Right-Angle Dissector Scissors Hybrid Surgical Instrument

BME 400

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Abstract

Breast reconstructive surgery is a common procedure performed by plastic surgeons after mastectomies to treat breast cancer. During latissimus dorsi flap breast reconstructive surgery, careful dissection around vascular and neurological structures requires precise instruments such as the right-angle forceps, which is often used to tease away or expose soft tissue to be cut or cauterized by an assistant. However, if the surgeon is operating in a deep hole where the assistant cannot see or reach, a problem arises because the surgeon's non-dominant hand is often occupied with another forceps or other instruments and therefore cannot cut the tissue. A hybrid instrument incorporating scissors into the right-angle forceps has to be developed to address this issue. 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.

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].

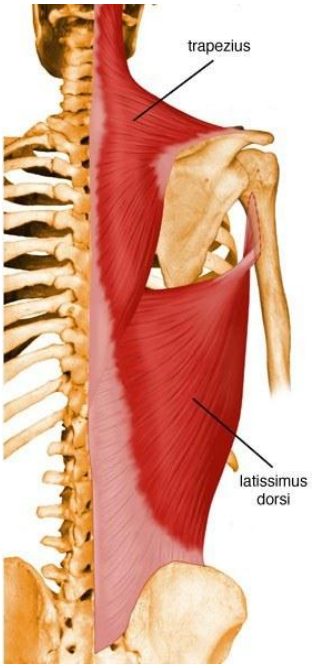

Figure 1: Latissimus dorsi muscle

Latissimus dorsi flap breast reconstruction surgery

Latissimus dorsi flap breast reconstruction is commonly done following a mastectomy of a patient due to breast cancer[2]. 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 be used to create a more natural look. The flap can sometimes take the place of 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 as well as to the thoracodorsal artery, the main source of blood supply to the muscle[3]. 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[4] (see fig. 2, right).

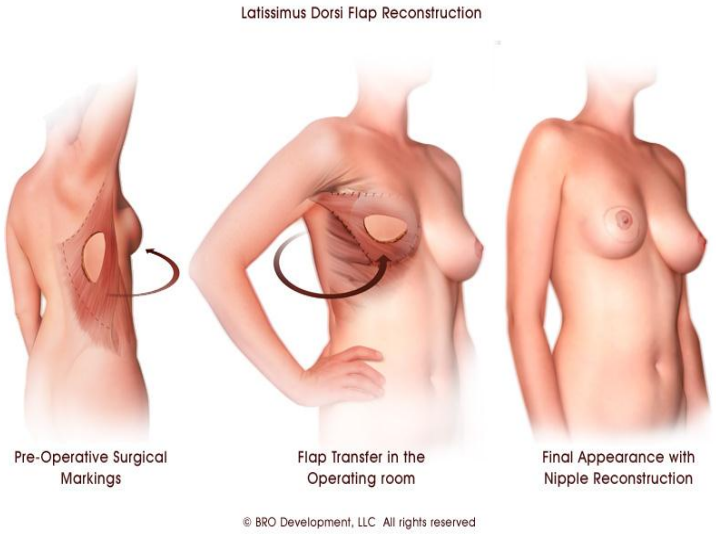

Figure 2: Overview of latissimus dorsi flap reconstruction[3].

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 the 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 see or reach, a problem arises because the surgeon's non-dominant hand is often occupied with another forceps or other instruments and therefore cannot cut or cauterize. Having the assistant estimate where to cut or cauterize is dangerous, as is forcing the surgeon to attempt to handle multiple instruments at once. Therefore, a hybrid instrument is required to minimize the risk of accidentally damaging surrounding tissue during surgery.

Client requirements

The device has to incorporate a surgical cutting scissors function in the existing right-angle forceps (see fig. 3) of length 19.1cm, 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 retain visibility in the region of interest. It has to be compatible with current surgical protocols: able to be autoclaved, produced out of stainless steel, and able to be sharpened. . It should be operational under normal operating conditions of a temperature of approximately 20°C and relative humidity of approximately 50%. Furthermore, it should be ambidextrous and adaptable for different forceps sizes. Finally, it should be produced with a budget under $200.

