

In vivo measurement of surface pressures and retraction distances applied on abdominal organs during surgery

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Published version

SHAH, Dignesh, ALDERSON, Andrew, CORDEN, James, SATYADAS, Thomas and AUGUSTINE, Titus (2018). In vivo measurement of surface pressures and retraction distances applied on abdominal organs during surgery. *Surgical Innovation*, 25 (1), 50-56.

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Title: In vivo measurement of surface pressures and retraction distances applied on abdominal organs during surgery.

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Funding: This work was supported by the Engineering and Physical Sciences Research Council [grant number EP/J501839/1] and the Central Manchester University Hospitals NHS Foundation Trust (CMFT).

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Abstract:

This study undertook the in vivo measurement of surface pressures applied by the fingers of the surgeon during typical representative retraction movements of key human abdominal organs during both open and hand assisted laparoscopic surgery. Surface pressures were measured using a flexible thin-film pressure sensor for 35 typical liver retractions to access the gall bladder, 36 bowel retractions, 9 kidney retractions, 8 stomach retractions, and 5 spleen retractions across 12 patients undergoing open and laparoscopic abdominal surgery. The maximum and root mean square surface pressures were calculated for each organ retraction. The maximum surface pressures applied to these key abdominal organs are in the range 1-41 kPa, and the average maximum surface pressure for all organs and procedures was 14 ± 3 kPa. Surface pressure relaxation during the retraction hold period was observed. Generally, the surface pressures are higher, and the rate of surface pressure relaxation is lower, in the more confined hand assisted laparoscopic procedures than in open surgery. Combined video footage and pressure sensor data for retraction of the liver in open surgery enabled correlation of organ retraction distance with surface pressure application. The data provide a platform to design strategies for the prevention of retraction injuries. They also form a basis for the design of next-generation organ retraction and space creation surgical devices with embedded sensors which can further quantify intraoperative retraction forces to reduce injury or trauma to organs and surrounding tissues.

Key words:

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Organ retraction, Open Cholecystectomy, Hand Assisted Donor Nephrectomy, Hand Assisted Laparoscopic Surgery, Surface pressure, Retraction distance

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Introduction

Laparoscopic surgery, or Minimally Invasive Surgery (MIS), has developed exponentially in the last two decades due to advances in technology and significant benefits over open surgery, including decreased post-operative pain, reduced length of hospital stay, decreased morbidity, and increased cost effectiveness.¹ However, loss of digital tactile feedback and visual restriction due to other organs, tissues and instrumentation are the prohibiting factors in the use of MIS in more advanced and technically complex procedures. During both open and laparoscopic abdominal surgery, access to, and optimum-visibility of, the surgical field is hampered by the presence of surrounding viscera, especially gut. ~~Consequently, For example,~~ during a routine laparoscopic cholecystectomy, ~~for example,~~ the ~~liver operator~~ may be required to ~~be retracted~~ ~~the liver superiorly~~ several times with variable force and ~~or to~~ ~~fixed the liver~~ in position with retractors to gain access to the gall bladder, cystic duct and bile duct. ~~This often requires an assistant surgeon, is distracting, time-consuming, with risk of trauma to the liver and fundamentally increases the cost of healthcare delivery. These manoeuvres with their potential disadvantages detract from the overall advantages of laparoscopic procedures. There are significant opportunities with modern biomedical technology is, then, a need~~ to design a newer generation of instruments both for open and laparoscopic surgery having improved space creation and organ retraction functions. ~~Data gathered from this and similar studies on~~ Quantifying the surface pressures exerted during organ retraction, and also the extent of organ retraction, can contribute to the design and development of such instruments. Additionally, precise surface pressure limits for key human organs and tissues can be incorporated into existing surgical simulators used in surgical training and simulation. Hence the

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measurement of retraction distances and surface pressures applied to organs during surgical procedures will ultimately lead to augmented surgical skills and instrumental feedback required to undertake complex laparoscopic surgery.

