Modification of Cauterizing Forceps for Microsurgery

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Abstract
This project has been undertaken for a neurosurgeon who desires a modified pair of bipolar forceps, a versatile tool used to cauterize blood vessels during microsurgery. The requested task was to incorporate a switch or button somewhere on the shaft of the forceps that would allow the surgeon to activate the cautery function with minimal movement or effort. Several different design proposals were considered, with special attention paid to concerns of safety and convenience. The final design involves a simple depressible button located between the two arms of the forceps. Exact placement of the button was chosen to accommodate the client's stated preferences. Due to various technical difficulties and time constraints, only a crude prototype could be constructed. Further work will be necessary in order to achieve a viable product for use in neurosurgery, including improvement of the button design, sealing of all parts connected to the circuit, insurance of the device's ability to withstand sterilization, and extensive product testing.

Design Problem
The design problem initially received from the client, Dr. Behnam Badie of the University of Wisconsin Medical School's Department of Neurological Surgery, read as follows:

When cauterizing blood vessels during microsurgery of the brain, an instrument similar to a standard tweezers is used. The ends are clamped over the vessel, and an electrical current is passed through, cauterizing the vessel. The current is typically initiated using a foot pedal. A useful innovation would be the development of a set of tweezers with the cautery switch on the shaft, allowing the surgeon to position the tips and cauterize in a single motion.[7]

Further research of both neurosurgical terms and surgical tools of this type yielded a much clearer understanding of the design problem. The ultimate purpose of cauterizing blood vessels is to minimize blood loss during surgery, as well as to prevent continued bleeding after surgery is complete. The "tweezers" described refer to a device commonly known as bipolar or electrosurgical forceps (Figure 1), which are used during neurological microsurgery. The most effective and widely used varieties of electrosurgical forceps use radio-frequency energy to provide a wide variety of functions, from simple cutting with tissue dehydration to complete tissue carbonization.[1] Because of the multifunctional nature of the device, the neurosurgeon must be able to activate and deactivate the cautery function as desired. Different frequency and temperature settings must also be allowed.

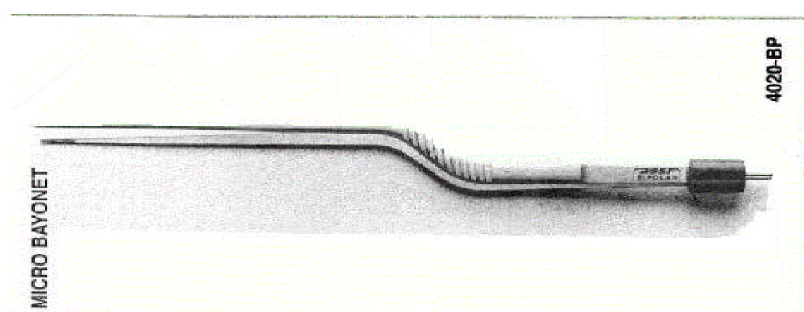

Figure 1: Bipolar cauterizing forceps

The bipolar forceps currently used by Dr. Badie only vaguely resemble a standard set of tweezers. The forceps are connected to a radio frequency generator. The generator is activated using a foot pedal (shown in Figure 2) located on the floor beneath the operating table. When the foot pedal is depressed, the cauterization function is activated along with a continuous warning tone; when it is released, cauterization ceases.

Figure 2: Various Foot Pedals Currently in Use
(ValleyLabs 2001[6])

Dr. Badie[7] is disappointed with the foot pedal activation of the bipolar forceps. He finds the use of multiple pedals beneath the table during surgery both awkward and potentially dangerous. The surgeon sometimes needs to pause his procedure during the surgery in order to find and depress the correct foot pedal. To avoid this, Dr. Badie would like to see a new design that allows the forceps to be activated from some mechanism on the forceps themselves, such as a button on or near the shaft of the forceps. He feels this improvement will allow him to grab tissue, coagulate any blood, and release in one fluid movement. Because the design must not interfere with the surgeon's ability to perform surgery in the manner to which he/she has become accustomed, it was decided that the new device should resemble the currently used forceps as closely as possible.

