last as long as an unmodified right-angle dissector forceps and be replaced only when damaged.

e. *Shelf Life*: There should be no major concerns regarding shelf life as the device is autoclaved after every use and stored in a sterile environment.

f. *Operating Environment*: The device is to be utilized in a surgical setting, specifically in reconstructive plastic surgeries. It should therefore be inert to all human tissue, fluids, and surgical equipment present in surgery. While in operation, the device should be cleanable whenever needed. The client should be able to open and close the device to whatever degree desired and the device should not malfunction even upon contact with debris.

g. *Ergonomics*: The device should be relatively simple and straightforward to operate, similar to the right-angle dissector forceps. It should be ambidextrous and should not interfere with the surgery in any way.

h. *Size*: The device should be almost identical to the unmodified right-angle dissector forceps. The current design is adapted to the forceps of length 19.1cm, but it should be adaptable to forceps of various sizes.

i. *Weight*: The device should weigh similarly to an unmodified right-angle dissector forceps in order to allow the surgeon to comfortably utilize it. The total weight of the device should not exceed 100g.

j. *Materials*: The device should be comprised of surgical-grade stainless steel and be non-allergenic, biocompatible, and hemocompatible. It should be able to withstand regular sterilization processes between surgeries without any change in its physical and chemical properties.

k. *Aesthetics*, *Appearance, and Finish*: The device should be clean, simple, and resemble a surgical device. Additionally, the client can choose to personalize the device using colored parts or components.

2. Production Characteristics

a. *Quantity*: Currently the client requires 1 device, but in the future could request additional devices to be manufactured.

b. *Target Product Cost*: The total cost of the device (including materials and manufacturing) should not exceed $500.

3. Miscellaneous

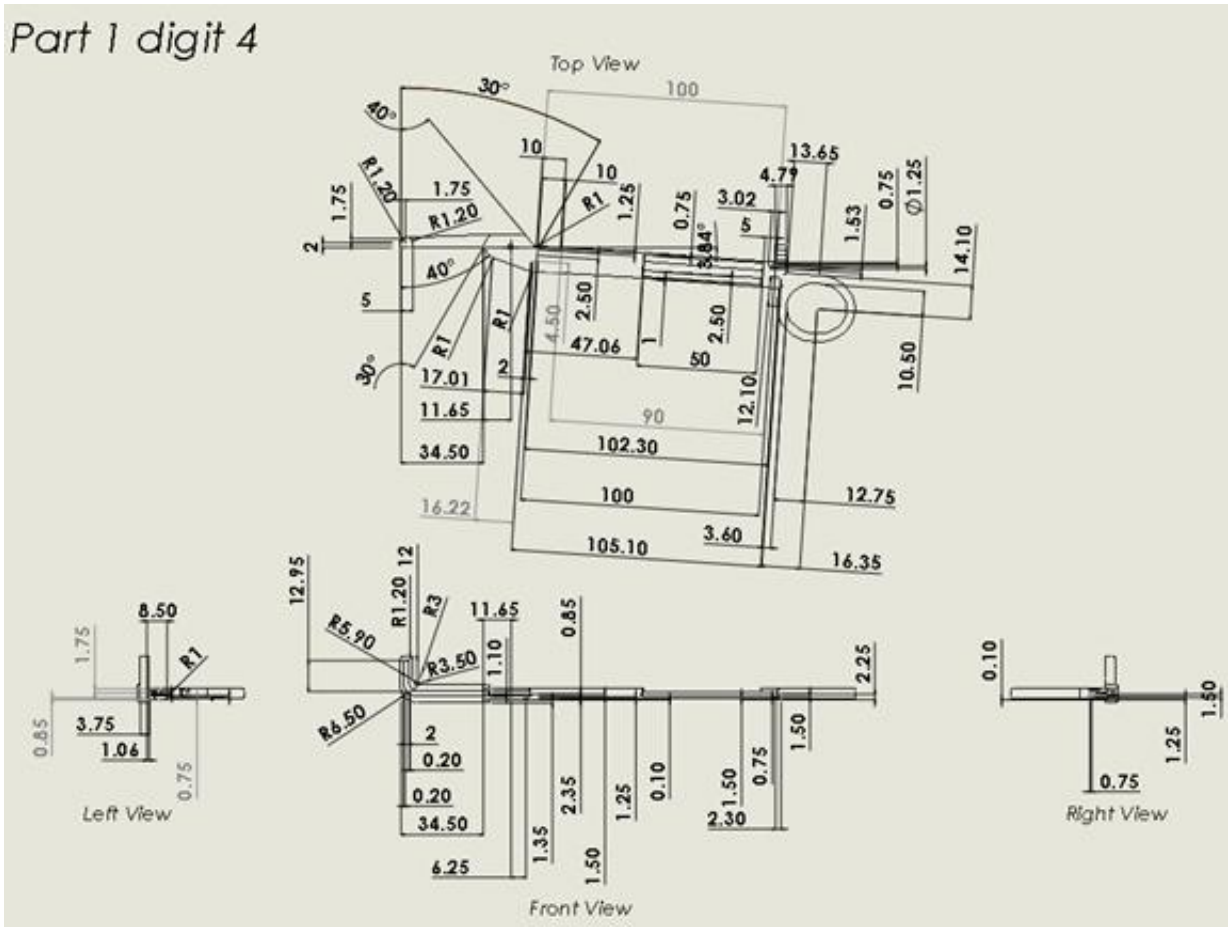
a. *Standards and Specifications*: No FDA-approval is required for the device.