~~To our knowledge no studies have been undertaken to accurately quantify the surface pressures applied by the fingertips of the surgeon to human intraabdominal organs undergoing typical retraction events during abdominal surgical procedures, which are carried out in large numbers in the UK, USA^{2,3} and globally. Several studies have been carried out for robotic-assisted surgery and MIS where force sensing capability has been introduced considered in robotic-assisted surgery and MIS.⁴²⁻⁶⁴ In vivo mechanical properties of human soft tissues and organs have also been measured reported during endoscopic, and analysed to diagnose, define and localize tumours.⁷⁵ Force feedback information has been collected for incorporation in computer-based surgical simulators.⁸ The mechanical properties of human liver have been reported from in vivo indentation tests during MIS⁸⁶ and open abdominal surgery.⁹⁷ The grasping forces have been measured employed in the during retraction of the major abdominal organs in an in vivo porcine model have been measured using a fenestrated grasper.¹⁰⁸ However, to our knowledge no studies have been undertaken to accurately quantify surface pressures applied by the fingertips of the surgeon to human intraabdominal organs undergoing typical retraction events during abdominal surgical procedures.~~

In this paper we report an in vivo study using flexible thin-film pressure sensors to measure typical surface pressures applied to human organs undergoing retraction during abdominal surgery. The sensor was placed between the flexor surface of the fingers of the operating surgeon and the abdominal organ undergoing retraction during

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open abdominal procedures such as liver resection or gall bladder removal surgery (Open Cholecystectomy - OC) and hand assisted donor nephrectomy (or hand assisted laparoscopic surgery - HALS) for transplantation. ~~Surface pressures were measured for retraction of the liver, kidney, spleen, stomach and bowel.~~ Video footage of the procedures was recorded and subsequently used in image analysis to determine the applied retraction distance for the liver in open surgery.

Methods and Materials

~~Ethical approval for this in vivo study was obtained from the North West National Research Ethics Committee, UK, study ref 13/NW/0258. Sheffield Hallam University ethics committee also approved the in vivo study. A patient consent form and an information leaflet were made available to each of the twelve participating patients 24 hours prior to surgery, and informed consent was obtained before the beginning of surgery.~~

All pressure measurements were taken using a Pressure Profile C500 Tactile Sensor (Quadratec Limited, UK), which consists of a thin film flexible capacitive sensor encapsulated within a fabric layer ~~(. The sensor had dimensions of 25mm x 25 mm x, with a thickness of ~1mm).~~ A 1-meter length cable connects ~~eds~~ the sensor ~~to via~~ an amplifier and signal conditioning unit (Figure 1a). ~~This connects via a USB interface to~~ a laptop with associated data logging software. The pressure sensor was placed in the terminal latex section of a sterile ultrasound probe cover (Figure 1b) ~~which. The ultrasound probe cover~~ encapsulated the entire sensor-cable-signal conditioning unit assembly (Figure 1c).

Figure 1

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~~The pressure sensor and cable assembly were located in the sterile operative field. The associated laptop was positioned adjacent to the sterile surgical field. The sensor was placed between the flexor surface of the fingers of the operating surgeon and the abdominal organ undergoing retraction.~~ Surface pressure measurements were collected during retraction of the liver, bowel, stomach, spleen and kidney for 6 patients undergoing open procedures and 6 patients undergoing laparoscopic procedures ~~at the Manchester Royal Infirmary of the Central Manchester University Hospitals NHS Foundation Trust (CMFT).~~ The retractions were undertaken by two surgeons having over 25 years of surgical experience (15 years of experience in laparoscopic surgery) and over 15 years of experience in open and laparoscopic abdominal procedures, respectively.

Surface pressure measurements were captured once access to the abdomen was established but prior to commencing the planned surgical procedure. Video footage of the organ being retracted was also recorded, ~~to enable the surface pressure measurements to be qualitatively correlated with organ retraction distance. It was not possible to locate a camera at a constant fixed location in respect of every patient on the operating table under anaesthesia.~~ The hand-held camera (Samsung S2 GTI9100) was positioned facing the abdomen of the patient at $\sim 45^\circ$ to both the coronal and transverse planes of the body of the patient (Figure 2) to the right or left of the operation table.

Figure 2

Surface pressure vs time data were obtained from the pressure sensor software.

Surface pressures were measured during several retraction events to key organs in

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each patient to confirm the repeatability and reproducibility of the measured surface pressure values. Across the 12 patients measurements were obtained during 35 typical liver retractions to access the gall bladder, 36 bowel retractions, 9 kidney retractions, 8 stomach retractions and 5 spleen retractions. It was, however, not practicable to undertake retraction of the spleen and kidney in patients undergoing open cholecystectomy due to their anatomical locations.