Background

Archaeological findings reveal that neurosurgery was actually first practiced over 10,000 years ago.[2] Since that time, enormous advancements have been made in neurosurgical tools and techniques, as well as in understanding of the physical and chemical science of the brain. Electrosurgical instruments date back to 1891, when doctors first harnessed the ability to use electricity to coagulate blood and cut tissue during surgery. The "bovie" was the first electrically charged metallic instrument to be used in clinics. Crude and unreliable in its ways, the bovie often subjected doctors and nurses to burns and electrical shock in the operating room. Not surprisingly, today's electrosurgery tools are much better designed. Rather than heating up to cauterize, most of today's instruments have radio frequencies pass between their tips to bring about cauterization or coagulation.

The design of improved electrosurgical forceps, like the design of any new device, began with extensive background research. We found a variety of supply companies that carried bipolar forceps, including Accurate Surgical & Scientific Instruments (ASSI), Conmed, and Valleylabs[6], but none of the companies carried bipolar forceps featuring a button on the shaft of the device. Kerwin Instruments indicated that they previously manufactured a similar product, but (most likely due to marketing problems) discontinued its production.

A key consideration when designing devices of this sort is the sterilization process, as any components added to the device must be sterilized along with all of the other surgical instruments. At the UW Hospital, the forceps themselves, the cords, and even the generator are sterilized with one of two general methods. If an item can withstand the temperatures, it is subjected to steam at 275°C for 1 hour; otherwise, it is sterilized with ethylene oxide for 130°C for 13 hours. Any buttons found on surgical tools must therefore be either removable or covered with some form of thermal protection.

Design Specifications

Bipolar forceps typically range from 10.2 cm to 22.2 cm in length, and the tips range from .7 mm to 1.5 mm in width.[3] The ideal frequency range for surgical use has been found to be 300-500 kHz.[1] Required temperatures produced within tissues during cauterization range from 100 to 500 degrees Celsius, depending on the nature of the surgery.[4] Performance requirements include the ability to withstand daily use for brief applications as well as procedures that may last for several hours.

One of the primary challenges facing the design team was to place the button or switch so that it was easy to access, yet remained out of the surgeon's way during surgery. Furthermore, the button could not be placed in such a manner that it altered the surgeon's grip on the device or presented the danger of accidental cautery activation. The button was to be accessible with only one finger (preferably the forefinger) and with minimal motion. Because even small, undesired movements have serious consequences during microsurgery (which is performed beneath a microscope), a button requiring very little tactile force was needed. The button also had to be free of any sharp edges that could catch on the surgeon's gloves, clothes, gauze, etc. Finally, all components of the device had to be made to withstand the sterilization process, as described above. For further design specifications, see the Product Design Specifications (Appendix 1).

Design Alternatives

The first solution proposed was also the most unorthodox. Shown in Figure 3, the design involved running a wire from the standard forceps to a small component resembling a thimble, which would fit on one of the surgeon's free fingers. A small button would be placed on the end of this "fingertip" device, so that the surgeon would need only press his/her fingertip to any random surface in order to activate the cautery function. In all designs considered, activation would cease immediately upon removal of pressure from the button/switch.

