



A Modular 2-DOF Force-Sensing Instrument for Laparoscopic Surgery



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ABSTRACT

Minimally Invasive Surgery (MIS) has enjoyed increasing attention and development over the last two decades. As MIS systems evolve, the surgeon is increasingly insulated from patient contact, creating a trade-off between surgical sensory information and patient invasiveness. Incorporation of haptic feedback into MIS systems promises to restore sensory information surrendered in favor of minimal invasiveness. We have developed a novel, biocompatible 2-DOF force-sensing sleeve that can be used modularly with a variety of 5mm laparoscopic instruments. The functional requirements for such a device are defined, and design strategies are explored. Finally, our formal device design is outlined and device calibration is performed and presented graphically with derived calibration functions. Illustrative experimental force data from a porcine model is presented. This device opens the door to intra-abdominal force recording in laparoscopic environments, and the implications and future potential for this technology are explored.

OBJECTIVE

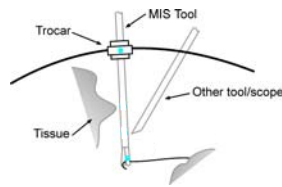
Develop a modular, biocompatible force sensing sleeve to be used for measuring forces applied to organs during laparoscopic retraction.

The device is to be ready for human use and must operate under the normal range of force inputs during laparoscopic retraction.

DESIGN

Requirements:

- Modularity:** The force-sensing sleeve to fits concentrically over an existing device shaft and ensures compliance with any 5mm stainless steel laparoscopic device.
- Biocompatibility:** The device is constructed with Surgical Stainless Steel grade 304 and Teflon®. Interfaces are sealed with Biocompatible USP Class-VI epoxy. All components are Ethylene Oxide gas sterilizable
- Provision for monitoring bending loads:** Because the forces commonly applied during laparoscopic surgery (0-10 N) create bending in the instrument shaft, we used strain gages to evaluate surface strain and serve as force sensors.
- Depth and Rotation Insensitivity:** It is necessary to measure strain in the two dimensions orthogonal to the long axis of the instrument. A full-bridge of 4 strain gages is dedicated to each of the orthogonal dimensions.
- Intra-abdominal force measurement:** We need to apply the strain gages to the shaft at a point that will lie inside the abdominal wall during most laparoscopic procedures. The distal shaft much smaller in cross-sectional area than the proximal shaft; this isolates the distal shaft so that it approximates a cantilevered beam, and maximizes the telescopic workspace of the device.



SIGNIFICANCE

This device enables us to:

- Apply sensory substitution to aid the clinician
- Quantify "normal" surgical forces and use this information for training and evaluation
- Set force limits to increase safety of robotic retraction

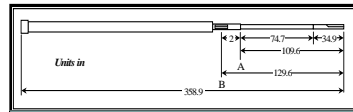


Figure 1 - Assembled device dimensions

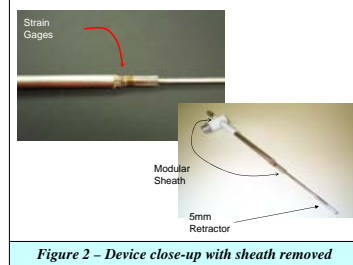


Figure 2 - Device close-up with sheath removed

DEVICE CALIBRATION

Figure 4 shows the relationship between load on the retractor vs. the DAC voltage. These plots were created independently for both axes.

We model the calibration curves as piece-wise linear relationships. The plot shows the results of the calibration and the division into three individual linear segments.

The transitions between the segments can be explained by evaluating the mechanical behavior of the device. Due to manufacturing tolerances, we propose that there are regions of contact between the retractor shaft and the force sensing sleeve described as: "pre-contact", "mid-contact", and "full-contact."

The data conforms very well to the three-zone model with each linear segment, achieving a mean R² value of 0.9991.

In order to assess device accuracy using these calibration functions, we apply random loads to each channel and measure accuracy. The results are presented in Figure 5.