Image processing and analysis open-source software, ImageJ (Version 1.48)¹⁴⁹, was utilized to calculate organ retraction distances from the video footage. ~~Sequences of images were selected from the video footage to determine retraction distance based on three key considerations:~~

- ~~• presence of instruments of known dimension to enable calibration of the image using the image analysis software~~
- ~~• presence of four stationary points in the plane of the image for determination of relative movements of points of interest~~
- ~~• two distinctive identifying marks on the edge or surface of the organ as defined points of interest to track the retraction movements in the plane of the image relative to the four stationary points~~

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In order to relate the measured surface pressures to retraction of a particular organ in specific directions, a global x-y-z coordinate system was defined with respect to the human body (Figure 2a). ~~The global x-y plane corresponded to the human coronal plane, the x-z plane to the transverse plane, and the y-z plane to the sagittal plane.~~

Additionally, an x_1 - x_2 coordinate system was defined for the plane of the images

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extracted from the video footage (Figure 2b). ~~By way of example, Figure 2b also shows the known dimension (width) of a retractor used for image calibration using known dimensions (width) of retractor used for open cholecystectomy, and example of two identifying marks (points 5 and 6) on the edge or surface of the organ whose retraction movements in the plane of the image were tracked relative to 4 stationary points (points 1-4) and two identifying marks (points 5 and 6) used in the image analysis for retraction of the liver.~~

For each identifying mark the movement ΔX_1 and ΔX_2 along the x_1 and x_2 axes, respectively, relative to the initial image location was measured in subsequent images. The overall retraction distance in the plane of the respective image was then calculated using $\Delta X = \sqrt{(\Delta X_1)^2 + (\Delta X_2)^2}$.

Results

Typical surface pressure versus time data acquired during open abdominal surgery and hand assisted laparoscopic surgery are shown in Figure 3 for all 5 organs. The data in Figures 3a, 3b and 3e display clearly identifiable ('clean') peaks corresponding to the retraction events. For cases such as these, the data typically show decay in the applied surface pressure during each retraction event. The data were analysed to calculate the maximum surface pressure (P_{\max}), or pressures in the case of multiple peaks, applied by the fingertips of the surgeon. The length of time the organ was retracted during each retraction event (T_{hold}) was also determined, with the start of the retraction event defined by the maximum pressure and the end defined by the onset of a sudden decrease in pressure (P_{end}), or a sudden increase corresponding to a further retraction event. The

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root mean square surface pressure (P_{rms}) was calculated over the period of T_{hold} for each retraction event. Figure 3e shows the measured parameters by way of example.

Figure 3

In cases similar to Figures 3c and 3d, where the data for an individual retraction event are less well defined in terms of a 'clean' peak, only the maximum surface pressure for each event was determined.

The typical range of maximum surface pressures applied during a single retraction episode for all organs and procedures was $1 < P_{max} < 41$ kPa. The average value of $\langle P_{max} \rangle$ for all organs and procedures was 14 ± 3 kPa.

Considering now only 'clean' retraction events, the average P_{max} and average P_{rms} values, with associated standard deviations and number of 'clean' retraction events, for each organ and procedure type are shown in Figure 4a, and the associated average T_{hold} data are shown in Figure 4b. The surface pressure relaxation observed during a single retraction event (e.g. Figures 3a, 3b and 3e, respectively) resulted in lower average P_{rms} values compared to the average P_{max} values (Figure 4a): $\langle P_{rms} \rangle / \langle P_{max} \rangle = 80 \pm 8\%$ over an average hold time of $\langle T_{hold} \rangle = 7 \pm 2$ seconds. The largest and smallest decreases in surface pressure occurred for the liver-OC ($\langle P_{rms} \rangle / \langle P_{max} \rangle = 67\%$) and liver-HALS ($\langle P_{rms} \rangle / \langle P_{max} \rangle = 93\%$) organ-procedure combinations, respectively, and these corresponded to the longest and second shortest average hold times ($\langle T_{hold} \rangle = 9 \pm 4$ and 4 ± 2 seconds), respectively. The shortest average hold time of 3.4 seconds occurred for the stomach-HALS combination, for which only one 'clean' event was recorded.