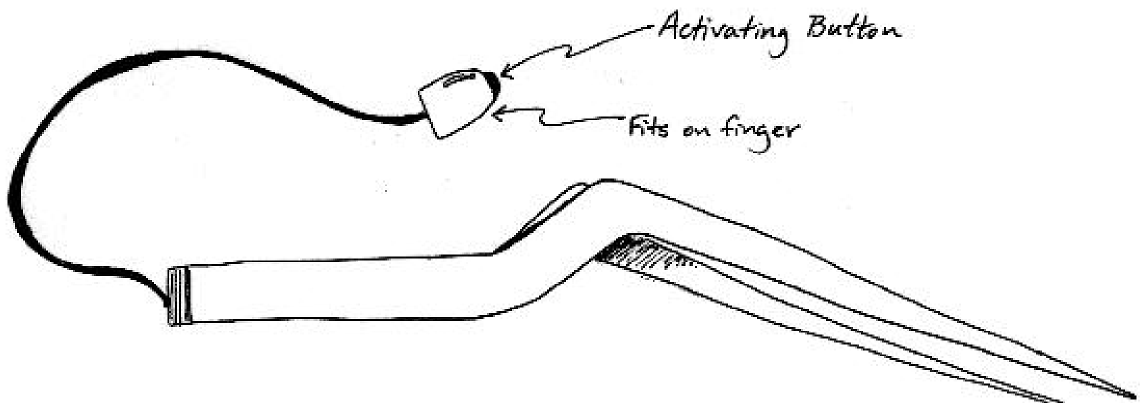

Figure 3: Fingertip Button Design

The portion with the button would have to be designed with a tapered tip (again, resembling a thimble) so that it would fit on the end of any finger. The electronics required by this design would not differ drastically from those of the present foot-activated device, as the wire that is presently run to the foot pedal would simply be connected to the fingertip device instead. The primary advantage provided by such a design would be the surgeon's freedom to essentially place the button in the most convenient location. By allowing any free finger to be pressed to any surface—most likely either the palm of the hand or the shaft of the forceps—the need to place the button at a "perfect" location on the device would be eliminated.

The second design proposed (shown in Figure 4) was less complicated. The shape, size, and appearance of the forceps would, again, remain essentially unaltered. The two most significant features of this proposal involved the button and the insulation around the instrument. The device would feature a spring-loaded sliding button that would automatically return to its original position when released. It was proposed that this type of button would be easier to use in surgery than a pushing/pressing button. This design would also presumably satisfy Dr. Badie's preference that activation require as little movement as possible.

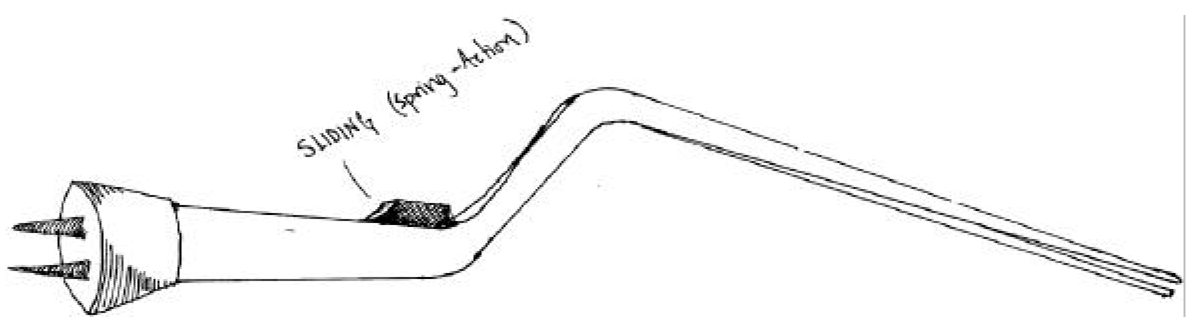

Figure 4: Sliding Button Design

Another important feature of this design idea was insulation of the forceps. Wiring to the button would be hidden and protected beneath a layer of durable insulation. This insulation could be designed to provide surgeons with better grip and more control. The insulation could also allow a miniature light to be included as a safety feature indicating when the cautery function was turned on or off.

The third design proposed (shown in Figure 5) would incorporate a button that could be depressed with minimal force. The fundamental design and wiring of the device would not differ greatly from that of the sliding button design; the most important difference would lie in the button itself. The push button design would require light pressing, which could be easier than the forward-directed sliding motion required by the preceding design. This design would also provide greater flexibility in the placement of the button, since a depressible button could be accessed from a wider range of angles than could a button that slides in one specific direction. The preliminary design plan, as shown below, placed the button in an indefinite location. It was not immediately clear as to whether the button would more appropriately be placed before or after the branching of the two arms of the forceps.

