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Restoring Haptic Feedback in NOTES Procedures with a Novel Wireless Tissue Stiffness Probe

Marco Beccani*,‡, Christian Di Natali*, Pietro Valdastri*,†, Keith L. Obstein*,†

*STORM Lab, Department of Mechanical Engineering, Vanderbilt University
Nashville, TN 37235, USA

†Division of Gastroenterology, Hepatology, and Nutrition
Vanderbilt University Medical Center, Nashville, TN 37232, USA

In the past two decades, several instruments have been developed to overcome the loss of haptic sensation in minimally invasive surgery (MIS). Unfortunately, none of the proposed instruments has been clinically adopted or utilized in natural orifice translumenal endoscopic surgery (NOTES) procedures. The challenge is that NOTES instruments require mounting upon flexible endoscopes thus altering endoscope flexibility and dexterity. We have developed a novel wireless tissue stiffness probe (WTSP) that can be used with a flexible endoscope and create a real-time stiffness distribution map with potential to restore haptic sensation in NOTES. The aim of our study was to assess the performance and feasibility of the WTSP in an *ex vivo* trial (three phantom models of different elasticity; comparing discrimination of human touch with the WTSP) and in an *in vivo* trans-colonic access NOTES procedure. Overall, the WTSP was able to detect the stiffness of the three phantoms with a relative error smaller than 3% and a success rate of 100% versus 95% when compared to human perception. The novel WTSP was successful in providing the operator with tactile and kinesthetic feedback for accurate discrimination between tissue phantoms. *In vivo* tissue palpation was feasible using the WTSP in a trans-colonic NOTES procedure. The WTSP did not encumber the maneuverability or dexterity of the flexible endoscope. This innovative approach to tissue palpation has the potential to open a new paradigm in the field of NOTES where no mechanical link between the external platform and the target region exists.

Keywords: Natural orifice translumenal endoscopic surgery (NOTES); endoscopy; haptic feedback; sensation.

1. Introduction

Natural orifice translumenal endoscopic surgery (NOTES) is an advanced minimally invasive surgical (MIS) technique that merges elements of flexible endoscopy and laparoscopic surgery [1]. The benefits of NOTES over traditional surgical technique include cosmetics and subsequent reduction in postoperative pain and postoperative analgesia [2–4]. These benefits have fueled adoption of NOTES techniques—with more than 533 NOTES clinical trials documented in 2013 [5]. The evolution of NOTES is contingent on the development of the next generation of platforms and endoscopes with multifunctional tools being able to enhance the surgeon's ability to perform high dexterity maneuvers and collect surgical site data in real time. [6] In this context, tissue palpation is an effective technique to explore nonvisible tissue and organs, identify buried structures and anatomic obstacles, and to locate tumor margins before resection. During MIS surgeons rely on intraoperative ultrasonography (IOUS) for visualization of these structures; however, adoption of IOUS in NOTES remains a challenge due to the constrained workspace that reduces instrument dexterity [7]. Moreover, IOUS probes can only provide a vertical slice of tissue density and guide instruments in a two-dimentional surgical plane [6]. Therefore, haptic sensation (which is present in open procedures and lost in NOTES) is an alternative method for locating the hidden structures and making real-time tissue assessments.

Restoring the sense of touch through tissue palpation can be achieved in MIS procedures when dedicated tools

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Email Address: ‡*E-mail: marco.beccani@vanderbilt.edu*