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Figure 4

In order to compare the surface pressure relaxation between organ-procedure combinations the pressure drop per unit time normalised by the maximum pressure,

$\left[\frac{\Delta P}{T_{Hold}}\right] / P_{max}$ where $\Delta P = P_{end} - P_{max}$, was determined from the Liver-OC, Bowel-OC,

Bowel-HALS and Kidney-HALS data. Figure 5a shows a clear trend of reducing

magnitude of $\left[\frac{\Delta P}{T_{Hold}}\right] / P_{max}$ with increasing T_{hold} for the Liver-OC data, corresponding

to a reduction in the rate of surface pressure relaxation the longer the retraction event persists for. This trend is also evident in the Bowel-OC, Bowel-HALS and Kidney-HALS data (Figure 5b). From the slopes of the least squares best fit lines to the data there is a suggestion that the rate of surface pressure relaxation is a factor of ~2-3 lower in the HALS procedures than the OC procedures, although the very low r^2 correlation coefficients for the HALS data in particular must be noted.

Figure 5

Figure 6 shows the surface pressure vs time data for the second liver retraction event of Figure 2a, overlaid with retraction distance (in the x_1 - x_2 image plane) vs time data extracted from the image analysis of the video footage for this event. Selected stills before, during and after retraction are also presented in Figure 6. There is a clear correlation between surface pressure and retraction distance.

Figure 6

Discussion

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This in vivo study was designed to quantify typical surface pressures applied to organs by the hand of the surgeon carrying out standard manoeuvres during abdominal surgery. The choice of open abdominal surgery and hand assisted laparoscopic nephrectomy allowed repeatable access to key abdominal organs and, therefore, repeating typical retraction manoeuvres of the liver, bowel, stomach, spleen and kidney readily whilst placing the pressure sensor between the organ and the flexor surface of the dominant hand of the operator.

To the best of our knowledge, this is the first time a study has electronically measured surface pressures typically applied on human abdominal organs during open and laparoscopic surgery. Carter et al⁸⁶ & Nava et al⁹⁷ have reported in vivo indentation tests on six human livers to characterize liver mechanical properties during MIS and open abdominal surgery, respectively. Sterile hand-held compliance probe and aspiration devices were employed ~~to study liver tissue~~ but no surface pressures were measured. ~~Barrie et al. 2016⁴⁰ have obtained the grasping force for the major abdominal organs using a fenestrated grasper for an in vivo porcine model.~~ In the in vivo study reported in this paper, a broad flat pressure sensor was deployed between the operator's fingers and the organ during a manoeuvre specifically to mimic typical organ retraction carried out with retractors intraoperatively. For example, the liver was retracted superiorly in the coronal (x-y) plane before the excursion was stopped by compression of the liver against the diaphragm and rib cage. This is typical of liver retraction to gain access to the gall bladder during open and laparoscopic cholecystectomy and other surgical procedures in the sub-hepatic region.

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Assuming full contact of the pressure sensor with the organ during retraction, the recorded pressure can be converted to applied force by multiplication of the pressure with the sensor cross-sectional area ($= 6.25 \times 10^{-4} \text{ m}^2$). In this case the values of $\langle P_{\text{rms}} \rangle = 9 \pm 3 \text{ kPa}$ and $\langle P_{\text{max}} \rangle = 12 \pm 5 \text{ kPa}$ for the Bowel-OC combination (Figure 4a), for example, correspond to average rms and maximum forces of $\langle F_{\text{rms}} \rangle = 6 \pm 2 \text{ N}$ and $\langle F_{\text{max}} \rangle = 7 \pm 3 \text{ N}$, respectively. Similarly, for the Bowel-HALS combination $\langle P_{\text{rms}} \rangle = 11 \pm 4 \text{ kPa}$ and $\langle P_{\text{max}} \rangle = 13 \pm 4 \text{ kPa}$ correspond to $\langle F_{\text{rms}} \rangle = 7 \pm 2 \text{ N}$ and $\langle F_{\text{max}} \rangle = 8 \pm 3 \text{ N}$, respectively. For comparison, Barrie et al. 2016 reported $\langle F_{\text{rms}} \rangle = 13.7 \pm 5.4 \text{ N}$ and $\langle F_{\text{max}} \rangle = 20.5 \pm 7.2 \text{ N}$ using a fenestrated grasper to manipulate the small bowel in an in vivo porcine model⁴⁰⁸.