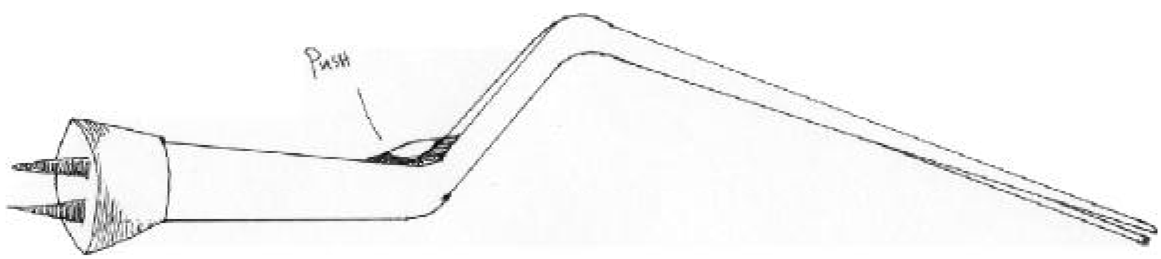

Figure 5: Preliminary Push Button Design

A more detailed proposal was to place a circular button enclosed by a durable rubber or plastic "bubble" beyond the division of the forceps arms. The most easily accessible location was determined from observation of the client as he held the forceps.

One possibility was to place the "bubble button" on the top edge of the forceps, approximately where the thumb is placed when squeezing the arms together (shown in Figure 6). The wiring for the button would include Professor Burke O'Neal's[5] suggestion for three wires, which would be placed in a thin groove down the inner side of the forceps. The groove would be used to make the forceps feel similar to present models. Wiring along the inside of the forceps would also prevent the wires from altering the surface of the original instrument. Like that of the sliding button, this design would require an insulation material to hold the wires within the groove.

This design would meet the requirements set by Dr. Badie[7] in that the button would be within the range of natural motion of the hand, easily depressed in one motion using the index finger. A problem, however, would be posed by the placement of the button on one arm of the forceps or the other, as it could only cater to either a left-handed or right-handed surgeon. This would require two forceps in each operating room, increasing the cost for the hospital. A second disadvantage would be that the button width would need to be incredibly small in order to fit on the arm of the forceps. This would most likely cause difficulties in construction.

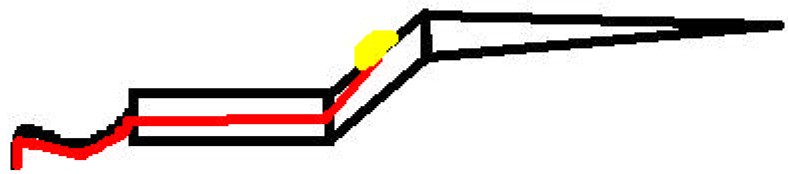

Figure 6: Placement of the button on the top edge of the shaft

An alternative design placed the button on a platform between the arms of the forceps. The platform would be fixated to one arm and span a distance no larger than the total distance between the two arms of the forceps in the closed position. Like the previous design, this would satisfy the client's need for a button easily accessible to the index finger. It would also enable either left-handed or right-handed surgeons to use the same forceps, decreasing the cost from two forceps to one for each operating room. One disadvantage to this idea was that the platform would need to be precisely constructed to minimize problems while in use. One potential problem would be that if the platform were to bend downward, the forceps would be rendered non-functional. A second problem would arise if the platform were to puncture or pinch the surgeon's latex gloves during surgery. Furthermore, if the platform were to be soldered to the arm, the strength at this connection could be an issue.

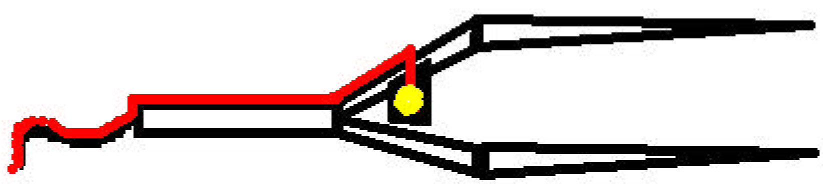

Figure 7: Placement of the button on a platform between the arms of the forceps.

