

Ischemia and Force Sensing Surgical Instruments for Augmenting Available Surgeon Information

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Abstract—Gaining access to a surgical site via retracting neighboring tissue can result in complications due to occlusion of the tissue blood supply resulting in ischemic damage. By incorporating oxygenation sensors on the working surfaces of surgical retractors and graspers, it is possible to measure the local tissue oxygen saturation and look for trends in real-time. Further, by measuring tissue interaction forces simultaneously, we can further augment the information available to the surgeon. The sensors provide a means for sensory substitution to help compensate for the decreased sensation present in minimally invasive laparoscopic and robotic procedures that are gaining significant popularity. Sensing surgical instruments will allow for safer and more effective surgeries while not interfering with the normal workflow of a procedure.

I. INTRODUCTION

During general open, laparoscopic and robotically-assisted surgery, a clear operative field and real-time monitoring of the target anatomy are essential. Surgical instruments, such as retractors and graspers, are often used to retract and manipulate surrounding tissues and organs, moving them away from the active site. Histological evidence shows that excessive forces on tissues applied through these instruments may obstruct the blood supply and lead to localized necrosis. Fig. 1 shows an example of retraction-induced ischemic damage in porcine liver. Currently, surgeons rely on little more than visual cues to determine the health of these retracted tissues, which may be pulled or pushed aside for several hours at a time [1]. The primary goal of this research is to increase the sensing capabilities of the surgeon by developing smart surgical instruments. Biofeedback sensors incorporated into standard surgical tools quantify the health of the tissue and measure the magnitude of force exerted on it. Thus, hypoxic damage to the manipulated tissue can be prevented, resulting in improved patient care in the operating room.

The health of the retracted anatomy is determined by its oxygen saturation level (SO_2). Oxygen is delivered to peripheral tissue cells of the body by hemoglobin, a protein found in red blood cells. Factors that affect the oxygenation level in the blood include perfusion, oxygen-hemoglobin dissociation and tissue-oxygen affinity [2]. Arterial blood oxygen saturation (SaO_2) is typically 90% and above in healthy patients [3]. When blood vessels to an area are constricted or blocked, the decrease in blood flow leads to reduced SO_2 and creates an

unhealthy, ischemic environment.

Ischemic conditions can be handled temporarily (O_2 delivery by hemoglobin significantly increases when the pressure of O_2 drops below 40 mmHg) [4], but clinical studies shown that prolonged ischemia may cause irreversible damage to the affected tissue [5], [6]. The human liver generally has a 15 to 20 minute normothermic ischemia tolerance, but major complications occur when hypoxia exceeds 90 minutes [5]. Computed tomography (CT) scans of the livers of 250 patients 2-6 months after gastric surgery showed that 10 livers had lesions and tumors adjacent to the site of retraction [6].

Non-intrusive intelligent surgical instruments may minimize unnecessary damage to tissues by alerting the surgeon when the oxygen saturation of the area drops below a 'safe' level. These "smart" instruments make localized, real-time ischemia sensing possible and can be easily integrated with existing patient monitoring systems. Furthermore, the original design of the instruments is generally preserved, and thus the modified tools can be used for open, laparoscopic and robotically-assisted surgery in the same way as their standard counterparts.

Following is a description of: 1) ischemia and force sensing technologies, 2) custom hardware interface, 3) design and manufacturing details of the sensing surgical instruments and 4) preliminary *in vivo* animal test results. The tools detailed in this paper are retractors for open and laparoscopic procedures and graspers for manual and robotic laparoscopic surgery.

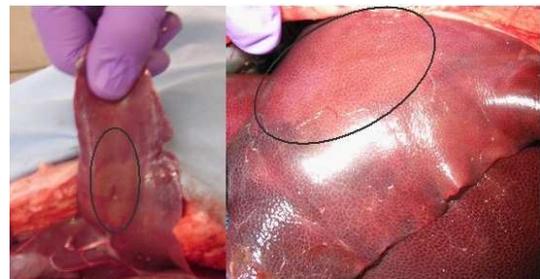


Fig. 1. Ischemic damage induced in porcine liver during retraction.