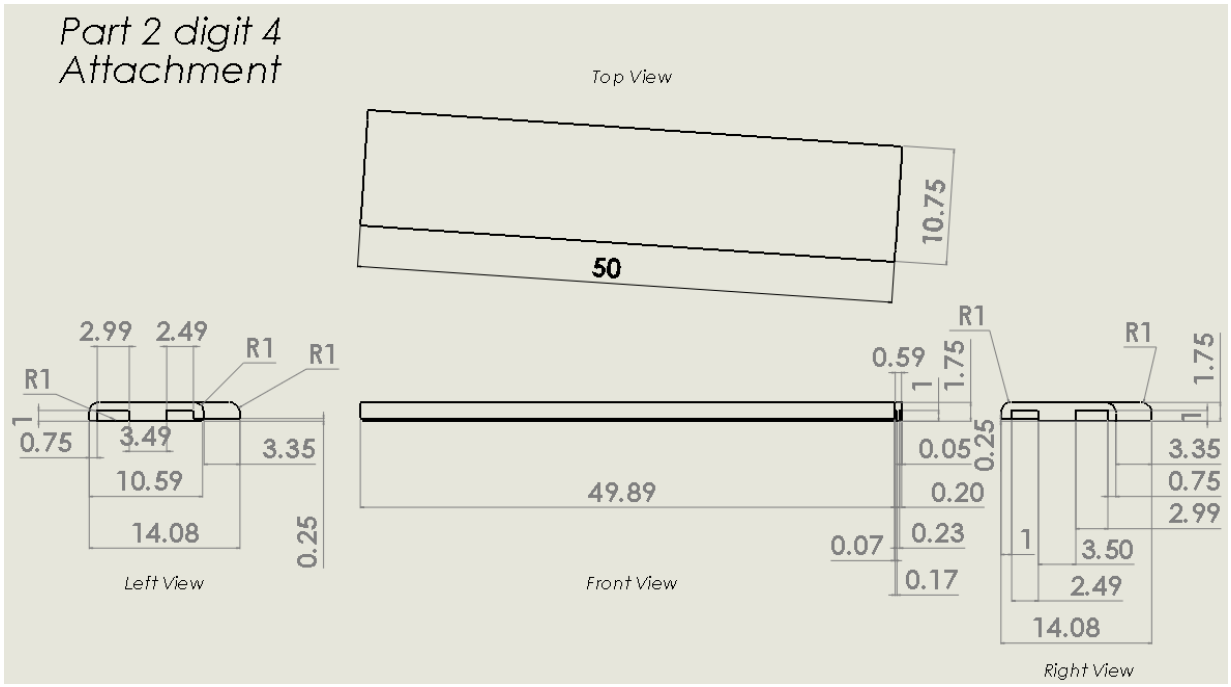
b. *Customer*: Client requests a reusable surgical instrument without any removable parts (i.e. the cutting blade should be built-in). The device should preferably be customizable according to preference if desired.