to measure tissue properties and to feel stiffness variations become clinically available for surgeons. Consequently, the development of tools to enable tissue palpation has been an active research endeavor for more than two decades involving multiple engineering disciplines [8–10]. Solutions thus far have addressed the problem of measuring tissue properties through vertical indentation [11, 12], or grasping [13, 14] and rolling [15–17]. Despite the increasing interest of researchers in developing devices to enable this functionality, the employment of these devices in the clinical arena has been almost nonexistent. Multiple instruments have been developed in an effort to restore minimally invasive tissue interaction and haptic sensation to surgeons; however, none have advanced to clinical trials in humans [18]. The restoration of palpation in NOTES is even more challenging due to the requirement for increased instrument maneuverability, autonomy, and precision when compared to MIS procedures [3, 4, 19]. In NOTES, tissue manipulation is performed with instruments that are inserted through the flexible endoscope. These devices are designed to provide the same functionalities of the equivalent laparoscopic rigid devices without taking up the maneuverability and dexterity of a flexible endoscope. Surgical devices designed for NOTES procedures [20] target several aspect of surgery, including access, dissection, ligation, tissue sampling, retraction, and tissue manipulation but do not address tissue palpation. The main limitation is that when an instrument is inserted through the flexible endoscope to manipulate tissue, the forces exerted on the tissue cause the endoscope to bend (due to the flexibility of the endoscope) and the endoscope is unable to resist the applied force; a significant difference when compared to traditional rigid laparoscopic instruments. There is a lack of suitable devices/platform that enables easy and proper use of flexible endoscopes [21], as all of the proposed devices thus far for tissue palpation consist of rigid shafts with a large diameter and are not compatible for utilization in NOTES procedures as they affect the flexible endoscopes maneuverability and dexterity. A wireless tissue stiffness probe (WTSP) was developed in order to overcome these challenges and enhance surgeon perception in MIS procedures [22]. This device creates a stiffness distribution map of the area of interest (tissue) in real time by merging pressure and probe position data with respect to an external magnetic field. In particular, the pressure is measured using an embedded pressure sensor while the relative WTSP position and orientation are derived from an embedded wireless localization unit. The surgeon can then use the resultant volumetric stiffness distribution map to locate tissue abnormalities and specific regions within the area of interest. In our previous work [22, 23] we described the WTSP principle of operation and we tested its ability to measure different stiffness phantoms. The probes silicone rubber cup mechanical properties have been derived and the device has been tested in an *in vivo* laparoscopic procedure. Until now, the device has been limited to laparoscopic use and the WTSP has never been tested using a flexible endoscope in a NOTES procedure. In this current work, we present the outcome of using the WTSP with a flexible endoscope to distinguish between different stiffness tissue simulators and how the proposed device enhances the physicians ability to detect buried structures within organs. The clinical feasibility of the WTSP was then assessed through a trans-colonic NOTES procedure utilizing a nonsurvival female porcine model.

2. Materials and Methods

2.1. *Platform description*

The proposed WTSP, schematically represented in Fig. 1, consists of four main components: (1) the WTSP probe, (2) the magnetic field source, (3) a transceiver, and (4) a personal computer (PC) where the algorithm and the visual user interface are integrated.

Specifically, the WTSP probe prototype, represented in Fig. 2, is a VERO CLEAR cylinder (60 mm length, 15 mm diameter, 9.5 g total mass), with a cylindrical plastic case fabricated by rapid prototyping (OBJET 30, Objet Geometries Ltd, USA), an embedded pressure sensing head, and a wireless localization module. Merging together the pressure data exerted by the WTSP probe and the relative position of the capsule, it is possible to evaluate the local stiffness of a target point on the tissue surface as the ratio between the measured pressure and the indentation depth. This parameter is computed once a certain pressure threshold is detected and located by the developed algorithm in a real-time volumetric stiffness map.

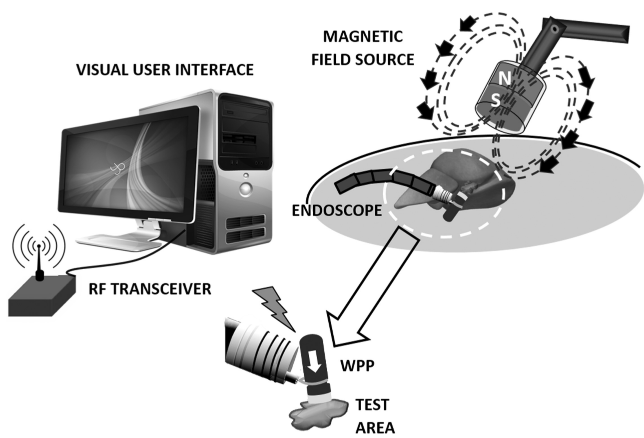

Fig. 1. Schematic of the WTSP. The WTSP is manipulated using the flexible endoscope. The position and orientation with respect to the external magnetic field source are transmitted externally to the PC where the user interface is implemented.