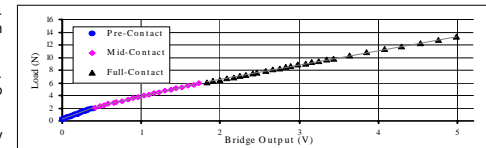


Figure 4 - Sample calibration curve and the three-condition interpolation

Axis		Error	
		Average	St. Dev
x	Negative	7.22%	4.9%
	Positive	2.63%	2.90%
y	Negative	2.67%	3.7%
	Positive	4.78%	5.18%

Figure 5 - Device accuracy

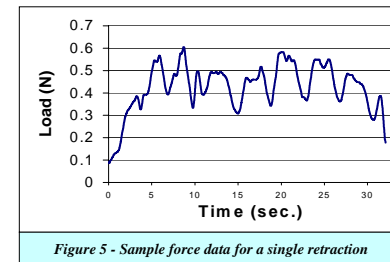


Figure 5 - Sample force data for a single retraction

DEVICE APPLICATION

To confirm proper operation and collect a sample data set, we recorded the output of the device during retraction of the liver in an *in vivo* porcine model. Two motions are presented: Figure 6 shows a continuous retraction and Figure 7 shows a repetitive retraction motion.

A primary goal of the device, as applied to freehand laparoscopic tools, is to allow sensory substitution to compensate for lost tactile sensation. We opted to couple our force-sensing device to an audio-feedback apparatus so that we could deliver sensory substitution easily and uniformly. We tested two methods of displaying the magnitude of the force: amplitude modulation and frequency modulation. Preliminary observations were that frequency modulation was easier for users to interpret.

Visual overlay of forces is another possible form of sensory substitution that may be implemented to allow surgeons to "see" how much force is applied.

FUTURE WORK

This device is a first-generation force-sensing instrument. To achieve widespread clinical utility, future generations would have to demonstrate greater sophistication including the following enhancements:

- Point-Load Insensitivity
- Axial-Load and Torsion Measurement Provision
- Complete and Uniform Moment and Load Transfer
- Incorporation of smaller silicon strain gages
- Embedded Sensors and leads

In addition, this device can readily be used in the development of surgical feedback and control models. We can also experiment with simultaneous collection of force and physiological information so that we can correlate force application with tissue response. Another application would be the use force information as a metric of surgical skill and develop learning curve models using this data.

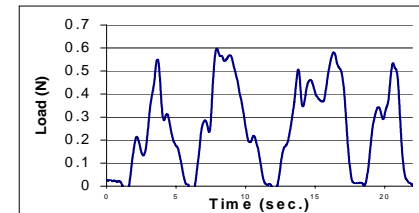
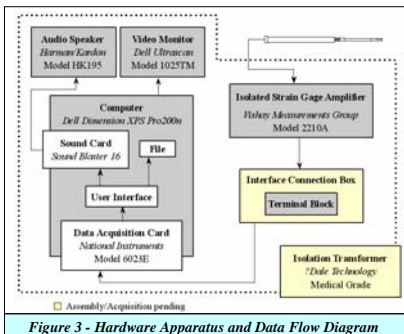


Figure 6 - Sample force data for repeated retractions



Implementation:

We adopted a reusable U.S. Surgical 5mm laparoscopic retractor as the predicate device and developed a compatible force-sensing sleeve.

Based on the device dimensions presented in Figure 1, we designed and developed a force-sensing sleeve using Grade 304 Stainless Steel that approximates a homogenous, solid shaft. The sleeve was designed to slip concentrically over the two-component shaft of the U.S. Surgical device. Figure 2 shows an image of the actual device with the distal section of the Teflon® sheath removed.

The strain gages have been sealed with silicon coating, all leads are Teflon coated and sealed with silicon, and the stainless steel shaft is fully encased in a Teflon sleeve. The remaining joints are sealed with biocompatible USP Class VI compliant epoxy.