

## **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.*

Further research of both neurosurgical terms and surgical tools of this type yielded a much clearer understanding of the design problem. In this context, cautery refers to the process of sealing severed blood vessels by heating the cells of the vascular tissue to such high temperatures that they coagulate, or fuse together. This process is also known as cauterization. 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.

Forceps of the type desired by Dr. Badie are used for grasping, pulling, and separating tissues, as well as for cutting and cauterizing blood vessels. Because of the multifunctional nature of the device, the cautery function must be able to be activated and deactivated as desired by the neurosurgeon. Different frequency/temperature settings must also be allowed. The forceps presently being used by the client feature a foot pedal that must be depressed during surgery in order to activate the cautery function. Our objective is to create a device that functions exactly as do the forceps currently in use, but featuring a button or switch on the shaft of the device in place of the foot pedal just described. Button/switch design and placement must be chosen such that it will not interfere with or alter the surgeon's technique. Dr. Badie's only free finger while using the forceps is his index finger, but the design must also cater to surgeons that hold the forceps in different manners and/or with the left hand.

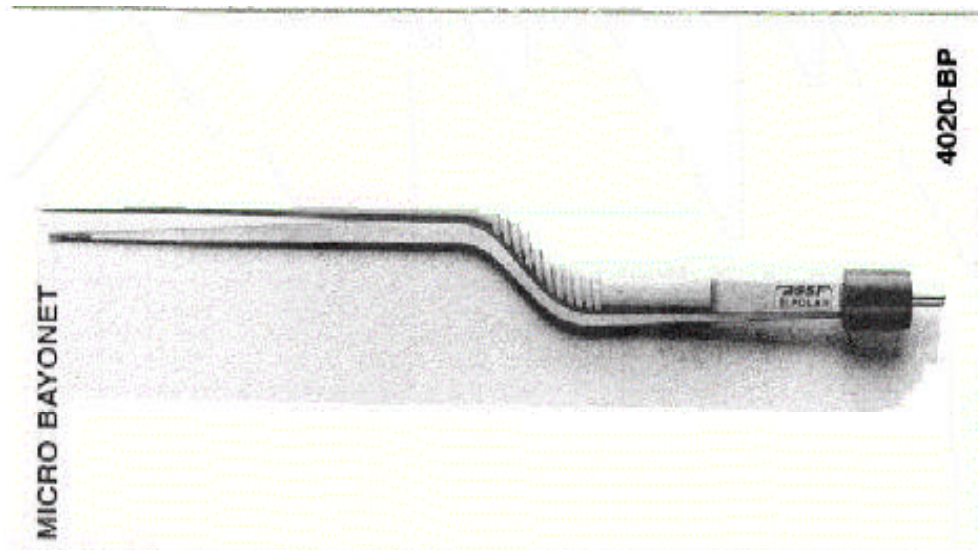
## **BACKGROUND INFORMATION**

Archaeological findings reveal that neurosurgery was actually first practiced over 10,000 years ago.<sup>1</sup> 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. This advancement can be credited in great part to the American Association of Neurological Surgeons (AANS), originally founded in 1931 as the Harvey Cushing Society. The AANS organizes conventions, publishes textbooks and reference manuals, and sponsors research with the aim of furthering advancements in the field of neurosurgery. Numerous technical innovations, including 3-D virtual imaging, noninvasive stereotactic surgery, and advanced surgical tools employing high-frequency energy have given neurosurgeons unprecedented capabilities for effective treatment.

Tools of the type described by Dr. Badie are commonly referred to as bipolar or electro-surgery forceps. The most effective and widely used varieties of electro-surgery forceps use radio-frequency energy to provide a wide variety of functions, from simple cutting with tissue dehydration to complete tissue carbonization.<sup>2</sup> As explained below, these functions require a wide range of temperatures. Choice of proper output intensity and impedance is essential to proper performance of electro-surgical devices.<sup>3</sup>

The common bipolar forceps actually only vaguely resemble “a standard set of tweezers.” Examples of currently employed forceps are shown in Figure 1. 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.

Figure 1



CURRENT BIPOLAR FORCEPS DESIGN  
(SOURCE: ACCURATE SURGICAL & SCIENTIFIC INSTRUMENTS CATALOG)

Research of electro-surgery devices was necessary in order to obtain the specifics described above. This included searches of several Internet sites on neurosurgery as well as the Thomas Register. No electro-surgery forceps featuring a switch or button were found to be in production. Two biotechnology companies, Micro Precision Swiss Company and Special Medical Devices, Inc., were also e-mailed with requests for information about devices of the type desired, but both replied that they had no such

products. Guidance and general information was also obtained from Burke O'Neal in the UW-Madison College of Engineering.