Existing devices

Right-angle forceps

Breast reconstruction surgery currently makes use of a right-angle forceps of length 19.1cm (7.5 inches), otherwise known as a 90-degree curved Kantrowitz forceps (see fig. 3). While most surgical clamps 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[5]. Because of the unique angle of the device, it can reach around blood vessels and other important structures that are impossible with other devices. It can be used to occlude blood vessels or other structures, or in dissection, where it can effectively expose hidden structures that may be blocked on all sides.

However, the issue with the current device is its lack of cutting capability. As a result, it must be often 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[6]. The device would make use of a right-angle dissector and Harmonic Scalpel® (Ethicon Endo-Surgery) 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, and no prototype has been 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[7].

Ethics

As the device will be used to directly interact with human patients, it is important to understand the ethical issues which may be a concern. Beauchamp and Childress' have proposed four ethical principles relating to plastic surgery, shown in table 1[8]. 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[8]	
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 in order to properly open, close, and stabilize the instrument during surgery. A surgeon usually inserts digits 1 and 4 into the finger holes 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. 4). 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.

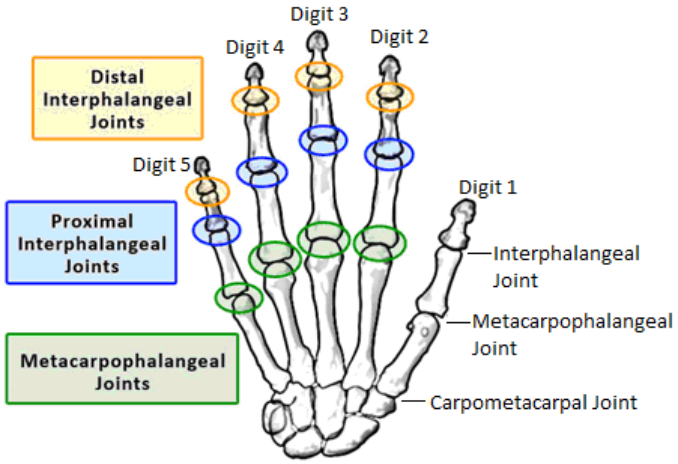

Figure 4: Joints of the hand[9].

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[9]. 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.

Index Finger Physiology

Consideration must be given to the forces generated by, and range of motion of, the index finger, since it is most likely used to activate the trigger mechanism. As shown in figure 5, 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[10]. With regards to range of motion, three different joints must be considered: the metacarpophalangeal joint, proximal interphalangeal joint, and distal interphalangeal joint (see fig. 4). The expected range of motion for flexion-extension and abduction-adduction at each of these joints can be seen in Table 2[11].

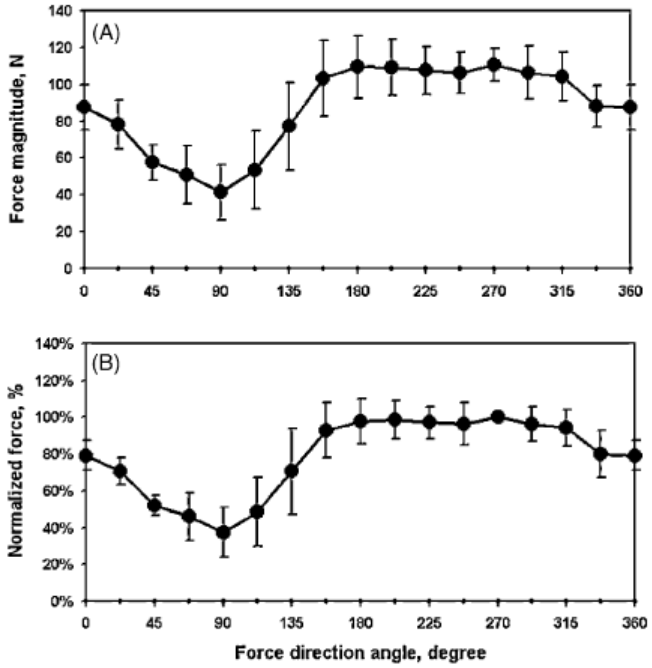

Figure 5: (top) Forces in N and (bottom) normalized forces in percent of maximum force in the possible range of motion, given as mean ± SD. Zero degrees corresponds to abduction, 90° to extension, 180° to adduction, and 270° to flexion[10].