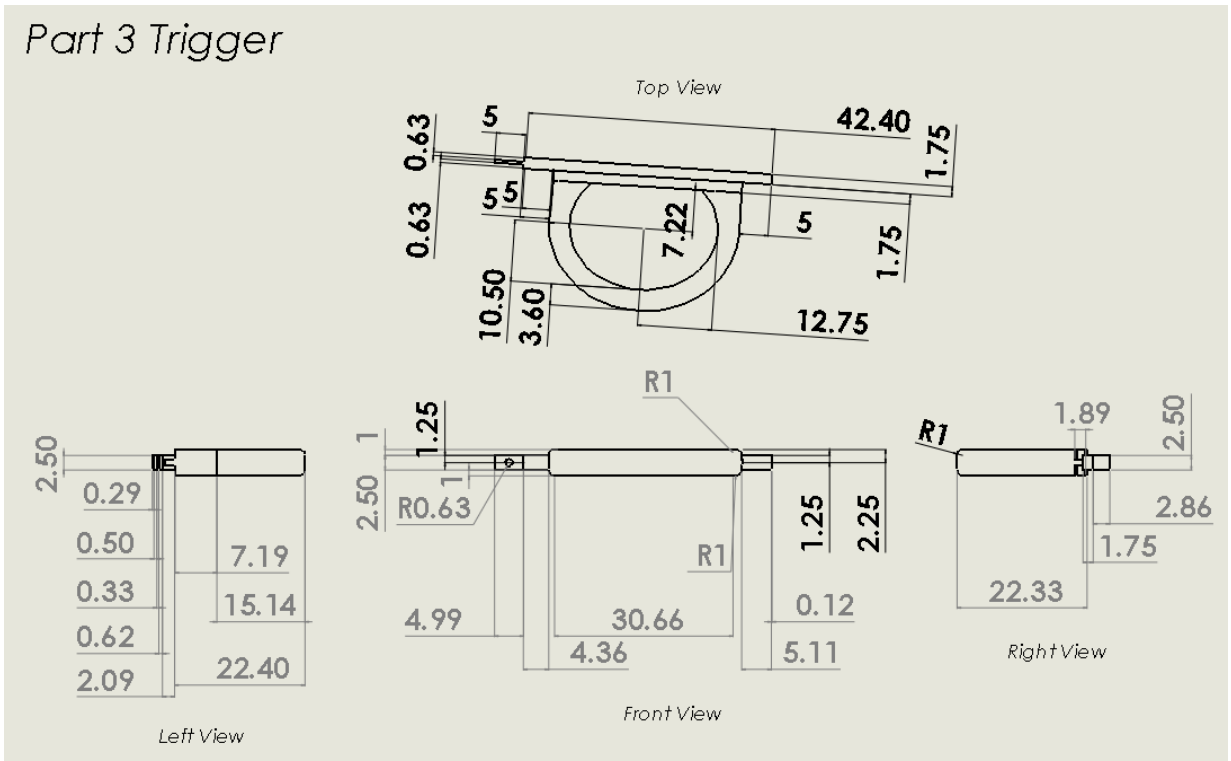
c. *Patient-related concerns*: The device has to be sterilized between uses, as per standard surgical protocol.