## **DESIGN CONSTRAINTS**

Electrosurgery 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.<sup>4</sup> Heat is actually generated in the tips of the forceps by radio frequencies, rather than a flowing current through the metal. The ideal frequency range for surgical use has been found to be 300-500 kHz.<sup>5</sup> The type of material used in insulation or any other features of the proposed product will have to be of high heat resistance due to the high temperatures involved. Required temperatures range from 100 to 500 degrees Celsius, depending on the nature of the surgery.<sup>6</sup> The device must also be easily cleaned and sterilized. Performance requirements include the ability to withstand daily use for brief applications as well as procedures that may last for several hours. For further design specifications, see the Product Design Specifications (Appendix 1).

Although different techniques may be used, Dr. Badie demonstrated use of the device by using his thumb and middle finger to pinch the sides of the forceps. Observation of the grip used was essential, as the desired device must feature a button or switch that can be accessed easily by a finger of the hand used in surgery. Thus, one of the primary challenges facing the design team is to place the button or switch so that it is easy to access yet remains out of the surgeon's way during surgery. The button cannot be placed in such a manner that it alters the surgeon's grip on the device or presents the danger of accidentally activating the cautery function.

## **FURTHER INFORMATION NEEDED**

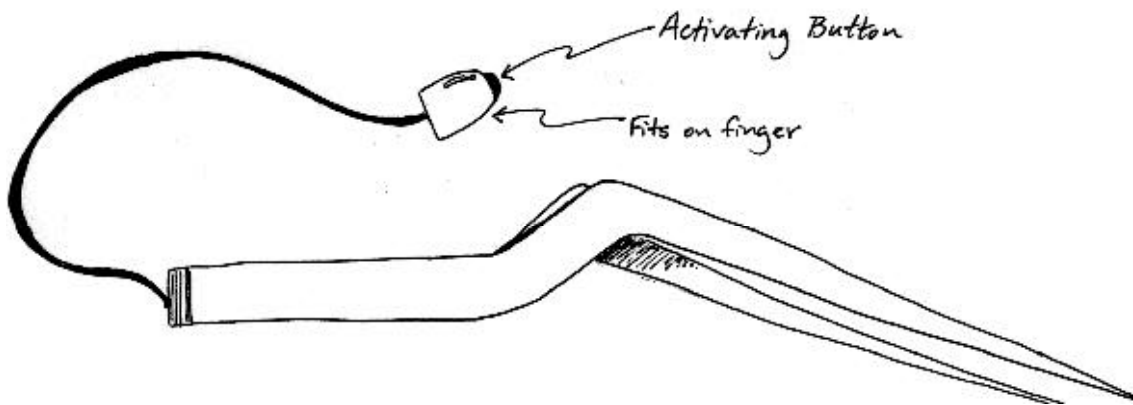
Lack of familiarity with neurosurgical instruments/procedures, radio frequency devices, and general electrical engineering presents a formidable challenge to the design group. Further information and guidance in these areas will be required for the design and implementation of a prototype. Information must also be gathered on the process of obtaining the needed materials for assembling a prototype, which could be complicated by the need for a button or switch of specific size/shape. Also necessary for the process of assembling a prototype is a set of forceps to use as a visual aid. The lack of a real pair of forceps has hindered the team from determining appropriate design and placement of an activating switch. Finally, a clear demonstration of the various grips and techniques used by surgeons is needed before a final design can be realized.

## **ALTERNATIVE SOLUTIONS**

The first solution proposed was also the most unorthodox. Shown in Figure 2, the design involves running a wire from the standard forceps to a small component resembling a thimble that 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 need only press his 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 2

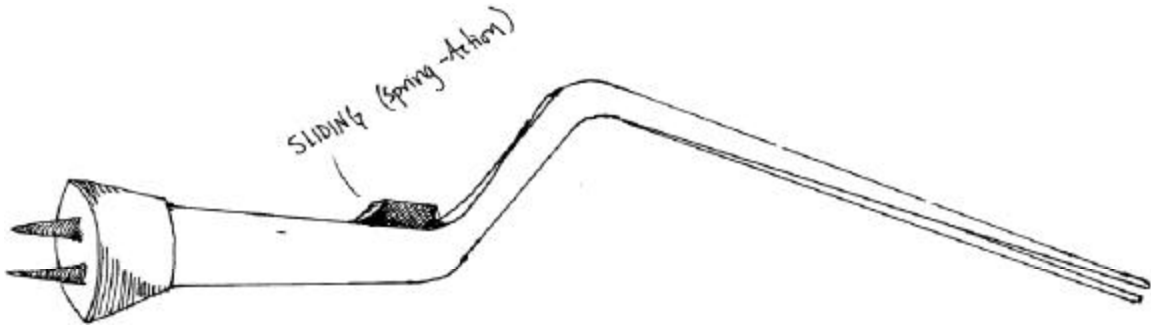


Fingertip Button Design

The portion with the button would have to be designed with a tapered tip 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 3) 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 3