II. SENSING MODALITIES

Currently, surgeons rely primarily on visual cues to detect the onset of physiological damage in manipulated tissue. By

the time induced damage has manifested itself as visible changes on the exposed tissue, it may be too late for the surgeon to correct his/her actions. Further, during tissue retraction, view of the damaged tissue may be obstructed or the tissue may have been pulled out of the active field of view. In such situations, still further damage can be inflicted on the tissue. Laparoscopic surgery presents an increased possibility to damage tissue as 1) the field of view is drastically reduced, 2) laparoscopic instruments restrict the surgeon to a few degrees of freedom, thereby reducing their dexterity and 3) the transmission of instrument-environment forces back to the surgeon is severely limited.

Relaying information about instrument-tissue interactions can serve to prevent such damage from occurring. Two sensing modalities are especially well suited for this. Sensing the applied forces and local oxygen saturation level can help to build a model that can predict when a surgeon's actions might inflict damage on manipulated tissue. As the surgeon applies force to the tissue through the instrument, the tissue being manipulated is compressed and blood flow is occluded, resulting in a drop of SO_2 . Measuring the tissue blood oxygenation saturation is a good indicator of the physiological condition of tissue because poorly perfused tissue is deprived of nutrients and oxygen, can become toxic as waste is not removed, and can result in permanent damage to the vasculature if the applied force persists.

The following two sections discuss sensing modalities that measure 1) the physiological condition of the tissue including the local oxygen saturation level and 2) the interaction forces between the instrument and the tissue it is manipulating. With these two measurements, it may be possible to limit unintentional tissue damage during surgery. This will help reduce patient trauma and potentially reduce infection risk, additional hospital visits and overall costs.

A. Ischemia Sensing

Ischemia occurs when the oxygen saturation of tissue falls below the required concentration and the cells in the tissue begin to die due to lack of oxygen. This is often caused by excessive forces that occlude the blood supply to the tissue. To monitor and help prevent ischemic damage, the local oxygen saturation directly at the working surface of an instrument is measured.

Oxygen saturation measurement has been available for quite a long time, but standard methods of pulse oximetry, such as in [3], are not suitable for internal tissues; in particular when there is not significant pulsatile flow. The methods used here are oximetry-based techniques that rely on the dependence of light absorption properties on tissue oxygenation. As shown in Fig. 2, the absorption of light is dependent on SO_2 (ratio of oxy- to deoxy-hemoglobin); further, this dependence changes for different wavelengths. Therefore, by introducing two or more wavelengths of light into the tissue, the received transmitted or reflected signals contain information about the status of tissue perfusion.

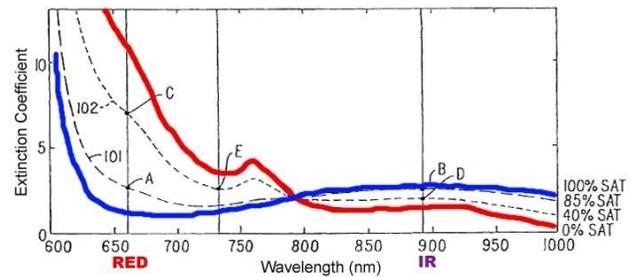


Fig. 2. Dependence of light absorption as a function of wavelength and the oxygen saturation of blood serving as the basis for oximetry measurements. Original figure courtesy [3].

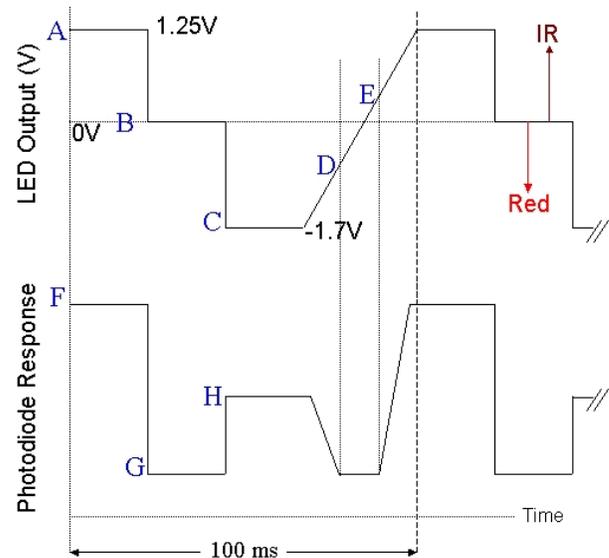


Fig. 3. Timing diagram used by the oximetry algorithm. Output waveform (top) and simulated received waveform (bottom)