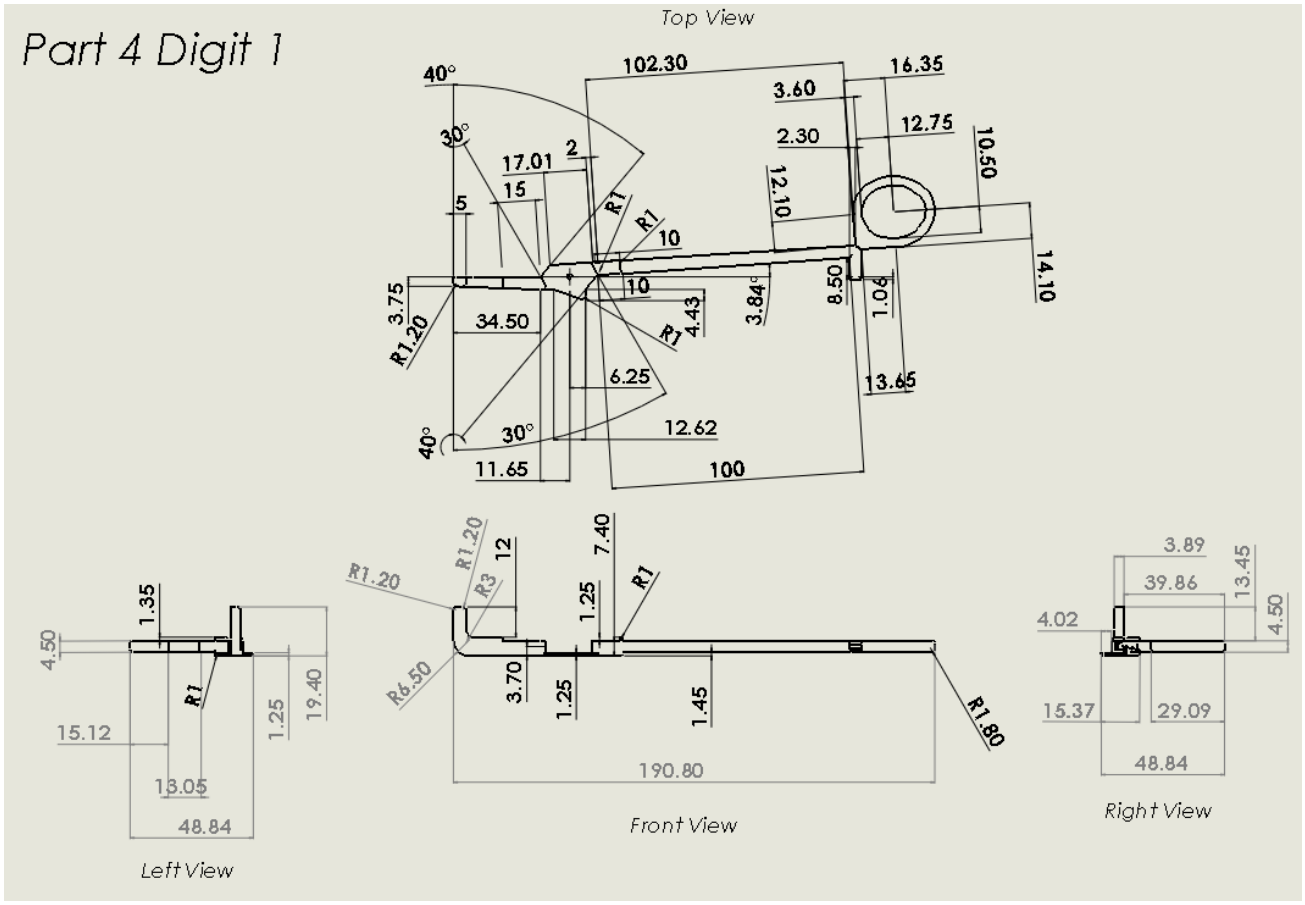
d. *Competition*: There are currently no existing products on the market addressing the problem.