In yet another proposed design, the button would be placed on a removable platform that could be temporarily fixated to the shaft of the forceps using a simple clamping device. The clamping device would include the platform secured to two clips that would wrap around the shaft of the forceps. The wiring for the button would be essentially the same as in previously described designs, except that the wires would be wrapped into a single cable placed along the top edge of the forceps shaft.

One of the major benefits of this design would be that the removable platform could be used on existing forceps, without the need for expensive (and potentially risky) mechanical modifications to the instrument. The platform could be clamped to the shaft of the forceps using a small nut and bolt to tighten the sides of the platform clips, as shown in Figure 8.

There would be two major disadvantages to this design. First, if the removable platform were not well secured, there could be movement of the platform during surgery. Such movement could force the surgeon to reconfigure the device during complicated and delicate procedures. Second, the wires would have to be placed on the top edge of the forceps in order to freely move, and thus could become tangled in other equipment during surgery.

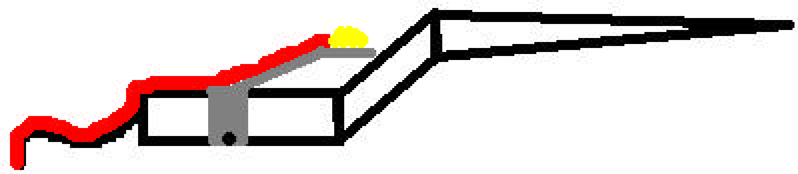

Figure 8: Placement of the button on a removable platform.

Chosen Design

The chosen design features a button located on a stainless steel plate between the two arms of the forceps (Figure 9). The button works similarly to the foot pedal in that cauterization is activated through depression and immediately terminated upon release. The primary problem predicted for this design had to do with bending at the junction of the plate and the forceps over time. Bill Hagquist, the mechanical engineer in charge of construction of the prototype, assured us that the plate would be sturdy, especially considering the low forces involved. With that problem eliminated, this design clearly presented fewer disadvantages than did the others. As the client also approved of the idea of a button mounted on a small plate, there was little question as to which design alternative was best.

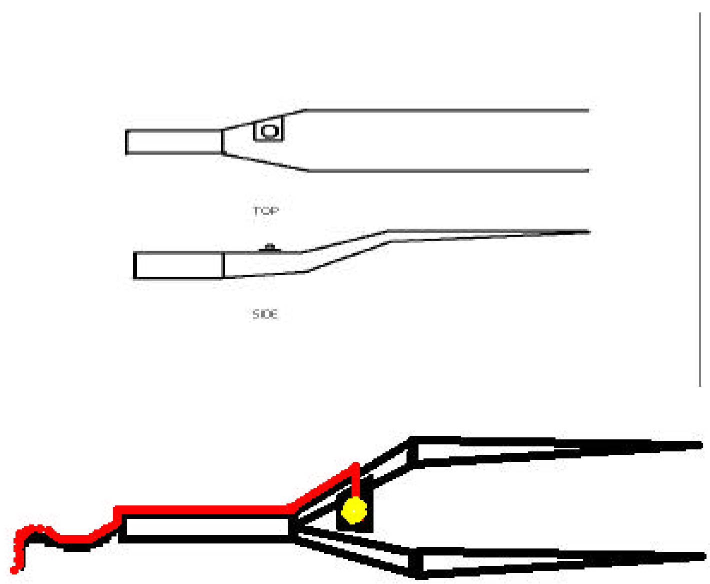

Figure 9: Placement of the button on a platform between the arms of the forceps.