The algorithm used to implement the oximetry-based measurement technique affects the accuracy and robustness of the measurement system. Fig. 3(top) shows the output waveform used to excite the red and infrared (IR) light emitting diodes (LEDs) operating at 660nm and 880nm respectively; since the LEDs used are bi-polar, bi-color, the red light excitation is represented as a negative value. The first three peaks at labels A, B and C represent full IR output, zero output baseline and full red output, respectively. The values of the output at labels D and E represent when the signal is lost and restored respectively; this is used to increase the robustness and stability of the measurement and make it invariant to different tissue thicknesses and optical densities because the measured signal is normalized by the amount of light that makes it through the tissue. The receiver waveform, shown in Fig. 3(bottom), represents a response that would be measured by a photodiode. In this application, the photodiode output is measured via a transimpedance amplifier to convert the signal to a voltage; a variable gain amplifier to maintain use of the full range of the analog to digital (ADC) converter regardless of signal intensity. On the plot, the level of the signal at labels F, G and H represent the corresponding signal intensities for

red, baseline (LEDs off) and IR outputs. The plateau between the vertical lines is used to determine the output intensities that correspond to where the signals are lost below a threshold and regained again as the signal ramps up. The gathered information is used to determine the ratio of the relative red absorption to the relative IR absorption which we termed the “Relative oxygen saturation.” This information is directly applicable for determining trends in tissue oxygen saturation; for an absolute measure such as SpO_2 , these numbers have to be calibrated against a known reference. A more detailed explanation of the oximetry algorithm is described in [7].

B. Interaction Force Sensing

There are many possibilities available for measuring forces; these include, but are not limited to, load cells, force/torque sensors and strain gages. These options differ not only in how they sense forces, but also the kinds of applications for which they can be used. Initially, we investigated the use of 6 degree of freedom (DOF) force/torque sensors (ATI, Inc.) embedded in the tool between the handle and the distal working surface to detect interaction forces. While this option provides superior force resolution, the cost of each sensor is quite high and the large size makes them extremely inconvenient for many open surgery applications and precludes them entirely from sensing on the distal side of a port used with laparoscopic tools. Strain gages offer the advantages of being very inexpensive and feature a very slim profile while still providing high quality force measurements.

The majority of the work presented in this paper uses foil strain gages configured in Wheatstone bridge configurations (Fig. 4) that are bonded to the instrument near the distal end for sensing interaction forces. This configuration provides the benefits of improved sensitivity to forces and high resistance to thermal changes; thermal sensitivity being a significant issue, as they gages are immersed into warm bodies. By using gages with high resistances (350Ω) lead wire attenuation effects and heat dissipation across the gage are reduced and high signal to noise ratios (SNR) can be achieved. To accurately translate gage outputs to interaction forces, loads are applied to the tool tip along each axis while monitoring the appropriate output. This generates a relationship between force and gage output voltage for each of the three axes; as expected, the relationship is very close to linear as shown in the representative plot in Fig. 4(right).

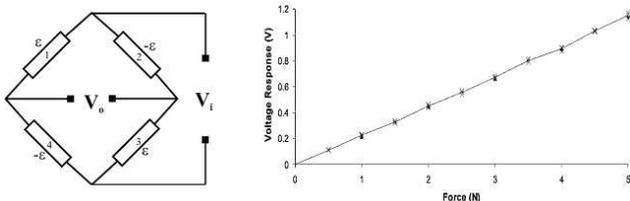


Fig. 4. A full Wheatstone bridge schematic for bending loads (left). Calibration plot for strain gages in gripper along one axis (right).

