BIOMEDICAL ENGINEERING

Development of force sensing forceps for the prevention of tissue damage during pediatric surgical procedures

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Team

Kelsey Hoegh – Co- Team Leader

Karin Rasmussen – Co- Team Leader

Vinodh Muthiah - Communicator

Stephen Young - BWIG

Tanner Marshall – BSAC

Client

Michael Zinn

Mechanical Engineering

UW Madison, College of Engineering

Advisor

Professor John Webster

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Abstract

There is currently limited available data about the strength of tissue when being grasped with a standard surgical forceps. If the pressure from the forceps on the tissue is too concentrated, it tends to result in micro-capillary damage. This is not immediately visible, but can be seen as scarring when observed later. Because this threshold is difficult to teach, new surgeons have to rely on a trial-and-error type learning method. The design team has developed a surgical forceps equipped with a pressure sensor that tells the surgeon how much pressure is being applied to the tissue. From calibration and testing, the relationship between output voltage of the instrument and force applied was found to be linear. For the present circuitry, the ratio between force and voltage was 1.264 N for every Volt. The forceps will now be used mainly to conduct research on the forces needed to cause damage to tissue, and could later be developed as a training tool for new surgeons.

Motivation

Our client's request to develop a "force sensing forceps" came from the need for new surgeons to quickly learn the thresholds for grasping certain types of tissue. Veteran surgeons have an excellent ability to judge how much force can be put on the tissue with the forceps without damaging the tissue. In most cases, this experience has come through years of practice and trial-and-error style learning. Currently, a new surgeon generally does not have the "feel" for grasping tissues without inadvertently damaging them. It is also extremely difficult to learn by observation which adds even more difficulty to the task. The surgeon has to practice on pigs, cadavers, etc. before they learn the range of forces to apply to tissue. There is essentially no quantitative data about the forces that can be looked up for reference. Therefore, our client would also like us to find out the exact range of forces that are commonly applied to tissue. Eventually, the tool that will have some sort of sensing unit built in. It will mainly be used as a training tool to quickly teach surgeons the limits for grasping tissue with different types of forceps. The mechanism that alerts the surgeon will either be auditory or visual. The requirement is that it should not interfere significantly with the surgeon's concentration. It could be dangerous if the surgeon has to avert their concentration to see the value of the force they are applying.

Client Specifications

The client, Dr. Michael Zinn, has asked the team to produce a “force sensing forceps.” The design will be used as a training and research device to determine the amount of clamping force surgeons apply to tissues while using a surgical forceps. Although there are a variety of surgical forceps types, the client has asked that a single initial prototype be developed which will integrate with the design of a standard forceps with a textured straight surface at the tips. The design must allow for proper holding technique, and it should be lightweight to avoid distorting the normal balance and “feel” of the forceps. Also, the design should not occupy “working area” on the forceps – the textured tip used to grab the tissue, and the textured grip areas shown in Figure 1. The forceps must measure the clamping forces applied to tissue and provide convenient output to indicate this measured force. The output must be digital so that it can be recorded and analyzed. The device will be used in surgical procedures, thus, the device must be able to be sterilized by either autoclaving (heat sterilization) or by gas sterilization techniques.

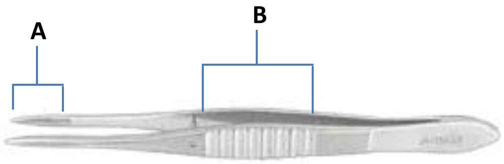

Figure 1. Generic Forceps with textured tip (A) and textured grip (B) areas shown - Claflin Medical Equipment.

The previously mentioned specifications are requirements for the device, but the client also requested some preferences to be treated as secondary areas of focus to incorporate into the design if possible. The client would like the design to be aesthetically pleasing, provide auditory warnings, have wireless capabilities, and provide both axial (clamping and pulling) and torsional (twisting of tissue) force measurements.

Current Devices

Although the technology to measure forces on tissue exists, no force sensing surgical instruments have been designed for use in clinical settings because of the drastic changes made to the instruments [1].

Piezoresistive Technology

One current device used with surgical tools to sense force is piezoresistive thick-film technology. Although this technology is efficient in the sense that it is inexpensive and effective at measuring pressure, the firing of the thick film wears down the components of metals that are used in surgical instruments. Researchers attempted to develop a low-firing thick film technology that would be compatible with the metals, but were unable to fully do so [2]. Future research must be conducted to determine whether this will be a superior, viable option.

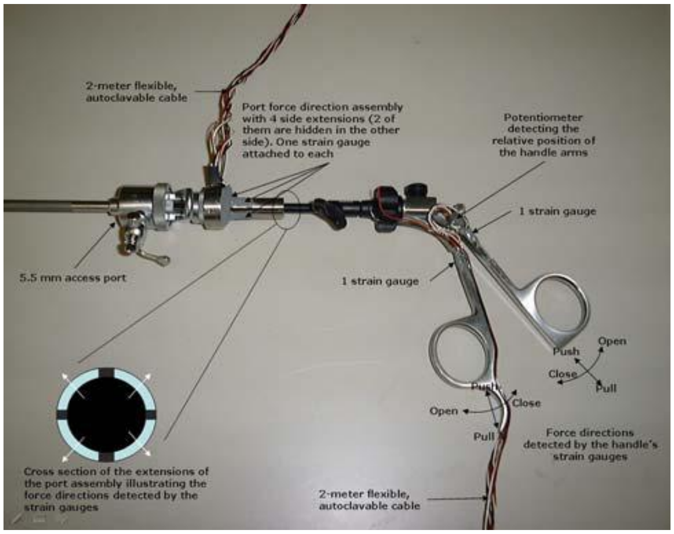

Figure 2. Strain gages and digital converters placed on forceps [1].

Strain Gages

Strain gages, considered to be very accurate in measuring forces, are also used with surgical instruments. In a design by Ana Luisa Trejos, et. al. [3], two strain gages were attached near the ends of instruments (where forces on tissue can best be measured) using polyurethane coating. Amplifiers were then attached to the gages and a computer for digital output. The researchers also calibrated their device by measuring the different voltages when different weights were placed on the ends of the instruments. In this case, the design is specific to research which focuses on finding the magnitude of forces necessary to conduct natural orifice transluminal endoscopic surgery [3]. Another research team created a similar force-sensing device; two strain gages were placed at the ends of forceps, analog to digital converters were incorporated in the design, and the same calibration technique was used (see Figure 2). However, the type of forceps used in the design are non-locking forceps that hinge in the middle, which are not the type of forceps specified by the client [1].

Design Options

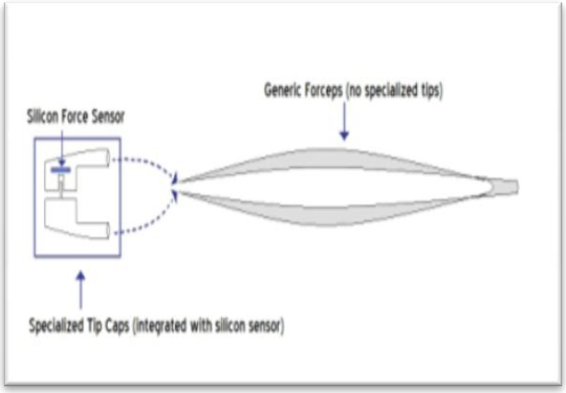

Figure 3. General schematic of the silicon force sensing caps design.

Silicon Macro Force Sensing Caps

The first design option is the silicon macro force sensing caps design. This uses a technology developed by a research group in France which uses changes in capacitance of thin silicon disks to measure force [4]. The sensors are very small – with a volume 3.5 x 0.7 x 10 mm, which would allow them to be directly integrated into caps formed in the varying shapes of different surgical forceps. The caps would be put onto the ends of a generic forceps as seen in Figure 3. This design would theoretically increase the accuracy of the force measurement, as the data are being taken directly from the spot where the force is going to be applied. Unfortunately, the silicon sensors are extremely temperature sensitive and the capacitance measurements taken could be difficult to convert into accurate force readings when temperature conditions are changing. The silicon force sensors have a sensitivity to distinguish different force measurements around 0.1 N, and a range of force measuring capability of approximately 2 N. At this point the design team has not determined what general range of forces could be expected to be seen, so it is unknown if this range will be sufficient to satisfy the needs of the project. The cap design would also greatly complicate the manufacturing process for the design as differently shaped ends would need to be produced for each type of surgical forceps tips.

Strain Gage

Strain gages have been used for years in converting mechanical motion into electronic signal [5]. They depend on the proportional variance of electrical resistance to strain. Most strain gages are made up of very fine wire or foil organized into a grid like pattern as seen in Figure 4. It is arranged to reduce the effect of the shear strain and Poisson strain – the strain perpendicular to the force.

There are possible reading output errors to consider when using strain gages. Since the force being measured is relatively small and in an operating room there is a lot of ambient noise, the electrical noise and interference may alter the output from the strain gages. Also, changes in temperature affects gage resistance and needs to be considered when using the gages at even slightly different temperatures. In order to insure accuracy when reading very small changes in resistance, it is important that the design takes into account how it will be mounted onto the forceps, how many strain gages to use, and the placement of the gages.

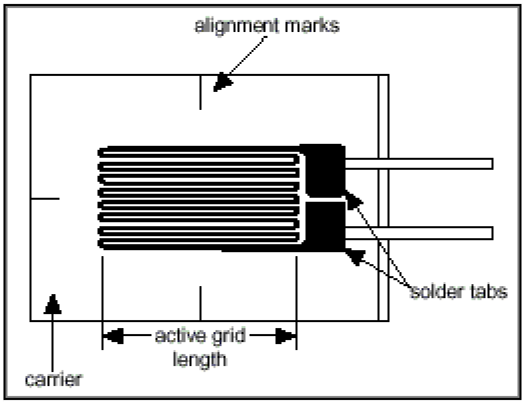

Figure 3. Standard strain gage set up. Active grid length would be parallel with forceps. [5]

By using a full-bridge circuit configuration, as seen in Figure 5, it is possible to eliminate temperature effects. Although the cost is significantly increased due to the fact we would be using twice as many strain gages, the forceps would become much more sensitive, and the measurement would respond more quickly and be more precise. This works because using the full-bridge configuration, the changes in temperature affects all of the gages equally. Therefore, their relative resistance to each other does not change, which means the output voltage would not change.

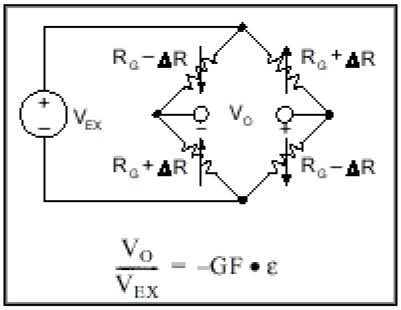

Figure 5. Full-bridge ciruit configuration to be used on forceps. [5]

The pros for using strain gages include that it is temperature resistant, we can choose the range and accuracy we want after doing initial tests with our client, and it is easy to manufacture and costs are relatively low. Also, it does not disrupt the forceps normal usage in that it is light-weight. However, using the extra strain gages to cancel out ambient noise and temperature changes creates four wires. Ideally, we will run the wires down the side of the forceps out of the surgeon's way. Even with careful installation, the Wheatstone bridge, full-bridge circuit would not be balanced. In order to counter the offset, we will need to measure the initial unstrained output of the circuit and compensate in software.

Piezoelectric Sensor

The third design option for sensing forces on the forceps is to use a piezoelectric sensor. A piezoelectric sensor relies on the piezoelectric effect of a material to measure the strain of a beam - the forceps in this case. A piezoelectric substance is one that will produce an electrical charge when some sort of mechanical stress is applied to it. This phenomenon is also reversible, if an electric stimulus is applied to the material, it will bend in response. This is a desirable effect because if the team uses this type of material, and connects wires to the upper and lower sides, the charge that is given off can then be measured. This can then be amplified and calibrated to relate a certain amount of force that's being applied to produce the corresponding strain. The transducer for these types of sensors can often be very small. Some are on the order of 30 times smaller than an equivalent strain gage transducer. This would be an advantage with the limited amount of real estate presented on the forceps. Also, since there would only be one sensor placed on the forceps, there would only be a need for 2 wires, as opposed to many of the strain gage setups that require 4 or more wires. Overall, the piezoelectric sensor provides very desirable space saving properties that allows for work on very small instruments. However, with the piezoelectric material comes significant drift. This drift value is often as much as 1 N/min, meaning that a measurement must be restricted to just a few minutes. In addition, as is a common concern with force sensors, the ability of the piezoelectric sensor to remain accurate in changing temperatures is low. The piezoelectric sensor has had minimal success with temperature compensation [6].

Design Matrix

A decision matrix was used evaluate the three design options (Table 1). The categories used to evaluate the alternatives were determined from the client's specifications (see Appendix). The categories chosen to evaluate the designs were: Ability to allow standard forceps usage, range of measuring capability, allows proper holding technique, precision of measuring capability, ease of manufacture, and measurement consistency.

Each category was first ranked by importance to the team's client. The most important aspect of the design, receiving 30 out of the 100 possible points, is its ability to allow standard forceps usage; taking into account ergonomics, this category ensures that the design will not detract from the function of standard surgical forceps. The next three categories were each weighted with 20 points. The range of force measuring capability, precision of measuring capability, and measurement consistency with varying conditions all take into account the accuracy and reliability aspect of the possible designs. The next category, allows proper holding technique, takes into account the safety and ergonomics of the design. It has a ranking of 10. The team wanted to make sure that surgeons would still be able to grasp and use the forceps as they normally would. Last, the team took considered ease of manufacturing. The easier the design is to manufacture, the cheaper it would be, increasing the likeness that surgeons would use this product on a day-to-day basis.

The Strain Gage Design accumulated the most points with a total of 92. The Strain Gages achieved relatively high scores in every category. Piezoelectric Sensors came in a close second with 84 points. The "Cap Design" accumulated only 78 points – clearly the weakest design option. This is mostly due to the high temperature sensitivity of the silicon force sensors and the difficulty in manufacturing this design. The main difference between strain gages and piezoelectric sensors was the precision of measuring capability and measurement consistency. Piezoelectric sensors vary more in temperature and cannot measure the steady state pressure. However, the sensors will continue to be considered along with further investigation of the strain gages.

	Weighting	Design #1 – Capped Ends silicon macro force sensor	Design #2 – Strain Gages	Design #3 – Piezo electric
Does not detract from function of standard surgical forceps	25	22	23	24
Range of force measuring capability	20	15	19	19
Does not obstruct proper forceps holding technique	10	10	10	10
Precision of measuring capability	20	15	18	16
Ease of manufacture	5	1	3	4
Measurement consistency with varying conditions	20	15	19	12
Total	100	78	92	84

Table 1. Decision matrix for measurement system. The winner is design #2 – The strain gage design scored considerably better than the other two.

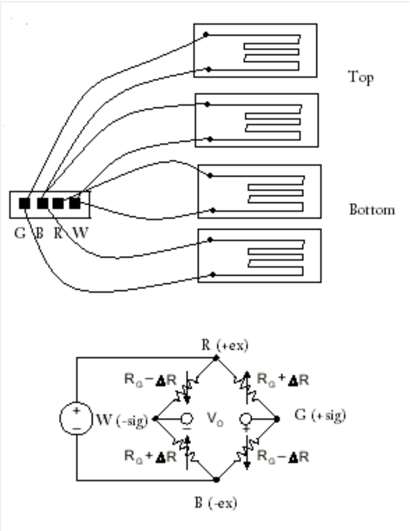

Figure 6. Schematic of the dual strain gage set-up. (G = green, B = black, R = red, W = white)

Final Design

The final design incorporates a full-bridge circuit configuration, a USB amplifier, and LabVIEW programing. Two strain gage rosettes (EA-06-125PC-350), which cost $55.00 a piece, were installed onto the forceps using an adhesive. The four wires from the strain gages are connected to a USB amplifier (Figure 6). The USB amplifier is formatted for bridge sensor readout. It has a 5V supply and a ground for the sensor drive. Also, the gain and bandwidth is settable using plug-in resistors and capacitor. Figure 7 shows the circuitry for the USB bridge amplifier. The original design, used as an ECG pressure sensor, was A/C coupled and unable to retain a steady DC output. To correct this, the capacitor (denoted: C6 in the diagram below) was short circuited, allowing for a steady voltage output without decay.

The voltage to force ratio is .9758 (R^2 for least squares regression = 0.9995, see testing section for more detail on acquisition of these numbers). The voltage readout is automatically converted to force using LabView programming. The forceps have little to no cross-talk and drift.

The total cost of the forceps prototype was $235.90. This money covers the strain gages, wire, adhesive, and labor.

Testing

The final design was put through a variety of tests to ensure the accuracy and reliability of the measurements it will take. First a calibration test was done, then a test to determine the importance of specific area of directed force to the accuracy of the measurement, 3 tests to determine the effects of drift, and lastly a test to determine if crosstalk would be a significant factor in the measured forces.

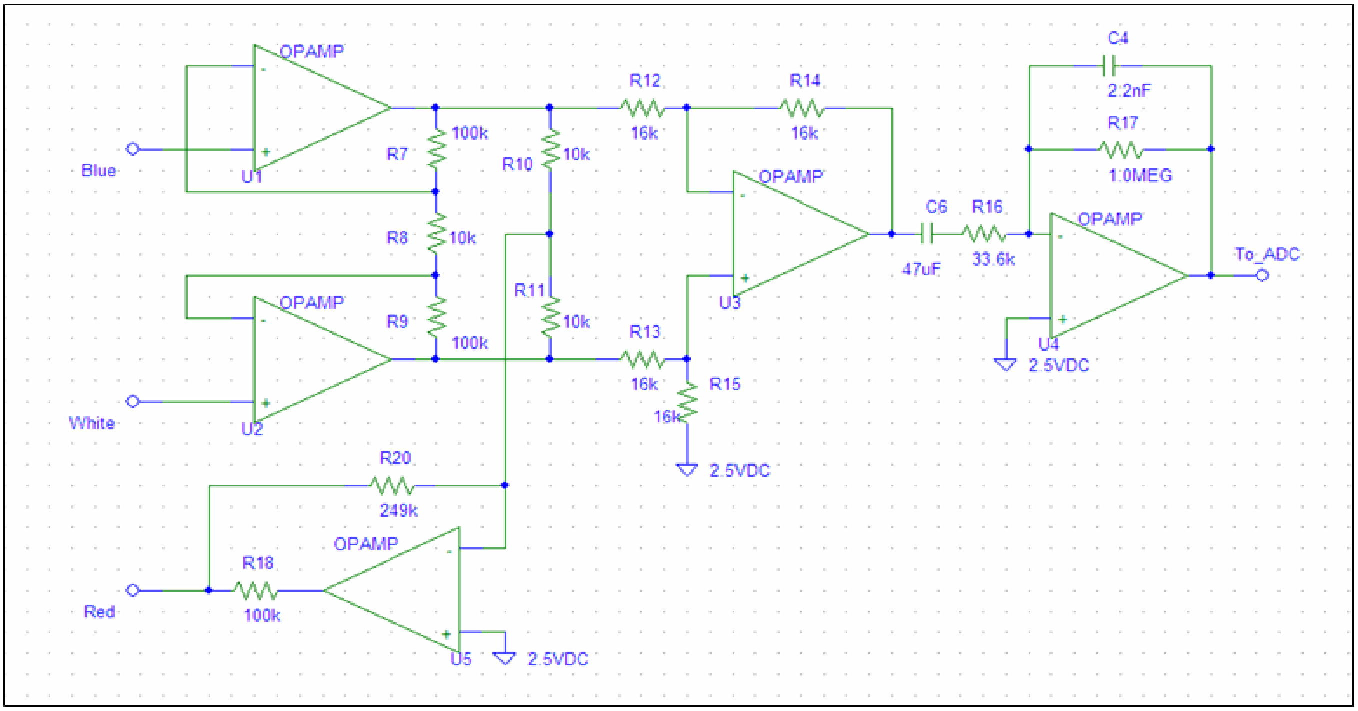

Figure 7. Circuit set up for the USB bridge amplifier. The R17 resistor is 22 kΩ, the R16 resistor is 1.5 MΩ. The C6 capacitor is short circuited [7].

Calibration Test

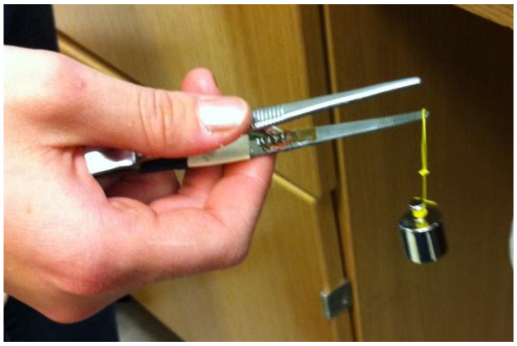

Figure 8. Weights were hung from the forceps in the calibration test and when determining the importance of position of force to accuracy of measurement

In order to calibrate the forceps the team had one member hold the forceps (in a specified position intended to mimic the positioning used by surgeons) while weights were hung from the tip of the forceps (as seen in Figure 8). The voltage reading for each weight was recorded and a nearly perfectly linear correlation (R^2 for least squares regression = 0.9995) was seen between the force and voltage reading (Figure 9).

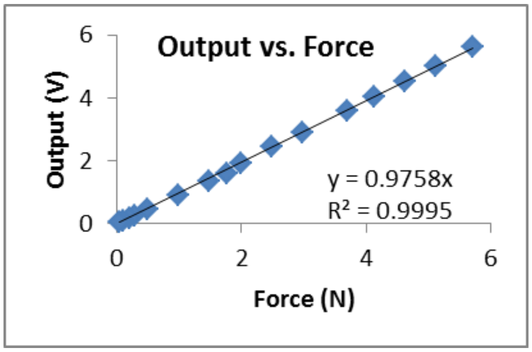

Figure 9. Correlation testing force vs. output and least squares regression line

As an extension of the calibration test the team wanted to determine if the specific area of directed force would significantly change the output given. In order to accomplish this a single weight was used and hung from the tip (the same spot as used for the original calibration test as seen in Figure 9), the middle of the serrated tip section of the forceps, and the widest end of the serrated tip section of the forceps. The voltage readings from this test can be seen in Figure 10. For a single force value the voltage reading varied from 2.1 V to 1.25 V – this is a significant range, and a problem that could be addressed in the future. Although, the range can be dismissed at this point in time because the surgeon will almost exclusively grip tissues with the very tip of the forceps, from which the calibration constant has been derived.

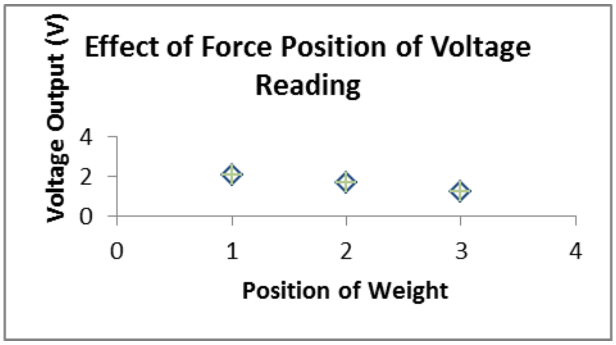

Figure 10. The effect of force position of voltage reading. This test was performed using a single weight.

Drift Tests

Drift tests were performed to see if the voltage reading when zero force was applied to the forceps would change over time. The first drift test was done while the forceps sat on a counter top (results from this test can be seen in Figure 10). There was no change in the zero voltage during the entire course of this test. Since the main cause of drift would be change in temperature, two more tests were performed: one where the forceps was held in a bare hand and another where the forceps was held in a hand covered with a rubber glove (again to simulate the environment in which the forceps would actually be used). Although more variation was seen in each of these tests (Figure 10) than in the original drift test, the variation was not in any clear pattern, nor was it significant enough to be problematic for the accuracy of force calculation for the final product.

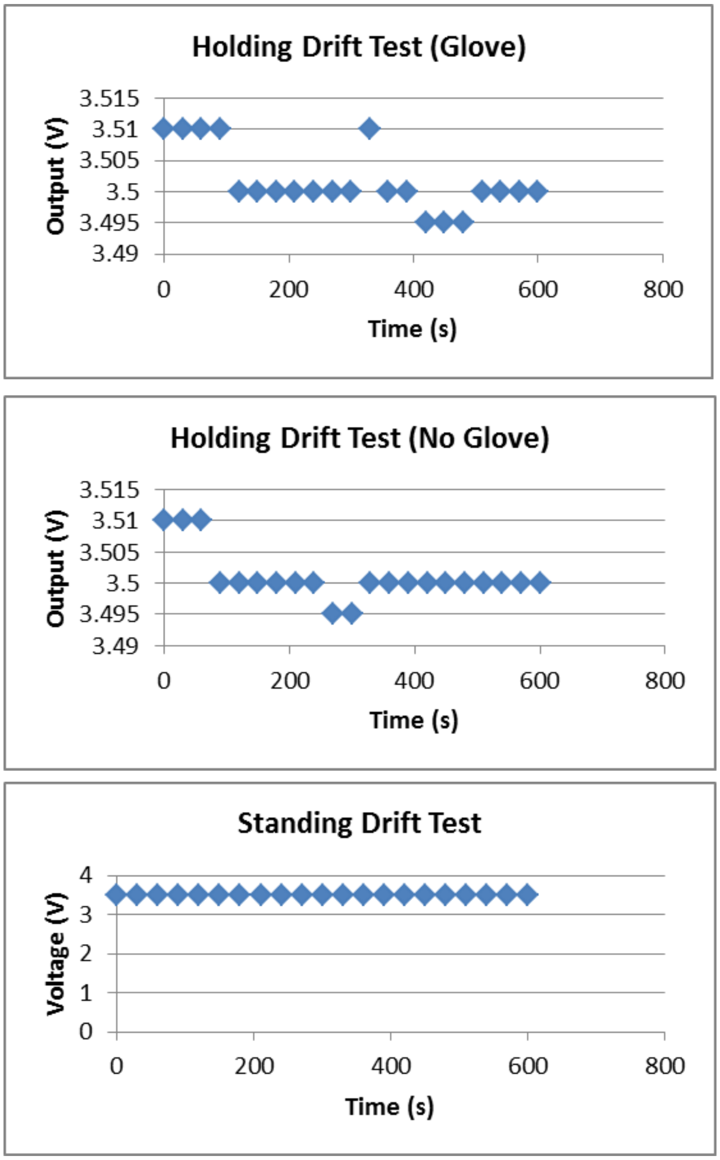

Figure 11. Drift testing data: with forceps sitting on counter (bottom), with forceps held in bare hand (middle), and with forceps held in hand covered in plastic glove.

Cross Talk Test

The final test that was performed on the forceps was to determine if crosstalk forces (those from pushing/pulling rather than gripping forces) would be picked up from the current strain gage sensors. This test was done by applying force in directions and looking to see if the voltage changed. It was found that these forces only cause minute changes in voltage compared to the force applied and will not be problematic. The force readings gained from the device should be accurate for gathering data on pure gripping forces.

Future Work

Although our final design fulfills many of the specifications laid out by our client, there are still a number of additions and improvements to be made on the prototype. The current design still relies on wires running from the forceps to a computer to relay information. It would be beneficial to replace the wires with a wireless system to increase the user's range of motion.

Another change that must be made is how the data output is displayed. The final design displays output through a computer, but it is not convenient to have a computer in all the environments the forceps could be used in. A user-friendly, easy to read, digital display should be designed to make the system more versatile.

In addition, there are several improvements that need to be made to the design of the forceps as well. One problem is that the manner in which the wires are attached to the forceps covers a portion of the grips on the forceps. In order for the forceps to be used properly and with a high degree of control, these grips must be completely available to the surgeon. A more efficient manner of keeping any necessary wires on the forceps attached and in place must be devised, such as adhering them to the underside of the forceps until they are clear of the length of the forceps that the grips cover.

Aside from the fact that the current design covers necessary components of the forceps, the design also has a rough, unfinished look to it. Now that the forceps are operational, the design can be refined and streamlined to make it more professional looking and more aesthetically pleasing.

Although the final design successfully displays an output in terms of force being applied, it does not alert the user of when excessive force is being applied without forcing the user to look at the computer display. Some type of audio or visual signal that allows users to recognize when they are applying too much force should be added to the forceps system. This could be an audio signal consisting of either alert noise that sounds when a certain force threshold is broken or a tone that varies over different force ranges. There could also be a small light that would be placed on the forceps itself. Alternatively, an actual mechanism that prevents excessive levels of force from being applied could be implemented to the design.

The final design will work in a research setting. However, in order for it to be implemented as a surgical instrument, the design must be made more robust so that it can handle sterilization techniques used on surgical instruments. No testing has been done on how the forceps handle sterilization techniques, so testing must first be done to identify where improvements will be required on the design. Any necessary changes must be made so that the forceps can be used in actual surgical procedures.

Since surgical forceps come in a large number of sizes and designs, testing will need to be done in order to investigate whether modifications must be made to the design when applying it to different types of forceps. Although no important changes are immediately apparent, it will be important to verify that the design works with a variety of forceps designs through testing.

Finally, although the client's primary interest is in the gripping force applied at the tips of the forceps, they would like to see the design expanded so that it can also separate and measure axial and torsional forces. This will require the sensor setup to be modified. Measuring axial and torsional forces could be difficult to accomplish due to the number of sensors that would be required as well as the amount of space available on the forceps for placing sensors.

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Appendix

Project Design Specifications

Problem Statement: Our objective is to design a training and research device that will interface with a standard surgical forceps. It must measure and provide quantifiable, electrical output of clamping forces applied to tissue, without obstructing proper forceps holding technique.

Client requirements:

- Provide quantifiable electrical output of measurements
- Measure clamping forces while avoiding crosstalk
- Permits proper forceps holding technique

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*
    i. Audio or visual output
    ii. Repetitive long term use
b. *Safety*:
    i. Must be able to be sanitized by standard, FDA approved procedures
    ii. Cannot obstruct surgeon's grip
    iii. Disallowance of excessive force
c. *Accuracy and Reliability*
    i. Measurements must remain accurate and account for changing conditions
        - Temperature
        - Crosstalk
    ii. Able to be calibrated
d. *Life in Service*
e. *Shelf Life*
f. *Operating Environment*
    i. Used by surgeons
    ii. Used during surgical procedures
    iii. Exposed to bodily fluids
g. *Ergonomics*
    i. Maintain balance of forceps
    ii. Cannot interfere with grip or tips of forceps
h. *Size*
    i. Compatible with a standard size of surgical forceps
i. *Weight*
    i. Cannot significantly affect feel/balance of the forceps
j. *Materials*
    i. Compatible with stainless steel forceps

k. *Aesthetics, Appearance, and Finish*
    i. Generally aesthetically pleasing

2. Production Characteristics

a. Quantity
    i. Production of one initial working prototype
b. Target Product Cost
    i. Less than $1000

3. Miscellaneous

a. *Standards and Specifications*
    i. Must meet medical device requirements
b. *Customer*: specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.
    i. *Preferences*:
        - Wireless
        - Digital display
        - Use of underside of forceps for sensor attachment
        - Axial and torsional measurements
c. *Patient-related concerns*
    i. Ripping of the tissue to be avoided
d. *Competition*
    i. Laparoscopic force measuring tool