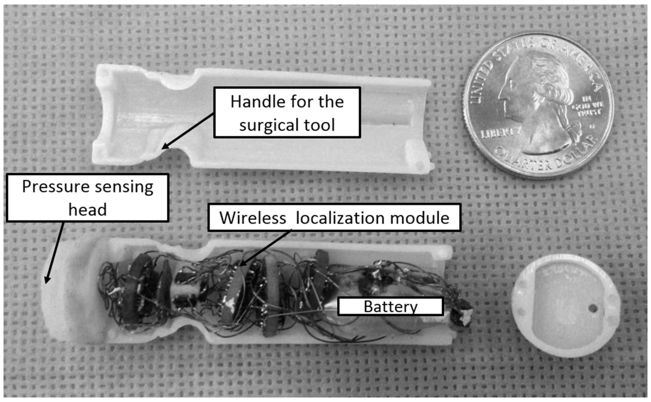

Fig. 2. A picture of the WTSP probe prototype.

The pressure sensing head consists of a barometric pressure sensor (MPL115A1, Freescale Semiconductors, USA) mounted underneath a 2.2 mm-thick silicone rubber (VytaFlex 20, Smooth On, USA) with a resulting pressure resolution of 36 Pa. The wireless localization module is built with three orthogonally mounted magnetic field sensors, an accelerometer used as inclinometer, and a wireless microcontroller. Each magnetic field sensor is based on the Hall Effect and has a full range of 2 T with a sensitivity of 0.6 mT; the accelerometer has an angular resolution of 1°. The microcontroller handles data acquisition and transmission over a 2.4 GHz carrier frequency to the external transceiver. This consists of a mirror wireless microcontroller and a universal serial bus (USB) controller to handle data communication between the WTSP probe and PC. The external magnetic field source is generated by an NdFeB cylindrical axial magnetization magnet (diameter 5 cm, length 5 cm), resulting in a residual flux density of 1.48 T. The selected magnet was mounted at the end effector of a 3-DOF (degree-of-freedom) passive 3DOF clutch arm. With this setup, the WTSP probe is then able to operate in a cubic workspace of 15 cm^3 (from the magnetic field source) with a battery life of approximately 90 min. When the pressure data and relative position of the WTSP probe are integrated, the local stiffness of a target point in the area of interest can be computed allowing for the generation of a real-time volumetric stiffness map on the user interface. The user interface displays in real-time the x, y, and z coordinates of the WTSP in the workspace and a real-time plot of the pressure exerted on the tissue. The reader interested in more details about the localization algorithm [24] and the mechanical characterization of the sensing head can refer to [22,23] where more details are provided.

3. Experimental Trials

The aim of this research study was to (1) assess the performance and feasibility of the WTSP in an *ex vivo* trial where a user was required to discern between different tissues using finger palpation and the WTSP and (2) assess the feasibility of the WTSP in an *in vivo* transcolonic access NOTES procedure.