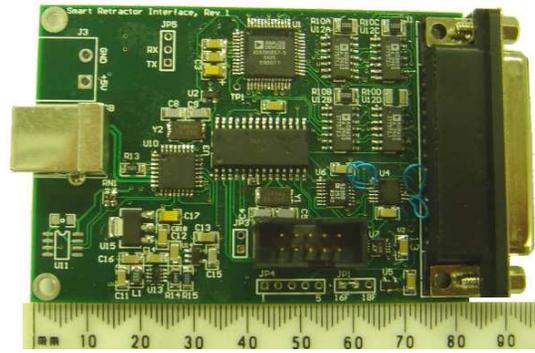


Fig. 5. Custom hardware interface for ischemia and force monitoring.

C. Measurement Hardware

Custom electronics hardware was designed and constructed for use with these tools. The hardware acts as a programmable, microcontroller-based data acquisition system with 16 14-bit buffered analog outputs, two 16-bit analog inputs with variable gains, and digital IO. The inputs can be modified such that they act as a transimpedance amplifier for photodiode inputs when used with an ischemia sensor and as standard voltage inputs when used with a strain gage amplifier. Interface with the hardware is via a USB connection; low level measurement protocols are run on the microcontroller and high level analysis, visualization and logging are performed on the host PC. Fig. 5 shows a closeup of the circuit board.

III. SENSING SURGICAL INSTRUMENTS

This section describes the development of surgical instruments that utilize both sensing modalities discussed in Section II to measure applied forces and the resulting tissue oxygenation saturation. The measurements are made directly at the surgical site and provide information about the instrument-environment interactions. Currently, prototypes for open surgery retractors, laparoscopic retractors and graspers, as well as robot-assisted laparoscopic graspers have been fabricated.

A. Open Surgical Retractor

In general open surgery, and in particular abdominal surgery, it is common to retract an organ or body wall with considerable force for extended time periods to allow access to a visually occluded surgical site. By doing so, there is potential for tissue damage by restricting blood flow to the retracted tissue and causing ischemic damage.

Two different sensing retractors for open surgery have been built and tested. The first is a standard Deaver retractor, typically used for liver manipulation, that has been fitted with a plastic sleeve that encases the sensing elements. The sleeve holds the LEDs and photodiodes such that they remain flush with the working surface; they are encapsulated in a biocompatible, optical grade UV curing adhesive. The device is shown on the left in Fig. 6. The handle of the retractor is split and a 6-DOF force/torque sensor is placed between the distal part of the handle and the retraction surface.

The second retractor is a custom instrument modeled after a Balfour retractor and is compatible with the frame for holding such retractors in place. Shown in Fig. 6(right), the configuration of this retractor is similar to that of the Deaver; again the force sensor is inline with the handle and a removable sensing sleeve is placed on the working surface. The sleeve's components can be seen clearly in the inset; they include a two-color LED (red and IR) and a photodiode. The large active area of this photodiode provides for high sensitivity even in the optically dense tissue of the liver.



Fig. 6. Force and ischemia sensing Deaver retractor (left) and custom Balfour retractor (right) for open abdominal surgery.

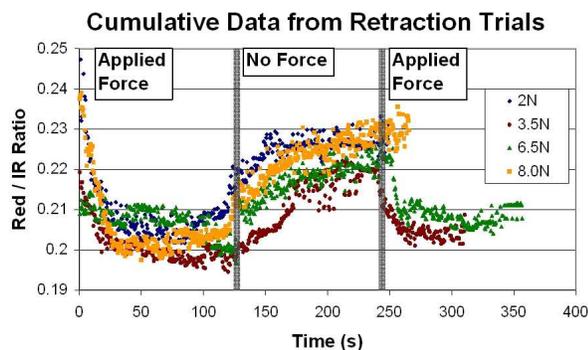


Fig. 7. Preliminary results displaying local tissue oxygen saturation during retraction, after being released and after repeated retraction with the sensing Balfour retractor.