Table 2: Range of motion values for each joint of interest with respect to the index finger[11].		
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 as well as 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 grasping tissue or clamping is optional and need not be considered in the design process. Lastly, the device has to comply with current surgical procedural standards.

Design 1: Built-in Scissors

The first design is a straightforward combination of the right-angle forceps and surgical scissors (see fig. 6), measuring 19.1cm 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 cut in a specific region in between the blades and has to be vigilant about not accidentally damaging tissue whenever the blades are opened and closed.

Figure 6: 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. 7). As before, the device is of an 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.

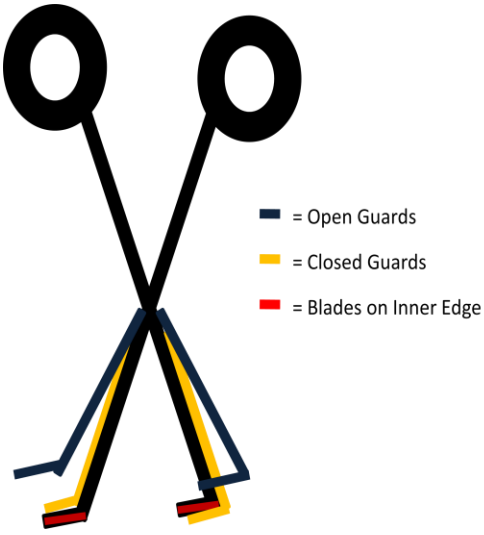

Figure 7: Guarded Scissors design

Design 3: Trigger Scissors

The third design incorporates a trigger mechanism to activate the cutting motion of blades into the right-angle forceps (see fig. 8). The device operates and enters the deep hole like regular right-angle forceps, with the blades protected in a shaft in order to prevent accidental injury to the patient. Once in place and opened to spread tissue, the cutting blades can be operated. The numbers in parentheses correspond to the numbered parts in figure 8. The surgeon pulls the trigger (1) with the index finger, which is met by some resistance from the spring (2) in order to control the swinging motion of the blades. The pulling force is transmitted by a cable (3), through the hinge joint (4), and finally to the cutting blades (5), which rotate out of the shaft and swing together to cut the desired tissue.

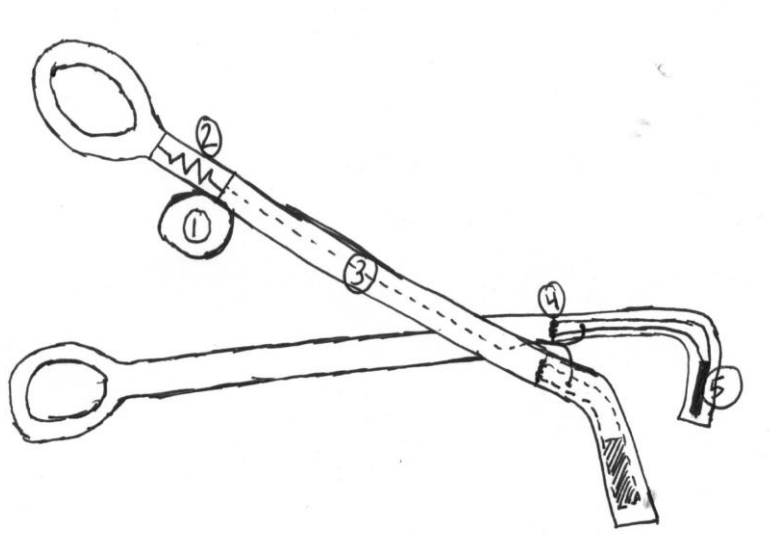

Figure 8: Trigger Scissors design. The numbered components shown are 1) trigger, 2) resistance spring, 3) connecting cable, 4) hinge, and 5) cutting blades**.**

Design evaluation

Table 3: Design Selection Matrix. 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

Five categories were chosen to judge the three designs and weighted based on how critical they were to fulfilling the design and client requirements that were set (Table 3). Total scores were judged out of 100. For each category, the design which 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 judgment of the designs based on how they compare to each other rather than simply an arbitrary standard.

Safety

The first category was patient safety, given 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 trigger scissors design allows the surgeon to maintain full vision in the deep hole while cutting, control the speed of cutting, and dynamically apply and adjust the cutting force.