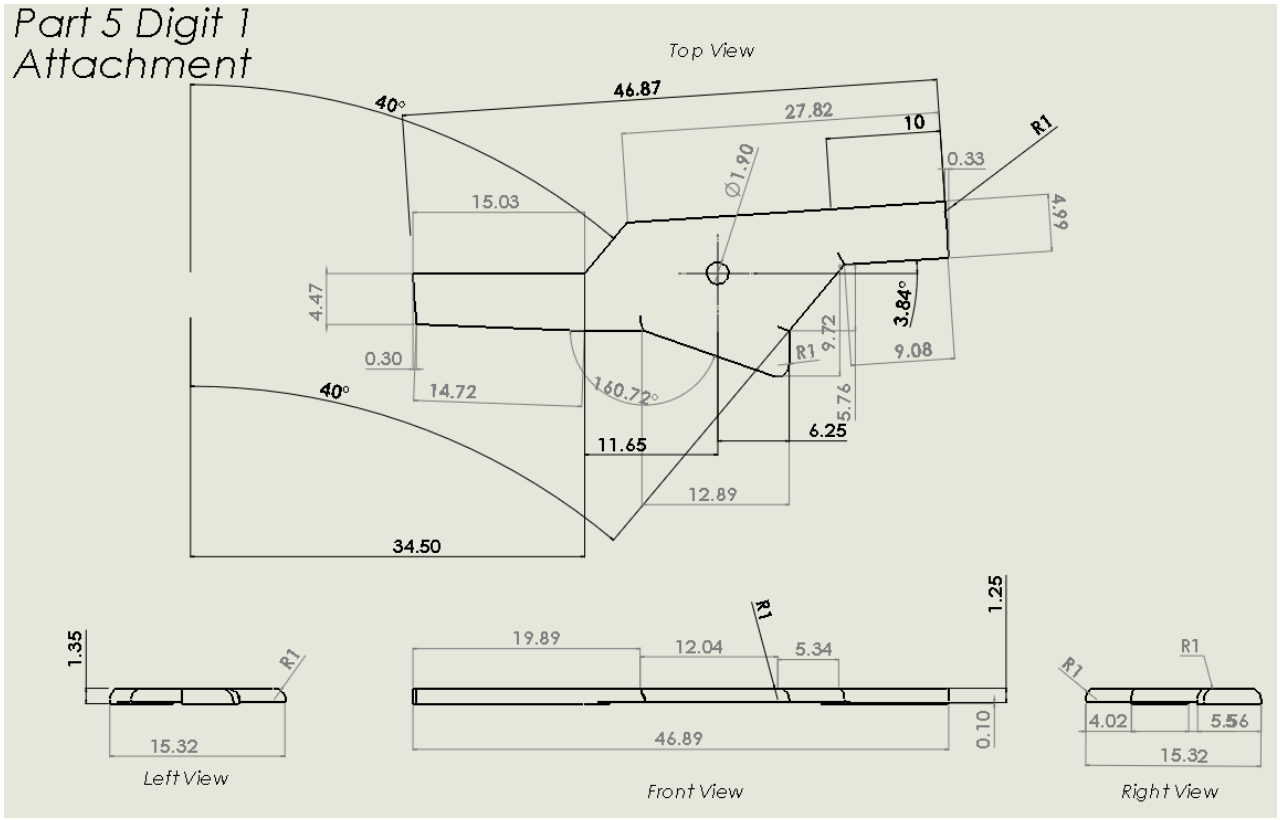
Appendix B: Detailed dimensions of the seven parts made in SolidWorks. All dimensions are in mm.