Controlled experiments where the Deaver retractor is used on the liver and the blood supply to the organ is periodically occluded and restored are presented in [7]; these results serve as a validation and proof-of-concept. An important application of these instruments is the correlation of retraction force and time to tissue damage and hypoxia. Experiments have been performed with the instrumented Balfour retractor where the tissue was periodically retracted and released; the force during the retraction was held constant for each trial and varied for each of the trials. These experiments were used to demonstrate the retractor's ability to measure both oxygen saturation and force during a procedure; further trials are necessary to determine the relationship between force, time and ischemic damage. Preliminary results showing a relationship between retraction force and ischemia are shown in Fig. 7. These results show little difference for varied retraction forces because the pressures for all of these tests exceeded that of the capillary flow, but none of them exceeded the arterial flow pressure. Further experiments will use a larger range of retraction forces.

B. Laparoscopic Surgical Retractor

Limitations of laparoscopic surgery include reduced visualization and access to the operative field. Laparoscopic retractors and graspers are passed through ports into the target area and are used to manipulate tissues and organs. These tools are often locked into place outside the surgeon's visual field [8]. Thus, the surgeon is one-step removed from the retracted anatomy and may not be able to use visual cues to determine its health.

A standard 5-fingered 10mm laparoscopic fan retractor was modified to include both force and ischemia sensors; fingers 2 and 4 were removed to allow space for the retractor to close and fit through a laparoscopic port even with the additional instrumentation. The instrumented fan retractor is shown in Fig. 8. Force sensing is performed by foil strain gages arranged in a full-bridge configuration and bonded to the central finger; the gages are calibrated against known loads as described earlier. The force sensing aspect of this device resembles that of an early device from our group described in [9].

To enable sensing of tissue oxygen saturation, the three fingers are instrumented such that the outer fingers have bi-color LEDs bonded to them and encapsulated in biocompatible, UV adhesive and the central finger housed a common photodiodes and an LED, respectively. (see Fig. 8). Each LED emits Red (660nm peak) and IR (880nm peak) light alternately while the photodiode detects the reflected light from each finger alternately. In this way, the SO_2 of two separate portions on the surface of the tissue can be measured. Future work with this instrument includes creating a grid of sensors so that an even larger area can be monitored with more sensing points.

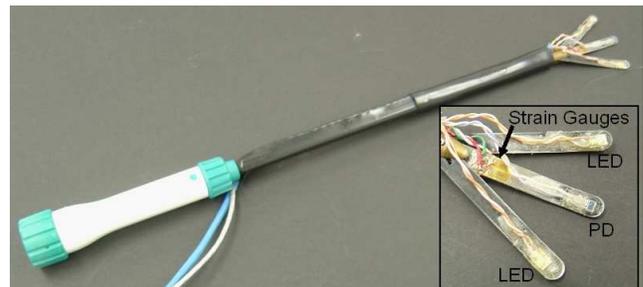


Fig. 8. Modified standard fan retractor for measurement of laparoscopic retraction forces and ischemia levels. Ischemia measurements are made at two points with a pair of bi-color LEDs and one photodiode (PD), force measurements are made with strain gages.

C. Laparoscopic Grasper

As noted in Section II, the instruments used in laparoscopic surgery do not effectively transmit force information from the instrument-environments interactions to the surgeon. A laparoscopic tool capable of sensing forces and tissue oxygenation is desirable because it can help prevent tissue damage.

This instrument is comprised of three components: 1) a gripper that contains all of the sensing components, 2) a metal sheath that slides over the instrument shaft to enclose the wires and 3) a modified Solos Endoscopy GS 1025

instrument, which acts as the interface between the surgeon and the gripper. The gripper is rigidly attached to the GS 1025 instrument by two screws as seen in Fig. 9. The gripper and the metal sheath are removable and sterilizable with Ethylene Oxide (EtO) while the instrument can be autoclaved as is typical for such instruments. This instrument senses applied forces in 3-DOF and local tissue oxygenation in the grasped tissue. The strain gages (used as force sensors), are placed on the gripper such that they maximize the sensitivity to applied forces; this is as opposed to placing them on the tool shaft as in [10], which results in decreased sensitivity. A CAD model of the gripper was developed with ProEngineer and static analysis was conducted to determine the strain profile in the gripper for force at the tip along the three cardinal axes with results similar to those shown in Fig. 12. The analysis was used to locate strain gages at sites experiencing maximum strain. For the 2-DOF of bending forces, a full and a half Wheatstone bridge are used. For axial forces, a full Poisson bridge is used. To minimize the size of the gripper, the two bending bridges are located on the same finger, while the axial bridge is located on the other finger. The 3-DOF force and ischemia sensing laparoscopic grasper is shown in Fig. 9.