The prototype includes a simple mechanical button requiring a force of 4 oz for activation. The stainless steel mounting plate was soldered to the forceps in the location specified by the surgeon, and a small circuit board with the button was screwed into the plate. The prototype was constructed using a standard pair of bipolar forceps obtained from the UW Hospital, a button ordered from Newark, Inc., and a small piece of a circuit board. The prototype measures 22 cm in length and approximately 1 mm at the tips. The button is elliptical, with a length of 4 mm and a width of 3 mm, and it protrudes approximately 1.5 mm from the top of the plate. Based on information obtained from the UW Hospital, the total cost of the finished product was estimated at $200. The generator would cost an additional $3000.

This design meets most of the requirements specified by Dr. Badie[7]. The range of motion required for depression of the button is small, and location the button is such that it may be easily accessed with the surgeon's free finger without any alterations of grip. It does this without obstructing the surgeon's view during surgery—another essential feature stressed by the client. This design would also enable either left-handed or right-handed surgeons to use the same forceps. There are a few issues with the button that were not dealt with due to time constraints. Some of these issues include: the force used for depression, the need for a protective covering during surgical use, and the circuitry needed to use the button.

Although the current prototype satisfies most of the client's stated desires, it is not suitable for use in neurosurgery. The first reason is that even a force as small as 4 oz. is too much for microsurgery in which every millimeter is crucial. Improvements to the button itself could include finding a capacitive switch, a photosensitive switch, or another mechanical button with a much lower depression force. The second improvement that needs to be made is the addition of a protective cover for the button and circuitry. In an environment such as that of neurosurgery, many minor parts of the tools used can cause large problems. During surgery, this tool will be exposed to many conductive materials including blood and body tissues. These pose the threat of malfunction by either causing a short in the electronics or a build-up of materials in the internal parts of the button. To remedy this either the entire tool, except the conducting tips, or just the platform and button, could be enclosed in a temperature resistant rubber or plastic. This solution would prevent materials from reaching the tool and cover any sharp edges, which could cut gloves or damage tissue. The final change that needs to be made is the construction of the circuit for the switch, which will have to precede any other future work on the project. Once the circuit is made, thorough product testing will have to become a top priority. The safety and effectiveness of the device must be indisputably confirmed before it can be used in actual neurosurgery.

Conclusion

This project was undertaken to assist Dr. Behnam Badie with modifications to a pair of bipolar forceps, a versatile tool used to cauterize blood vessels during microsurgery. The requested task was to incorporate a switch or button somewhere on the shaft of the forceps that would allow the surgeon to activate the cautery function with minimal movement or effort. After considering several different design proposals a final design was chosen. The final design involves a simple depressible button located between the two arms of the forceps. Exact placement of the button was chosen to accommodate the client's stated preferences. Due to various technical difficulties and time constraints, only a crude prototype could be constructed. Further work will be necessary in order to achieve a viable product for use in neurosurgery, including improvement of the button design, sealing of all parts connected to the circuit, insurance of the device's ability to withstand sterilization, and extensive product testing to guarantee the safety of the modifications as well as the effectiveness.

This highlights an important ethical point that arises in any engineering endeavor—the question of safety vs. economy. We have already rushed to complete the prototype by the end of the semester, and the result has been a product of highly questionable quality. Such "fast tracking" of the design process is often done in the interests of time/money and at the expense of sufficient testing. If the same were to occur with the design of the final surgical forceps, the consequences could be as grave as human death. Thus, every engineer has to maintain sight of the ultimate goal of the field, which is not to make money, but to help other human beings.

Appendix 1

References

[1]Hausner, Karl. "Laser vs. Electrosurgery. http://elmed.com.

[2]Neurosurgery://On-Call. http://www.neurosurgery.org.

[3]Accurate Surgical & Scientific Instruments, Inc. 2001 catalog.

[4]Bio-Tek Instruments, Inc. *Electrosurgery Analyzer Primer*. http://www.biotek.com/biomed.

[5]O'Neal, Burke, University of Wisconsin Instrument Innovator Researcher, (Madison: 28 September 2001), In-person interview.

[6]Valleylab, www.valleylab.com (2001).