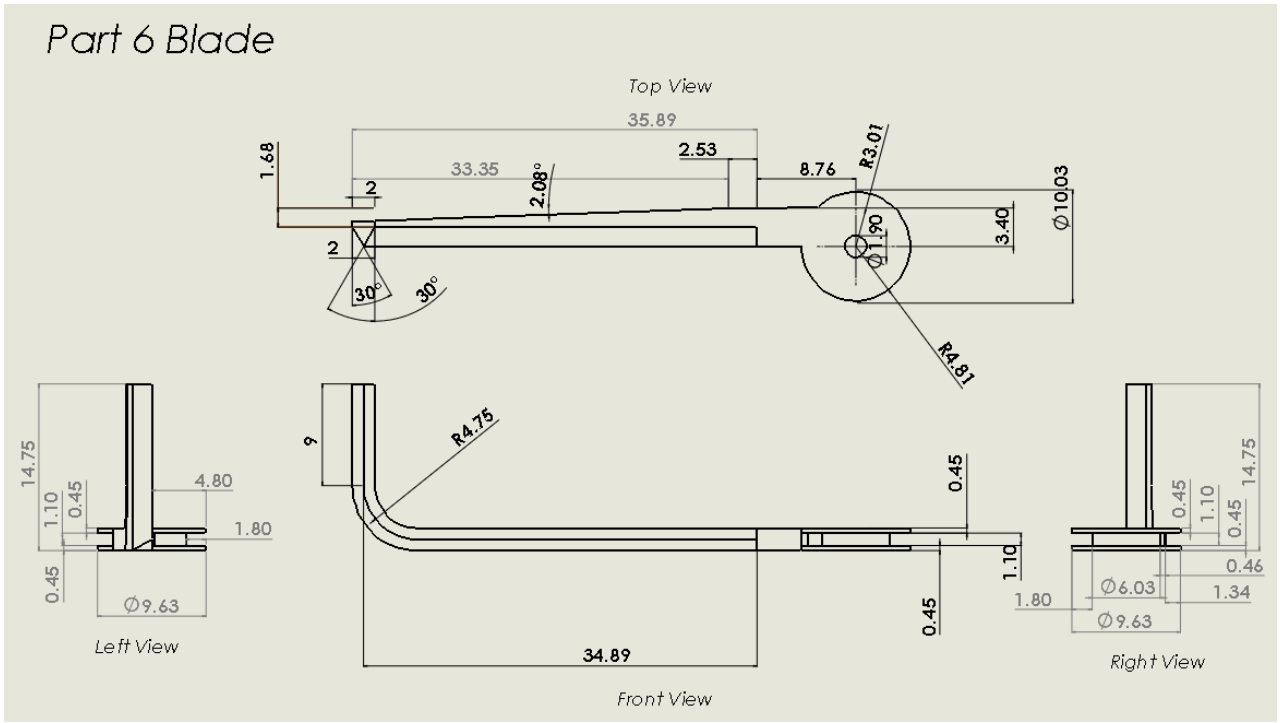


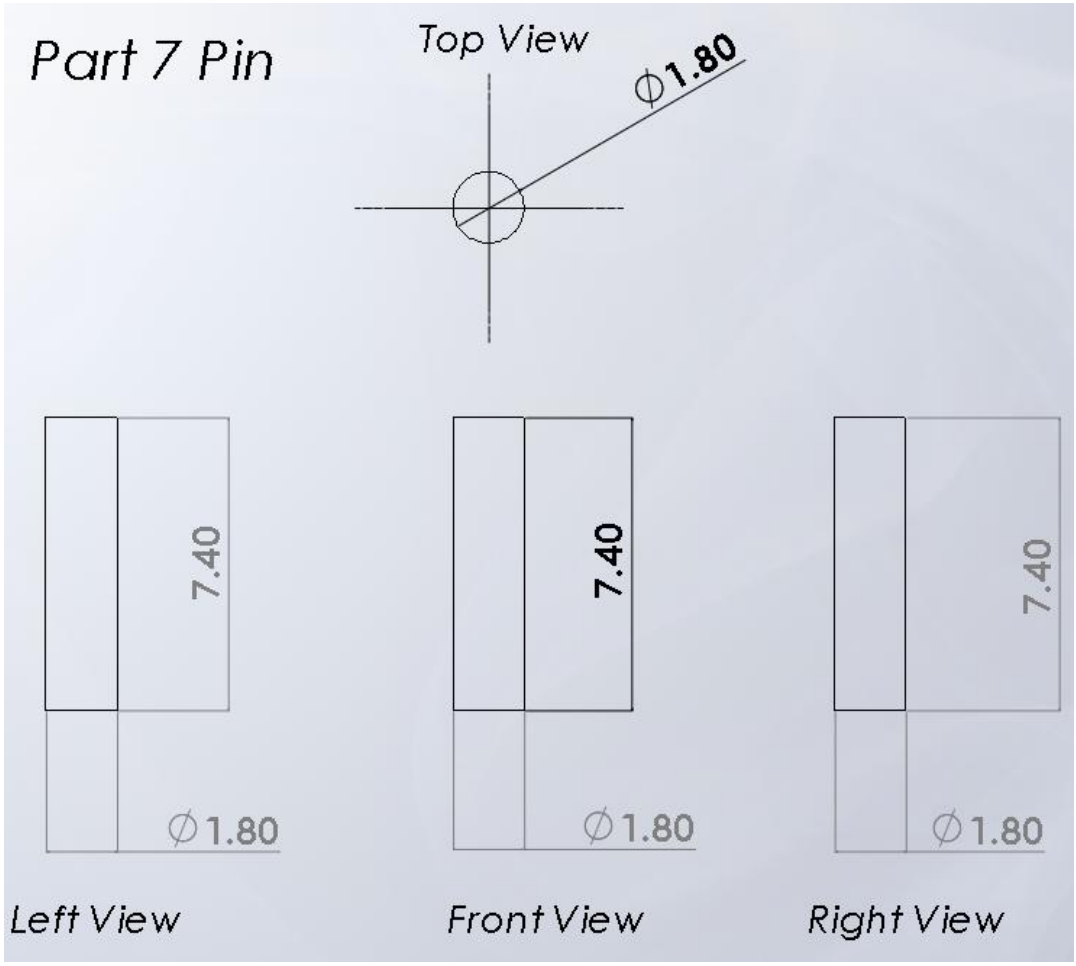

Part 2 digit 4
Attachment
Top View
10.75
50
2.99
2.49
R1
R1
R1
1
0.75
3.49
3.35
10.59
14.08
0.25
Left View
0.59
1
1.75
0.05
0.25
0.20
49.89
0.07
0.23
0.17
Front View
R1
R1
1.75
1
3.35
0.75
2.99
1
3.50
2.49
14.08
Right View


Part 3 Trigger
Top View
0.63
5
42.40
1.75
0.63
5
5
7.22
5
1.75
10.50
3.60
12.75
2.50
0.29
0.50
0.33
0.62
2.09
7.19
15.14
22.40
Left View
R1
1.25
1
2.50
R0.63
1
1.25
2.25
R1
4.99
30.66
4.36
0.12
5.11
Front View
R1
1.89
2.50
2.86
1.75
22.33
Right View


Part 4 Digit 1
Top View
40°
102.30
16.35
3.60
30°
2.30
12.75
10.50
17.01
2
15
5
R1
R1
10
12.10
14.10
10
3.75
R1.20
34.50
R1
4.43
3.84°
8.50
1.06
6.25
13.65
40°
30°
12.62
11.65
100
R1.20
R1.20
R3
12
7.40
R1
1.25
4.50
1.35
R6.50
3.70
1.25
1.45
R1.80
R1
15.12
1.25
19.40
13.05
48.84
190.80
Left View
Front View
3.89
39.86
13.45
4.02
4.50
15.37
29.09
48.84
Right View


Part 5 Digit 1 Attachment
Top View
40°
46.87
27.82
10
R1
0.33
Ø1.90
15.03
4.99
4.47
3.84°
0.30
14.72
160.72°
R1
9.72
9.08
40°
5.76
6.25
11.65
12.89
34.50
1.35
R1