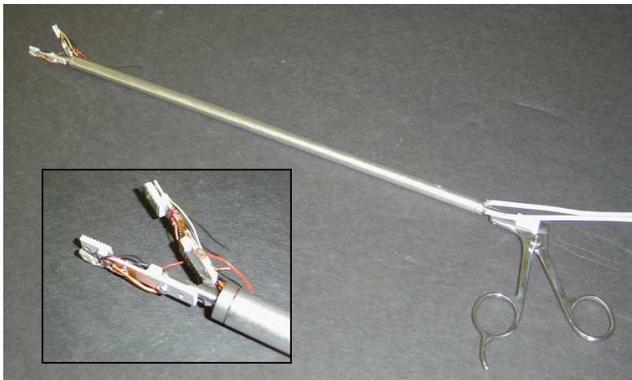


Fig. 9. Standard laparoscopic grasper instrumented with detachable 3-DOF interaction force sensing and oxygenation sensing for grasped tissue.

Fig. 10 shows results in the bowel obtained by using a laparoscopic grasper that is instrumented for oxygenation sensing. In this experiment, a section of bowel was isolated, and the radicals in the mesentery supplying blood to that section were periodically clamped off and restored. As would be expected, the oxygenation drops after the supply is cut off, and is restored after the supply is restored. Notice that the oxygen saturation is higher for the second peak, and higher still for the third peak; this is partially due to ischemia-induced vaso-dilation that allows more blood to enter the tissue.

D. Robotic Laparoscopic Grasper

Robot-assisted grasping and retraction introduces a potentially hazardous environment because surgical telemanipulators are capable of generating very large forces. Forces sensed at the instrument's end effector can help augment the surgeon's perception of the instrument-tissue interactions. This can be accomplished by implementing a system, which uses sensory

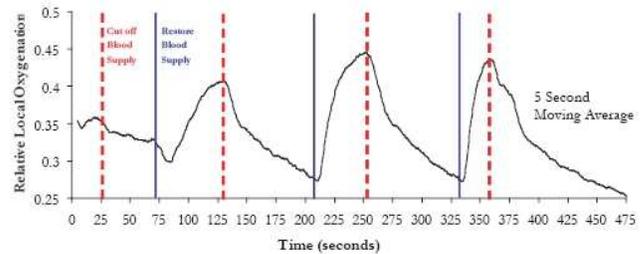


Fig. 10. Result demonstrating local oxygen sensing ability with a sensing laparoscopic grasper in a controlled experiment where blood supply is clamped and restored periodically in an isolated bowel segment.

substitution (using one sense to relay information instead of another) to relay force information back to surgeon. The addition of ischemia sensing to such a sensory substitution system can help to further reduce tissue damage by monitoring for physiological damage. Eventually, this information can be used to close the control loop on a robotic retraction system.

This instrument is comprised of two components: 1) a gripper that contains all of the sensing components and 2) an unmodified Cadere Forceps, which act as the interface to the da Vinci system. The two are rigidly attached by two screws as seen in Fig. 11. This instrument senses applied forces in 3-DOF and the tissue oxygenation of the grasped tissue. Strain gages (used for force sensing), are placed on the gripper to maximize their sensitivity to applied forces. As with the laparoscopic grasper, a CAD model of the gripper was developed with ProEngineer and static analysis was conducted to determine the strain profile in the gripper for three force directions. As seen in Fig. 12, strain gages were placed at sites that experienced maximum strain. The strain gages are configured identically to the laparoscopic grasper.



Fig. 11. Instrumented grasper fingers attached to robotic tool for augmenting available information during robotic surgery (left), closeup of the fingers (inset), sensing grasper on Intuitive Surgical's da Vinci robot.