The surface pressure relaxation phenomenon associated with the hand-tissue interaction observed in this in vivo study on human abdominal organs (Figure 3) was also found in the tool-tissue interaction of the in vivo fenestrated grasper study of pig abdominal organs⁴⁰⁸, and is known to be a feature of the biomechanical properties of soft tissues under an applied surface pressure.⁴²¹⁰ Barrie et al. 2016⁴⁰⁸ attributed the force relaxation phenomenon in their work to a combination of a maximum force to lift the organ initially and subsequent tissue response and grasper handle applied pressure. Similarly, we believe in the work we report the initial applied pressure is higher to initiate movement of the organ (the dynamic retraction phase), followed by a static retraction phase where the organ is held in one place. The surface pressure in this static retraction phase is less, since the organ is in a state of rest, and decreases due to a combination of tissue relaxation and pressure applied by the surgeon fingertips.

The suggestion of a lower rate of surface pressure relaxation in the HALS procedures compared to the OC procedures (Figure 5b) possibly indicates the surface pressure

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relaxation is affected by external constraints: the more constrained abdominal environment in the HALS procedure providing some degree of mitigation against surface pressure relaxation. This may have implications in the design of organ retractors and other surgical implements used in laparoscopic surgery.

Caution should be applied in drawing firm conclusions between organ type and open versus hand assisted laparoscopic surgery given the relatively low number of retractions studied in this study. The average maximum and rms surface pressures applied to the solid organs (liver and kidney) were both higher in comparison to the hollow organs (bowel and stomach) for both types of procedure – Figure 4a. With the exception of $\langle P_{\max} \rangle$ for the liver-OC case, which has a large associated standard deviation, there is a slight tendency for higher average maximum and rms surface pressures applied in HALS than in open surgery, again consistent with the more constrained abdominal environment in HALS.

Due to logistical and infection control imperatives in the operating theatre to position the camera, and movements of the operators hands and organ retraction out of the line of sight of the camera lens and behind the abdominal wall, full tracking of abdominal organ retraction in a controlled frame of reference relative to the defined human coordinate system (Figure 2a) was not possible in this study. ~~Consequently, a fully quantitative measurement of retraction distances and directions has not been undertaken.~~

Nevertheless, a direct correlation has been established between the organ retraction distance data extracted from image analysis and the surface pressure data measured using the pressure sensor for retraction of the liver in open surgery (Figure 6). A more detailed study employing fixed cameras at appropriate locations is now merited for a

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fully quantitative assessment of surface-pressure and retraction distance relationships for specific organs and procedures.

While the degree of surface pressure used to retract tissues and organs is subjective and learnt through experience of surgical craftsmanship, in the current era of increasing technology in surgery, methods of objective assessment of surface pressures in real time could be of immense value in improving outcomes and decreasing morbidity in the

form of traction injuries. This includes robotic surgery and mechanised tissue manipulation which employ force sensing and feedback. The approach reported in this work could be used to develop databases of typical surface pressures (or forces) and retraction distances for specific organs and procedures, against which applied forces and distances can be monitored. This will improve control and accuracy for improved dexterity, and mitigate against both excessive forces causing trauma and tissue damage, and insufficient forces in grasping devices leading to slippage.¹¹ Well-defined

objective retraction surface pressure parameters could be of value in the training of surgeons in all disciplines of surgery. ~~Accurate definition of these surface pressures may be, and~~ especially of value in laparoscopic surgery. For example, surface pressure data can be incorporated within the software of advanced laparoscopic simulators to improve haptic feedback during simulated laparoscopic surgery ~~which is becoming increasingly sophisticated~~. In addition, quantified surface pressures and organ retraction distances for key abdominal organs will be key inputs for the design and development of organ retraction and space creation devices for use during laparoscopic surgery.