3.1. *Human finger perception versus WTSP*

A test bench was designed to evaluate a user's ability to utilize the WTSP probe in discerning three different stiffness tissue simulators and comparing that approach with that of their own finger perception. To this end, two different ratios of liquid plastic and hardener (PVC Regular Liquid Plastic Hardener, MF Manufacturing, USA) were combined to obtain the three tissue simulators of an elastic moduli ranging between 50 and 100 kPa. The phantoms, of the same dimensions (12 cm each side with a resulting thickness of 3 cm) were then palpated by 15 subjects (10 male, 5 female) using their dominant index finger. The tissue simulators were placed in a box so that their position and stiffness was unknown to the user until they were palpated as shown in Fig. 3. The user was then asked to associate the phantom positions (A, B, C) with a stiffness index ranging from 1 to 3 where 1 was the hardest material, 2 medium, and 3 soft. Each user performed a set of three separate trials where, for each trial the tissue simulators were rearranged. This lead to a total of 45 palpations performed by all subjects. The user feedback and the time for each of the three separate trials was recorded. At the end of each trial, the user palpated the same tissue simulators using the WTSP probe three times for each phantom. The trial time and the measured stiffness were recorded. The stiffness values were then compared to a material testing machine (MTM) mounting a cylindrical indenter of the same diameter of the WTSP at the end of the subject trials. The MTM consisted a robotic manipulator mounting a 6-DoF load cell (MINI 45, ATI Industrial Automation,

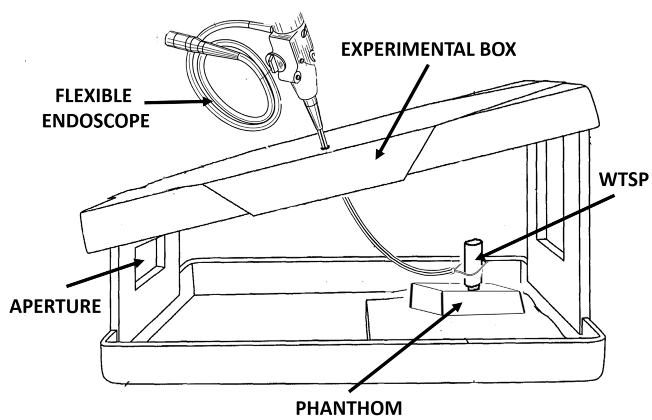

Fig. 3. A drawing of the setup for the experimental trials. The WTSP is grasped with a snare to palpate the different stiffness phantoms.

USA, resolution 1/16 N) at the end effector together with a cylindrical probe emulating the WTSP probe.

3.2. *In vivo testing*

A nonsurvival *in vivo* trans-colonic NOTES procedure was then performed to assess the performance and feasibility of the WTSP. A 40 Kg Yorkshire-Landrace cross female swine was utilized for the trial. General anesthesia was induced with Telazol (4.4 mg/kg intravenously; Fort Dodge, Ames, Iowa), xylazine (2.2 mg/kg intravenously), and ketamine (2.2 mg/kg intravenously). Following endotracheal intubation and throughout the procedure, the animals were maintained on a semi-closed circuit inhalation of 1% to 3% isoflurane and ventilated. The Olympus colonoscope (CF-160AL) was then inserted into the rectum and advanced to the spiral colon. A needle-knife was then utilized to gain access into the abdominal cavity. The colonoscope was then inserted through this point and the abdominal and pelvic organs were evaluated. Two 12 mm trocars were then placed in the umbilical area to allow for abdominal insufflation and laparoscopic camera placement for visualization of the WTSP and colonoscope. The colonoscope was removed and the WTSP was inserted into the rectum. The WTSP was then grasped with a cold snare and brought through the abdominal access point into the abdominal cavity. The WTSP was then utilized to palpate the swine liver. A stiffness map of the liver was then created. The WTSP and colonoscope were then withdrawn. The animal was sacrificed at the end of the procedure. The study was approved by the local Institutional Animal Care and Use Committee.