IV. RESULTS

We have developed a system that makes it possible to incorporate measurement of tissue interaction forces and local levels of tissue oxygenation directly into surgical instruments. The system includes a software GUI for logging and presentation of data, a hardware interface, tissue ischemia sensing, interaction force sensing and the tools themselves. In addition to sensor design, significant effort has been put into biocompatibility and sterilizability of the instruments by investigating adhesives, material types, electronics and test sterilizing the components. In particular, the laparoscopic grasper has been

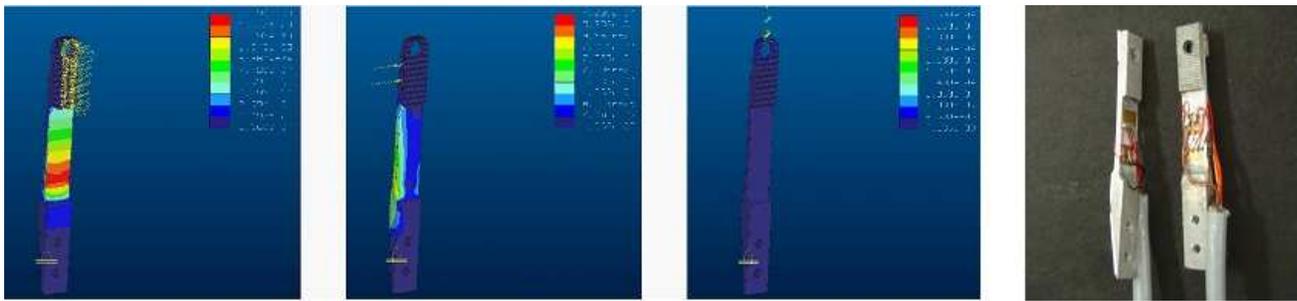


Fig. 12. Strain analysis of grasper fingers for determining optimal strain gage location (left 3 images). Both assembled fingers (right)

designed with clinical trials in mind. The complete system with a retractor used for open surgery is shown in Fig. 13. Experiments with the previously discussed instruments (both in the lab and *in vivo*) have been performed successfully and select results are shown above with their respective tools.

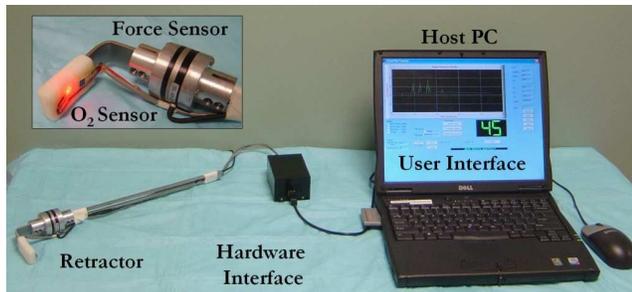


Fig. 13. System components used for experiments. Shown with force and ischemia sensing Balfour retractor.

V. FUTURE WORK

The current iteration of instruments allow for real-time measurement of oxygenation and/or interaction forces. Clinical trials are planned and are pending IRB approval. Not only will these devices be able to supply additional information during surgery, but they can serve as data collection devices for : 1) quality assurance (QA), 2) training, 3) studying standard retraction forces and 4) helping to correlate retraction and grasping forces and durations to ischemic damage. Further upcoming work includes developing more advanced instruments capable of measuring oxygen saturation over a surface of the tissue using a grid of sensors and developing more compact sensors that make their use even less intrusive to the standard workflow of a surgical procedure.

VI. CONCLUSION

The system discussed is capable of measuring the interaction forces of a surgical instrument with the manipulated tissue as well as the local oxygen saturation of the tissue. This information allows the health of the tissue that is being interacted with to be determined and uses this to help prevent ischemic tissue damage. By monitoring tissue status and interactions with the tool, sensory substitution and sensory augmentation can be implemented; these allow additional

information to be supplied to the surgeon to help them cope with the decreased information available during a laparoscopic, or especially a robotic, procedure. The information can also be used for research (correlating forces and times or retraction and grasping to tissue damage), training and quality assurance. The system is now awaiting IRB approval to begin preliminary human trials.

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