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Force measurement in Laparoscopic Stapler for Ex-Vivo Tissue Characterization

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Summary:

Minimally invasive surgical (MIS) procedures of the gastric tract often involve resection of tissues such as the bowel, colon or part of the stomach. Modern surgical trends point toward surgical robotics being more and more widely applied, but manual laparoscopy is still prevalent. We believe that gathering large quantities of mechanical data through tissue characterization is fundamental for the improvement of laparoscopic tools and procedures. A crucial feature of small-scale integrated measurement systems is the coverage of the sensor and the accompanying readout electronics. In our work we intended to test our proprietary MEMS force sensor developed by HUN-REN CER's Microsystems Lab for in-situ tissue characterization by integrating it into a stapler currently used in medical practice. Using a flexible printed circuit board (PCB) carrier and customized 3D printed enclosures, a series of stapler-compatible sensor casings were developed. These were tested both with hard cover used in our tabletop measurement system [1] as well as combining with polydimethylsiloxane (PDMS) to evaluate its effectiveness as a biocompatible sensor encapsulation.

Keywords: tissue; biomechanics; compression; MEMS force sensor; encapsulation; PDMS;

MEMS force sensor for MIS application

During MIS the palpation of tissues is done via miniature grippers which give surgeons an indirect tactile sense. This feeling of stiffness which correlates to elasticity is essential in decision making during surgeries. Grippers used for tissue palpation have a touch area of roughly 5 × 15 millimeters, while staplers cover about 10 × 60 millimeters. Due to the developed piezoresistive MEMS force transducer has a lateral dimension of 2 × 2 millimeters, its form factor is optimal to integrate into the staple cartridge of a laparoscopic stapler currently used in MIS procedures. This allows us to measure the forces exerted on the tissue at the moment of stapling as well as testing the effects of tissue deformation caused by the non-parallel operation of the stapler jaws by placing multiple sensors along the staple surface.

Biocompatible sensor encapsulation

Whether used in ex-vivo tissue measurements or integrated into the prototype of a smart laparoscope the sensor needs adequate encapsulation because the end goal is to make in-vivo application possible. Before such a device can even be considered for FDA or MDR qualification biocompatibility and the sterilizability must be validated. The use of electronics means that the system must be hermetically sealed since most of the electrical components are not trivially biocompatible. This includes the sensor, the printed circuit board (PCB), the electrical components and of course their soldering materials.

Ex-vivo measurements on resected samples allowed us to test the sensor without any encapsulation utilizing its full sensitivity. In this tabletop measurement system, a metal disc cover was used on the sensor's force transmission rod to adequately transfer tactile force onto the deforming membrane. [1] Moreover in the case of a previous ENIAC INCITE project [2], the sensor system was installed into a 3D printed PLA (later changed to SLM stainless steel) laparoscope tip and covered with PDMS. According to recent literature, the most practical material to use for sensor integration in biomedical applications is still PDMS. Among the advantages of using PDMS the most notable for our application are physiological indifference, biocompatibility, resistance to biodegradation while it also has good mechanical properties and is relatively easy to fabricate in the desired geometry. [3] It is popular in the fabrication of novel sensing techniques for wearable electronics, but also in the development of mechanical sensors. PDMS's elasticity is also well programable by simply increasing or decreasing the amount of curing agent during mixing. [4] Although this encapsulation can significantly modify the sensing characteristics of the integrated device.

Figure 1. 3D printed stapler cartridge with the integrated MEMS force sensor

Results

A pair of special stapler cartridges were designed, fabricated and implemented with high integrability, equipped with piezoresistive force sensors (see Fig. 1). The cartridge case was modeled and 3D printed to fit into a laparoscopic stapler currently being in medical use. For easy insertion and to reduce size, a flexible polyimide-based PCB carrier was designed to fit into the cartridge. In the previous designs the sensor was still wire bonded to the PCB [1], while this newer type of sensor works as a surface mounted component. The base cover of the sensor was still a metal disc manufactured from Ni stencil material.

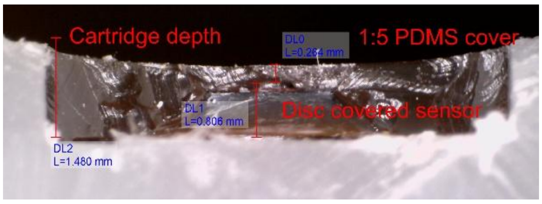

Figure 2. Cutaway view of the finished cartridge

After mounting the sensor in the cartridge, it was filled with de-gassed PDMS characterized with 1:5 curing agent-elastomer ratio as demonstrated in Fig. 2. The complete cartridge was cured on 65°C for 1.5 hours. This ratio was chosen to ensure optimal mechanical transfer considering the PDMS elasticity analyzed by our previous tests.

The sensor was calibrated before and after the cartridge was filled up with PDMS. The resulting force dependent output voltage response curves in Fig. 3 suggest that, both the sensitivity and the linearity of the force sensor is affected by the encapsulation. The flexibility and the viscoelasticity of the PDMS cover material has to be taken into account.

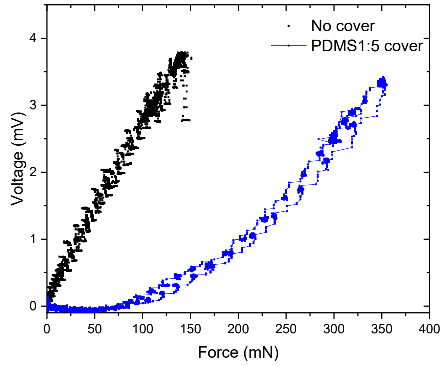

Figure 3. Voltage vs. force calibration curves of the original bare sensor and the encapsulated one embedded in the 1.5 mm deep trench of the cartridge

Our work supports the identification of optimal geometry and material composition for elastic coverage of highly sensitive mechanical transducers and testing them on practice models as well as ex-vivo tissue samples. Although for better comprehension of the material effects of elastic coverage, a larger series of sensor-enhanced cartridges must be fabricated and characterized.

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