4. Results

4.1. *Human finger perception versus WTSP*

Of the 45 palpating procedures using human finger perception, all volunteers were able to discriminate the position of the stiffest sample among the three while they were not able to discriminate between the medium and soft samples five times. This corresponds to an error of finger perception equal of 8.88%. The average time required to palpate and discern the three phantoms by finger perception was equal to 14.8 ± 3.2 s. The longest palpation procedure (t_{max}) was 24 s while the shortest (t_{min}) was 9 s. The WTSP was able to accurately discern among the three tissue samples with a success rate of 100%. The average indentation depth that was reached during the trials was equal to 3 mm. Since the thickness of phantoms is known, given this is possible to determine the strain Overall, the WTSP, was able to detect the stiffness of the three phantoms with a relative error equal to 2.29% for phantom 1, 3% for phantom 2, and 2.85% for phantom 3 respectively in decreasing order of stiffness. Experimental plots obtained from a single loading with the WTSP probe for one of the trials and the MTM are represented in Fig. 4. A typical plot obtained; the graph shows six slopes corresponding to the elastic moduli measured by both the WTSP and the MTM. As the plot shows the softest and the medium stiffness phantom differ in only 9.06 kPa elastic moduli. When the WTSP was utilized, the average time required to palpate and discern the three phantoms was 7 ± 2.3 s. The t_{max} was 16.4 s while the t_{min} was 2.8 s.

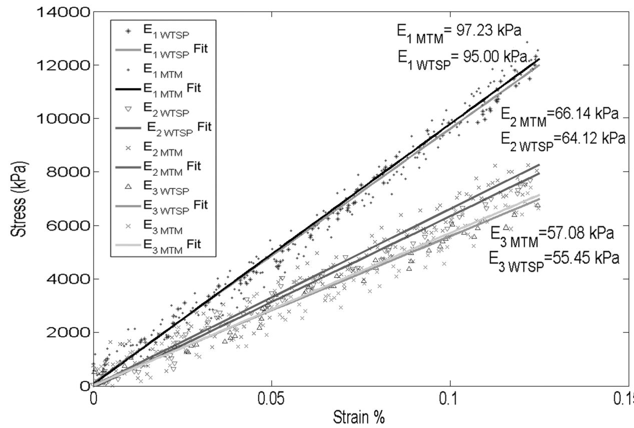

Fig. 4. Standard stress strain plots obtained with the material testing machine compared with the WTSP.

4.2. *In vivo testing*

The WTSP was successfully transferred into the abdominal cavity via the trans-colonic approach. The size of the WTSP was not a limitation or a challenge in maneuvering the device during the endoscopic procedure. The total intra-abdominal procedure time after NOTES access was completed was 10 min. The WTSP was easily grasped and manipulated with the cold snare. On occasion, the orientation of the WTSP when grasped interfered with endoscopic visualization. This was easily overcome by manipulation of the positioning of the colonoscope and occasionally by re-grasping the WTSP in a different orientation with the cold snare. Figure 5 demonstrates the WTSP successfully palpating the swine liver. There was no encumbrance to the endoscopist during the procedure from using the WTSP. An external grasper was not needed to manipulate the WTSP. There was no acute bleeding or tissue trauma. The WTSP was able to operate continuously for 15 min without the need for device retrieval or interruption of the procedure. Battery consumption resulted in 20% of the total device battery lifetime.

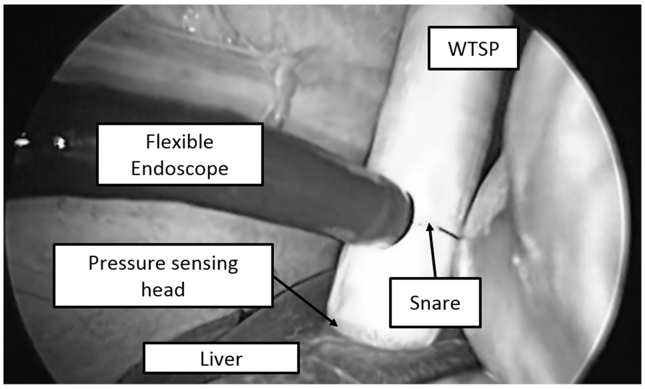

Fig. 5. Laparoscopic view of the WTSP palpating the porcine liver. The WTSP was grasped using a snare inserted through the accessory channel of the endoscope.