Conclusions:

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In summary a novel in vivo pressure sensing experiment has been carried out to study hand-tissue surface pressures generated during human abdominal surgery, including hand assisted laparoscopic procedures, ~~in humans~~. The surface pressures applied to retract abdominal organs are typically 1-41 kPa, the average maximum surface pressure for all organs and procedures is 14 ± 3 kPa, and surface pressure relaxation during the retraction 'hold' period has been observed. There is a tendency for higher surface pressures and lower rate of surface pressure relaxation in HALS procedures compared to open surgery. Surface pressures also tend to be higher in the retraction of solid organs than for hollow organs. The increased surface pressure has been shown to correlate with retraction distance for retraction of the liver in open surgery. ~~While this is a first of its kind study, it perhaps provides a glimpse of potential utility of obtaining. The~~ reported objective surface pressures for retracting abdominal organs. ~~In our opinion these results~~ will be of relevance to the design, development, and fabrication of future organ retraction devices, with a potential for real time feedback on applied surface pressures. ~~It may enable the manufacture of leading to~~ safer retractors ~~with feedback sensors indicating excessive retraction forces~~ and ~~reduc~~eding surgical morbidity. The results ~~generated~~ could also contribute to the development of newer generation surgical and especially laparoscopic simulators for surgical training.

Authors contributions:

Study concept and design: Titus Augustine, James Corden, and Andrew Alderson.

Study set up: Dignesh Shah, James Corden, Andrew Alderson, and Titus Augustine.

Acquisition of data: Dignesh Shah, James Corden, Thomas Satyadas, and Titus Augustine.

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Analysis and interpretation: Dignesh Shah, Andrew Alderson, James Corden, and Titus Augustine.

Study supervision: Andrew Alderson, James Corden, and Titus Augustine.

Acknowledgements:

Funding: This work was supported by the Engineering and Physical Sciences Research Council [grant number EP/J501839/1] and the Central Manchester University Hospitals NHS Foundation Trust (CMFT).

Competing interests: The data of the in vivo study reported in this manuscript is integrally linked to the development of the Laparosphere™, a conceptual laparoscopic instrument for the organ retraction and space creation functions. Two patents applications have been filed for the Laparosphere™. Titus Augustine is named inventor for an inflatable version of the Laparosphere™ (WO2011128622 (A1) - SURGICAL DEVICE AND METHODS) whilst Dr. James Corden and Titus Augustine are named inventors for an auxetic version of the Laparosphere™ (WO2013054093 (A1) - SURGICAL DEVICE AND METHODS).

Ethical approval: Ethical approval for in vivo study was obtained from the North West National Research Ethics Committee, UK, study ref 13/NW/0258. Sheffield Hallam University ethics committee also approved this study. A patient consent form and an information leaflet were made available to each of the participating patients 24 hours prior to surgery, and informed consent was obtained before the beginning of surgery.

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Captions for Illustrations:

Figure 1: Pressure sensor system and ultrasound probe cover. (a) Components of C500 Pressure Sensor System (b) Enclosure of the Pressure Sensor (c) Sterile Ultrasound Probe Cover encapsulating Pressure Sensor System.

Figure 2: Global and Local co-ordinates. (a) Anatomical planes and Global co-ordinates for human anatomy, (b) Local co-ordinate system ($x_1 - x_2$) and origin (0, 0) for plane of image; calibration using known distance (width) of retractor employed for open cholecystectomy; and stationary points (points 1-4) and identifying marks on liver surface (points 5 and 6) in plane of image used during image analysis.

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Figure 3: Surface pressure applied to key abdominal organs. Surface pressure vs time data for retraction of (a) liver (OC), (b) bowel (OC), (c) spleen (HALS), (d) stomach (HALS), and (e) kidney (HALS). OC = Open Cholecystectomy; HALS = Hand Assisted Laparoscopic Surgery. Properties extracted in analysis are indicated in (e). Inserts show direction of organ retraction in the coronal ($x-y$) plane.

Figure 4: Average surface pressures and hold times applied to key abdominal organs. (a) Average rms pressure and average maximum pressure applied, (b) Average hold time for pressure applied to abdominal organs. OC = Open Cholecystectomy; HALS = Hand Assisted Laparoscopic Surgery; numbers in parentheses are number of retractions.

Figure 5: Surface pressure relaxation: $\left[\frac{\Delta P}{T_{Hold}} \right] / P_{max}$ vs T_{Hold} . (a) liver (OC); (b)

liver (OC – empty squares), bowel (OC – empty triangles), bowel (HALS – filled

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diamonds) and kidney (HALS – filled circles). OC = Open Cholecystectomy; HALS = Hand Assisted Laparoscopic Surgery.

Figure 6: Correlation between surface pressure and retraction distance. Surface pressure versus time and retraction distance in the x_1 - x_2 plane versus time data for the second retraction event of the liver of patient 3 during open abdominal surgery. Selected stills from the video footage are also included.