[7]Badie, Behnam, MD, Lapsiwala, Samir, MD. Personal Interview. 24 Sept. 2001.
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Appendix 2

Product Design Specifications (PDS)

October 19, 2001
Updated December 12, 2001

Title: Modification of Cauterizing Forceps for Microsurgery

Function: Finger button on or near the shaft of cauterizing forceps to replace the current foot pedal for activation of radio frequency.

Client requirements:

- Button will not obstruct view down shaft
- Be reusable (i.e. – able to be sterilized)
- Light finger pressure activation
- Located on forceps in a position where one finger can activate without changing the position of the hand on forceps
- Depressible button preferred over a sliding button design

Design Requirements:

1. Physical and Operational Characteristics:
    a. Performance Requirements –
        The device must function both as general surgical forceps and as a blood vessel cauterizing tool. The surgeon must be able to grasp the device in one hand and easily manipulate it with as little as a thumb and an opposing finger. This manipulation would include cutting, grasping, pulling, and separating tissues and blood vessels. The cauterizing function of the device is to involve heating of the tips of the forceps using high frequency electric current ranging from 300 kHz to 500 kHz. This heat will allow the surgeon to cauterize, or close, blood vessels as they are severed, thus minimizing blood loss. The high frequency current is to be activated via a button or button that can be depressed with one of the free fingers of the hand in which the device is held. The device must be capable of both extended and interrupted (i.e., on-off) use on a daily basis. A load resistance of 100 ohms is expected, based on typical values.
    b. Safety –
        It is essential that the surgeon is able to instantly activate and deactivate the current in the forceps, and care must be taken to minimize the chances of accidental activation. As the device's operation involves current flow and high temperatures, sufficient thermal and electrical insulation must be provided to prevent electrocution and/or unwanted burning of tissues. The device also must be designed in such a way that no features hinder the surgeon's ability to operate on the patient as necessary.

c. Accuracy and Reliability –

The device must be capable of repeated heating to a temperature sufficient for cauterization. This level of precision requires a power generator that consistently produces frequencies between 300 and 500 kHz.

d. Life in Service –

The surgeon must be able to rely on this device to work as desired throughout the day, every day, for several years. Use of the forceps will be sporadic, lasting anywhere from a few seconds to several hours.

e. Shelf Life –

- Store at room temperature (68°±10°F)

f. Operating Environment –

- Possible exposure to blood, water, acids/bases, and dust
- Operation temperature range: 65°F to 90°F
- Must be able to withstand autoclaving procedures (heat/vibrations)
- Used by: Surgeons

g. Ergonomics –

- Button on tweezers must not obstruct view during surgery
- Button must be completely protected/insulated from liquids or debris to prevent malfunction
- Button must be easily depressed
- Button should be easily accessible
- Use of the button should feel “natural” to the surgeon

h. Size –

- Tweezers:
  - Length: 22 cm
  - Tip: 1 mm
- Button
  - Length: 4 mm
  - Width: 3 mm
  - Height: 1 mm

i. Weight –

The probe should be light enough so the surgeon can work hours without trouble.

j. Materials –

The forceps and mounting plate are stainless steel, and both the button and circuit board are plastic. The button itself would not withstand autoclaving procedures.

k. Aesthetics, Appearance and Finish –

The forceps are sterile, unadorned steel. The button is a light orange color. Further finish may include a casing or protective membrane over the button and circuit board contact points.

2. <u>Production Characteristics:</u>

a. Quantity –

- One working prototype

b. Target Product Cost –
- The total cost has been estimated at $300

3. <u>Miscellaneous:</u>

a. Standard and Specifications –
(None)

b. Customer Input–
- Button will not obstruct view down shaft
- Must be reusable
- Required pressure must be very small
- The button must be located on forceps such that a finger can activate without changing hand position
- Depressible button preferred over a sliding button design
- Should be "on" only when button is depressed
- No wires should be exposed
- Should not inhibit normal use of forceps

c. Patient Related Concerns –
- Sterilization between uses

d. Competition –
- Valleylab[6] produces a device that is activated not by a button, but by pressing the two arms of the forceps together with enough force. This design differs enough from ours that it is not considered real competition.