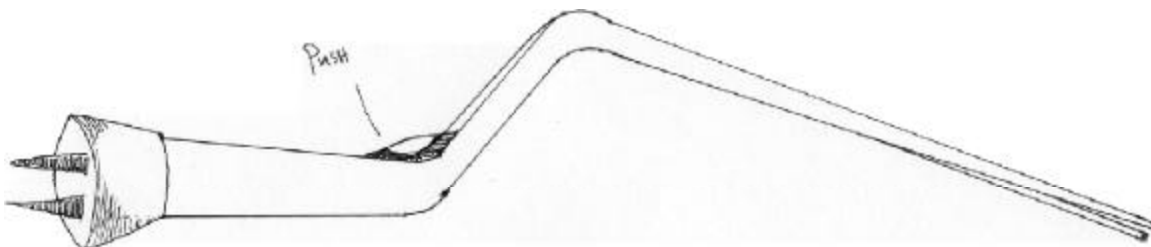


Sliding Button Design

Another important feature of this design idea involves 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 4) incorporates 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. Exact placement of the push button could not be determined without the use of a visual aid (i.e., a pair of real forceps) and more information on various grips employed by surgeons.

Figure 4



Push Button Design

After analyzing all of the designs carefully, potential problems were identified, primarily in the first two design proposals. The first design, with the button placed at the end of a finger, presents an increased risk of having the button accidentally pressed at anytime during surgery. Moreover, a cap placed at the end of the surgeon's finger and attached to a wire would make rapid switching between instruments during surgery more difficult. This fact was only realized upon observation of Dr. Badie during surgery. One potential problem with the sliding button design is the added complexity of a spring-loaded button. The nature of the button would also limit its placement to a position that would accommodate a linear sliding motion. Furthermore, the client has indicated that such a design would require too large of a motion to be convenient. Holding the spring-action switch in place might also put too much muscle strain on the finger, especially in prolonged surgeries.

As illustrated by Figure 5, the push button design was found to offer the greatest number of benefits and the least disadvantages out of the three alternatives considered. The simplicity of the push button design would most likely result in both greater durability and higher likelihood of producing a working prototype. The button could be depressed from multiple angles and with minimal effort. Complications with switching between tools during surgery would also be eliminated, as no part of the design would hinder the surgeon's activity. The risk of accidental activation during surgery remains even with this design, but careful placement of the button will hopefully minimize that danger.

Figure 5-- Table of pros/cons

PROS/CONS						
	Ease of Use	Safety	Simplicity to Design	Accuracy/Reliability	Button Placement	Cost
Fingertip Button	+	--	--	+	+	?
Sliding Button	--	+	--	+	--	?
Push Button	+	+	+	+	+	?

## **FURTHER CONSIDERATIONS**

Other possibilities for refinement of the design include the incorporation of a small magnifying glass at the tip of the forceps to provide better vision for the surgeon. This would have to be of low profile so that it would not obstruct the surgeon's line of view. It has also been suggested that the button could somehow be made adjustable, or that more than one button could be included in the design to accommodate different gripping techniques. Because these further proposals may present too much of a change from the standard design, consideration of them will be postponed until after the final design idea has been chosen.

As stated earlier, further difficulties will most likely arise as a result of the team's lack of training and experience with electrical design issues. Further research and outside aid will be required to deal with such problems. Again, obtainment of a pair of forceps is crucial to the progress of the project. Another primary concern deals with the safety of the device, which will also undoubtedly depend on the quality of information and assistance received in the area of electrical design. Various safety issues with electrosurgical devices of this type include the possibility of RF current leakage, undesired burning of tissues, and improper intensity and impedance settings. Electrosurgical devices have been widely used to this point, however, and most surgeons are comfortable with the general safety of electrosurgical devices and procedures.

## CITED REFERENCES

- <sup>1</sup>Neurosurgery://On-Call. <http://www.neurosurgery.org>.
- <sup>2,3</sup>Hausner, Karl. "Laser vs. Electrosurgery. <http://elmed.com>.
- <sup>4</sup>Accurate Surgical & Scientific Instruments, Inc. 2001 catalog.
- <sup>5</sup>"Application Note: Electrosurgery Analyzer Primer." Bio-Tek Instruments, Inc. 2001.

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