15.32
Left View
19.89
12.04
R1
5.34
1.25
46.89
0.10
Front View
R1
R1
4.02
5.56
15.32
Right View


Part 6 Blade
Top View
35.89
1.68
33.35
2.53
8.76
R3.01
2
2.08°
Ø10.03
3.40
2
Ø1.90
30°
30°
R4.81
14.75
1.10
0.45
4.80
1.80
0.45
Ø9.63
Left View
9
R4.75
0.45
1.10
0.45
34.89
Front View
0.45
1.10
14.75
0.45
0.46
Ø6.03
1.34
1.80
Ø9.63
Right View


Part 7 Pin
Top View
∅1.80
7.40
∅1.80
Left View
7.40
∅1.80
Front View
7.40
∅1.80
Right View

Appendix C: Ergonomics Survey

Rate the following on a scale of one (bad) to ten (great). Five is average:

Trigger location:

1 2 3 4 5 6 7 8 9 10

Ability to maintain visual (can you operate blade with forceps open):

1 2 3 4 5 6 7 8 9 10

Sufficient range of motion:

1 2 3 4 5 6 7 8 9 10

Control:

1 2 3 4 5 6 7 8 9 10

Additional effort required to use:

1 2 3 4 5 6 7 8 9 10

Comparison to current practices:

1 2 3 4 5 6 7 8 9 10

Overall ease of use:

1 2 3 4 5 6 7 8 9 10

Comments on any of the above criteria:

What one thing did you like most about the device?

If you could change anything about the device, what would it be?

Additional comments: