BIOMEDICAL ENGINEERING

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

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Abstract

Very little is known about the forces applied to tissue with forceps during surgery. Too much force can result in tissue damage, but new surgical interns are expected to learn by trial and error what this limiting force value is. Thus, a tool that will quantitatively measure the forces applied to tissue and provide convenient output to the surgeon is needed. It would be used as a training and research device. The design team constructed three design options to address this problem. The first design option utilized a silicon macro-force sensor developed by a research team in France integrated with caps for the forceps tips. The second design option would use a piezo-electric sensor to measure the bending strain of the forceps. The third, and final design, uses 4 strain gages arranged to maximize sensitivity to bending and eliminate interference from temperature and other forces. After evaluating these designs with a design matrix it was determined that the strain gauge design would best satisfy the client's requirements. There are still many steps to be taken in order to complete this design, including wireless capabilities and developing a calibration technique.

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 destroying the tissue. In most cases, this experience has come through years of practice and a 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.

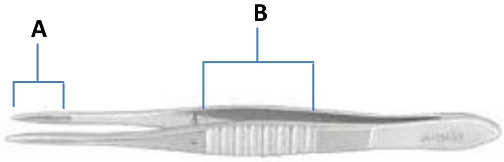

Figure 1. Generic Forceps with textured tip (A) and textured grip (B) areas shown - Claflin Medical Equipment.

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.

Strain Gages

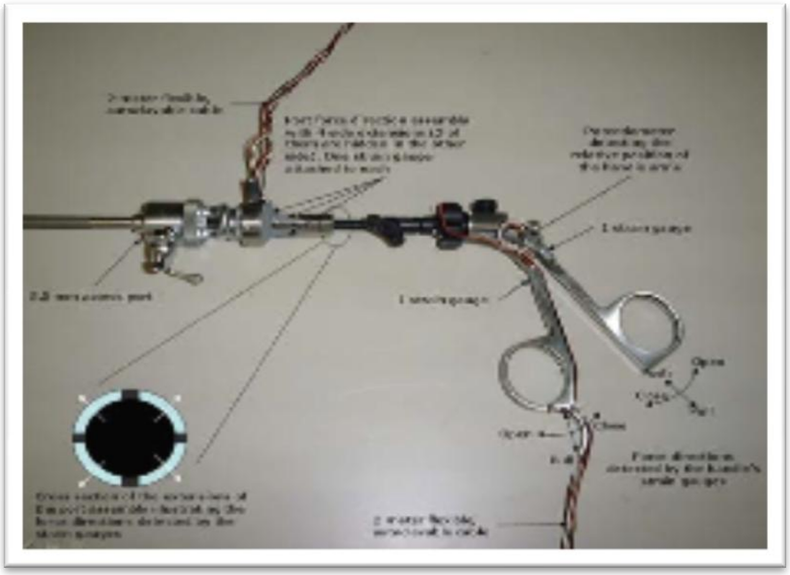

Figure 2. Strain gages and digital converters placed on forceps

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., 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

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^3, 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 is 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 0.1N, 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.

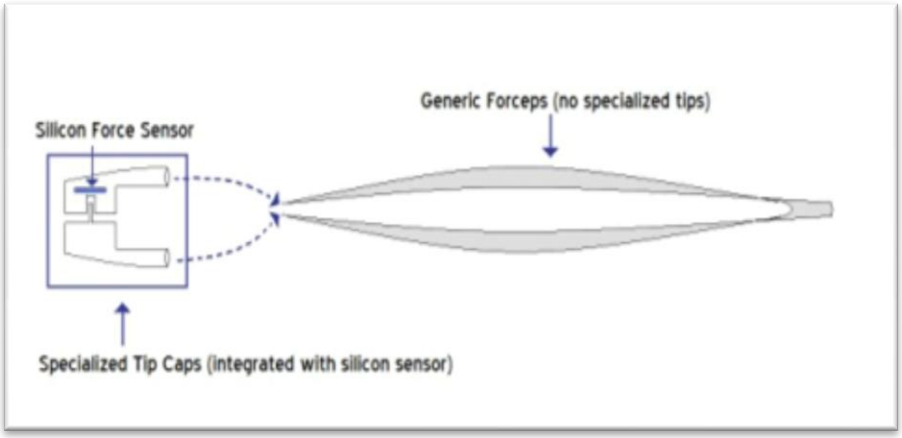

Figure 3. General schematic of the silicon force sensing caps design.

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 very fine wire organized into a grid like pattern as seen in Figure 4. It is arranged like so 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.

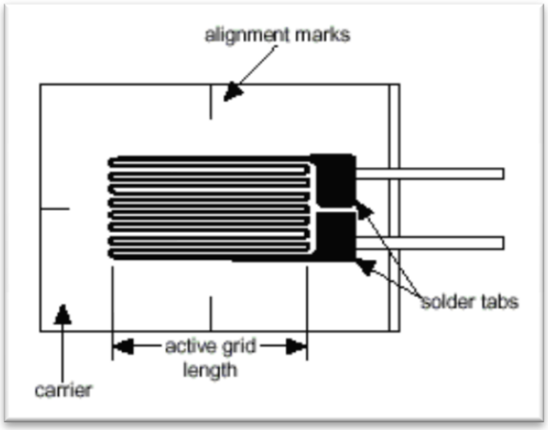

Figure 4. Standard strain gage set up. Active grid length would be parallel with forceps.

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.

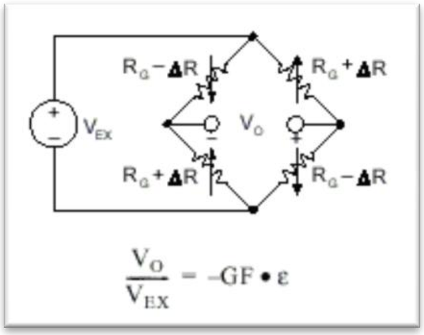

Figure 5. Full-bridge ciruit configuration to be used on forceps.

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 relatively low costing. 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 – Strain gages beating the piezoelectric sensors by 8 points.

Future Work

The future work of this project begins with selecting the specific components needed for the final design. Little quantitative data is known in terms of the forces the forceps will apply to tissue. Thus, surgeons that are familiar with the types of loads that are typically applied during surgeries will need to be consulted. The minimum and maximum loads that can be expected to be applied to tissue can be determined through demonstrations performed by the surgeon. Having an idea of these parameters will allow for selection of specific design components (i.e. type of strain gage). A signal conditioning system will then have to be assembled. Components of particular interest here are an appropriate source of strain gage excitation, such as a battery or an amplifier. Since the raw output of strain gages is very small, it is important that a suitable amplifier is selected to amplify the signal so as to improve measurement resolution and the signal-to-noise ratio.

Once the core elements of the design have been selected, a rough version of the forceps will be built. These forceps will be used to test measurement accuracy under varying conditions in an attempt to determine possible sources of error in measurements. Particular areas of concern are how the signal changes with increases in temperature and how the signal varies if operators hold the forceps at varying locations. After this testing is done and other problems have been addressed, the next step will be to develop a calibration technique, such as a calibration curve, so that signal from the strain gages can be equated with actual force values.

The last two steps in designing the forceps will be to implement a wireless system and create some sort of alternative feedback for the surgeon. A wireless system that will relay data from the forceps to a computer may be implemented into the design so that surgeons will not be tethered down or have to worry about long cords during use of the forceps. The alternative feedback must be some sort of feedback supplied to the surgeon other than numerical force readout on a computer screen, such as some sort of audio/visual feedback. A current idea being considered by the team is using a varying pitch or tone to alert the surgeon. This will enable the user of the forceps to get an idea of how much force they are applying and when they are approaching dangerous levels of force without averting their attention from what they are doing.

Although the client is currently only asking for a set of forceps that can measure the squeezing force of the forceps’ teeth, he would like to see future improvements on the design that will allow the forceps to measure force in multiple dimensions. Additional forces he would like to see measured are axial forces as well as torsional forces applied by the forceps. This will require a more complicated sensor setup than the one being used in the final design for this project. The client has also asked us to determine if the forceps can be used for the cauterization technique which requires running electric current down the forceps without compromising the electrical components of the forceps. Although the client is currently only interested in whether or not the forceps are compatible with this technique, it would be beneficial to make future improvements if the forceps are not compatible so that they become safe to use for cauterization.

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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