Functionality

Functionality, evaluated as the amount of control allowed the surgeon while cutting, was the next category and was assigned 20 total points. The designs were compared mainly on their ability to allow the surgeon visibility and control while dissecting and cutting tissue. While all the designs scored similarly in this aspect, the guarded scissors design and trigger scissors designs scored better than the built-in blade design in this respect.

Client Preference

Client preference was the next category, and was judged based on the client's preference for each design and was assigned 20 total points. The trigger scissors design is the most innovative and the safest, the guarded scissors design is functional, and the built-in blade design is satisfactory but not ideal. The designs were scored according the client's comments on the designs.

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 effective criterion because all the designs are sterilizable to a certain degree. The built-in blade 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.

Total

After computing the total scores for the designs, it was determined that the trigger scissors design had the highest score 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. The standard sterilization process is by autoclaving, which may sometimes be necessary multiple times during a surgery. Therefore, the device needs to be composed entirely of a material or materials that are autoclavable, hemocompatible and biocompatible, 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. In addition, there are autoclave-able polymers available, but 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. Currently, local and national manufacturers working with stainless steel have been contacted to obtain their expert opinions on the grade of stainless steel best suited for the device. The final decision for the stainless steel grade to be used will be made based on cost, durability, and ease of manufacturing.

Future work

Firstly, the mechanism of the trigger scissors has to be designed. The section below on the endoscopic surgical instrument describes a technology that can be applied to design the trigger mechanism. After the design is finalized, a SolidWorks version of the design will be created and the sketch will be printed using 3D printing technology and PVC as the material for the initial prototype. Next, testing and analysis will be conducted, specifically to measure the forces generated by the trigger mechanism and to evaluate the learning curve of the device. The client and other residents will be asked to learn and practice using the device in practice surgeries to assess its clinical usefulness. After testing on the prototype is completed and all comments are collected, relevant changes can be implemented to the design and the final device will be produced out of surgical grade stainless steel.

Endoscopic Instrument

Although this device is not used in breast reconstruction surgery, US Patent 5,281,220 describes an endoscopic instrument which has technology related to the desired final product (see fig. 9)[12]. 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 1 hand.

The method for transmitting forces from the handle to the end of the final destination can be applied to the trigger scissor design. Although the trigger scissors design does not involve any rotation about the long axis, the basic principle of force transmission may be useful.

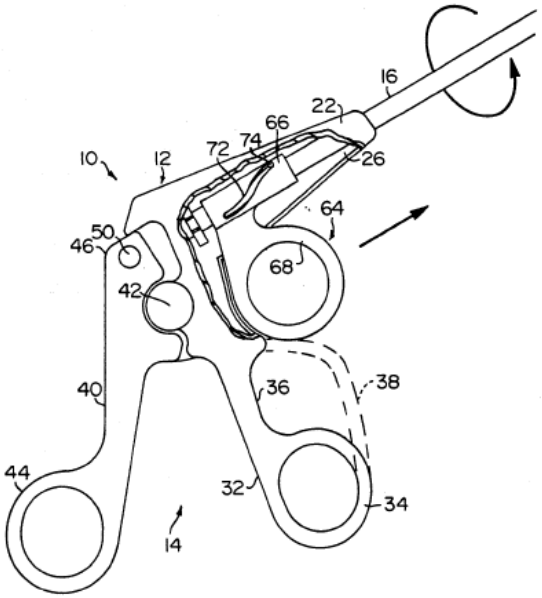

Figure 9: One-handed rotating tube endoscopic surgical device[12].

Timeline Evaluation:

To properly plan the steps involved in completing the final device, a schedule was composed and followed as strictly as possible, as shown in Table 4. As shown, the project is currently on schedule and has not experienced any major delays except for minor scheduling conflicts.

Table 4: Projected timeline for the semester

Aim	September				October				November					December	
	7	14	21	28	5	12	19	26	2	9	16	23	30	7	14
Meetings															
Client	X			X											
Advisor	X		X	X	X	X									
Group	X	X	X	X	X	X									
Deliverables															
Progress Report	X	X	X	X	X	X									
PDS	X	X													
Midsemester					X	X									
Final poster															
Final report															
Project R&D															
Brainstorming		X	X	X											

Designing					X	X									
Prototyping															
Testing															
Website															
Update	X	X	X	X	X	X									

Shaded boxes: projected schedule

X: in-progress or completed

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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.