5. Conclusion

The WTSP, unlike other devices designed to restore tissue palpation in NOTES procedures, is completely wireless and does not need an external physical link through the endoscopes instrument channel. The WTSP can be manipulated with a flexible endoscopic instrument (e.g., a cold snare) and, once it is grasped and dragged into the region of interest for tissue palpation, can be wirelessly activated and extracted when the procedure has been completed. While prior studies using our WTSP have demonstrated how the WTSP was efficiently able to detect *in vivo* tissue abnormalities by reconstructing in real time a stiffness map of the palpated region, in this work we evaluate the feasibility of its usage in NOTES procedures. This work demonstrates that palpation in NOTES can be achieved with the WTSP and furthermore highlighted the device performance in discriminating between different stiffness tissue phantoms when compared to human finger perception. Efforts toward improving the maneuverability in order to further reduce the time needed to complete the procedure as well as increase the endoscopic dexterity when the device is operated are currently underway. This can be achieved through further miniaturization of the device, especially its length, to avoid the WTSP from occluding the endoscopes camera field-of-view when palpation is performed. While the prototype probe used for the trials was small enough for simple insertion through the anus/colonic aperture in an *in vivo* NOTES procedure, future generations of the device are focused on continued size reduction by miniaturizing the embedded electronic and reducing the battery size. Additionally, we aim to embed the WTSP into the head of the endoscope or directly attach the WTSP to the tip of the endoscope in a cap-like manner. In order to address the concern of the probe being limited to vertical motion, we have designed the sensor head so that it may easily exchanged with an alternative series of sensors that lie in a different orientation as described in [23].

Overall, the novel wireless tissue palpation system was successful in providing the operator with tactile and kinesthetic feedback for accurate discrimination between tissue phantoms. The WTSP results in improved sensitivity as well as speed to evaluate the tissue stiffness when compared to human perception. This innovative approach to tissue palpation has the potential to open a new paradigm in the field of NOTES, where no mechanical link between the external platform and the target region exists.

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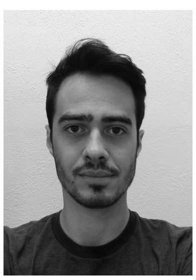
Marco Beccani received a Master's degree in Electronic Engineering from the University of Pisa, Pisa, Italy, in 2010 and a Ph.D. in Mechanical Engineering at Vanderbilt University. He is currently researcher fellow at the University of Pennsylvania at the MLAB. His field of research is miniaturized embedded system design for wireless robotic capsular endoscopy and robotic surgery.



Christian Di Natali received B.S. and M.S. degree's (Hons.) in Biomedical Engineering from the University of Pisa, in 2008 and 2010. In 2011, he joined the Institute of BioRobotics of Scuola Superiore SantAnna (SSSA), Pisa, Italy, as Research Assistant. In 2015, he graduated with a Ph.D. in Mechanical Engineering from Vanderbilt University, Nashville, TN, where he was actively involved in the design of advanced magnetic coupling for surgery and endoscopy, controlled mechatronic platforms and magnetic localization.

Pietro Valdastri received a Master's (Hons.) degree in Electronic Engineering from the University of Pisa, Italy, in 2002, and a Ph.D. degree in Biomedical Engineering from SSSA, Pisa, Italy. He is Assistant Professor in the Department of Mechanical Engineering at Vanderbilt University and Director of the STORM Lab. In 2015, he received the NSF Career award to study and design capsule robots for medical applications.

Keith L. Obstein received the B.S. degree in biomedical engineering with material science concentration from Johns Hopkins University, Baltimore, MD, USA, in 2000, the M.D. degree from Northwestern University, Chicago, IL, USA, in 2004, and the M.P.H. degree from Harvard University, Boston, MA, USA, in 2010. He completed his residency in internal medicine at the Hospital of the University of Pennsylvania, Philadelphia, PA, USA, and fellowship in gastroenterology at the Brigham and Womens Hospital, Boston, MA, USA. He is currently an Associate Professor of Medicine, an Assistant Professor of Mechanical Engineering, the Clinical Director of the STORM Lab, and the Program Director of the Gastroenterology Fellowship Training Program at Vanderbilt University, Nashville, TN, USA. His research interests include the areas of robotic endoscopy, new technologies, device development, endoscopic training, capsule endoscopy, and healthcare quality improvement.