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Flexible piezoelectric sensor for real-time image-guided colonoscopies: a solution to endoscopic looping challenges in clinic

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ABSTRACT

Colonoscopies are routine, low-risk procedures that are used to screen patients for diseases like colorectal cancer. However, often times they are performed with moderate sedation (i.e. conscious sedation) which may result in pain for patients. With moderate sedation, these procedures can be extremely painful, with one study reporting that more than 20% of patients experienced severe pain. This pain is often the result of a phenomenon called "endoscopic looping," which occurs when the scope loops within the patient's bowels and stretches out their intestines. Looping is extremely common, and can occur in up to 90% of procedures. This study reports a low-cost endoscopy visualization device aimed to decrease patient pain during colonoscopies and time lost due to complications experienced during procedures. The device consists of a flexible piezoelectric sensor to detect applied forces during looping, bending, or compression. In order to use the device, the endoscopist inserts the piezoelectric cable fully within the working channel of the colonoscope before the colonoscopy begins. The piezoelectric cable is connected to an external monitor. If extreme forces or bends are detected by the piezoelectric cable, a notification can appear on screen that a loop is forming. Once the colonoscope reaches the desired location, the endoscopist removes the piezoelectric cable, leaving the working channel open for use by other tools, such as biopsy forceps.

Keywords: image-guided therapy, colonoscopy, endoscopic looping, force sensors, piezoelectric sensors, PDMS, flexible electronics, ultrasound

1. INTRODUCTION

A colonoscopy is a procedure used to screen for colorectal cancer, remove polyps, and evaluate overall intestinal health.[1] The American Cancer Society recommends that individuals without a family history of colon cancer begin screening for colon cancer at age 45.[2] In 2017, over 19 million colonoscopies were performed in the United States.[3] This number is expected to rise as the National Colorectal Cancer Roundtable started an initiative to have 80% of adults aged 50 and older begin regular colorectal cancer screening by 2018.[4] To perform a colonoscopy, the endoscopist inserts a colonoscope, a flexible tube with a light, and camera attached to the end, into the colon of the patient (Fig. 1a-b).[5] The endoscopist then advances the colonoscope in a retrograde fashion toward the cecum, which is the beginning of the colon. There are times when the colonoscope is further advanced into the terminal ileum, the end of the small intestine. One common challenge that an endoscopist may face is a phenomenon known as endoscopic looping, which forms when the colonoscope bends in on itself within the colon, which occurs in about 91% of colonoscopies (Fig. 1c).[6] Looping of the colon can be painful,[7] with 79% of pain during colonoscopies resulting from looping.[8] De-looping the colonoscope can add between 2-45 minutes to the duration of the procedure, depending on the experience of the endoscopist, since the exact location of the loop may not always be known. As the endoscopist must work to reduce the loop and straighten the colonoscope, extending procedural time, requiring the patient to be under anesthesia for a longer duration, thereby increasing risk of complications.[6] Furthermore, this may translate to a higher cost of the procedure as well as a reduction in operating room efficiency.[9]

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This study focuses on loop prevention as a solution to endoscopic looping. We have developed a visualization tool designed to provide real-time imaging of the shape of the colonoscope within the colon in order to inform the endoscopist of loop formation before it can occur. The reported device uses piezoelectricity to detect an applied force (i.e. bending or compression). From these voltage readings, a three-dimensional representation of the orientation and location of the colonoscope within the colon can be created. In order to use the device, the endoscopist inserts the piezoelectric cable fully within the working channel of the colonoscope before the colonoscopy begins. The piezoelectric cable is connected to an external monitor. If extreme forces or bends are detected by the piezoelectric cable, the clinician will be alerted. The endoscopist will know where the loop is and what type of loop is forming (e.g. n-loop, alpha-loop, and u-loop), allowing the endoscopist to prevent that loop from forming and, as a result, avoiding causing the patient pain. If the loop does form, knowing what type of loop has formed can help the endoscopist accurately determine how to de-loop the colon, possibly shortening the time of the procedure and reducing costs. Once the colonoscope reaches the desired location, the endoscopist removes the device, leaving the working channel open for use by other tools, such as biopsy forceps. This study reports the results of our tests to determine the relationship between voltage response and applied force.

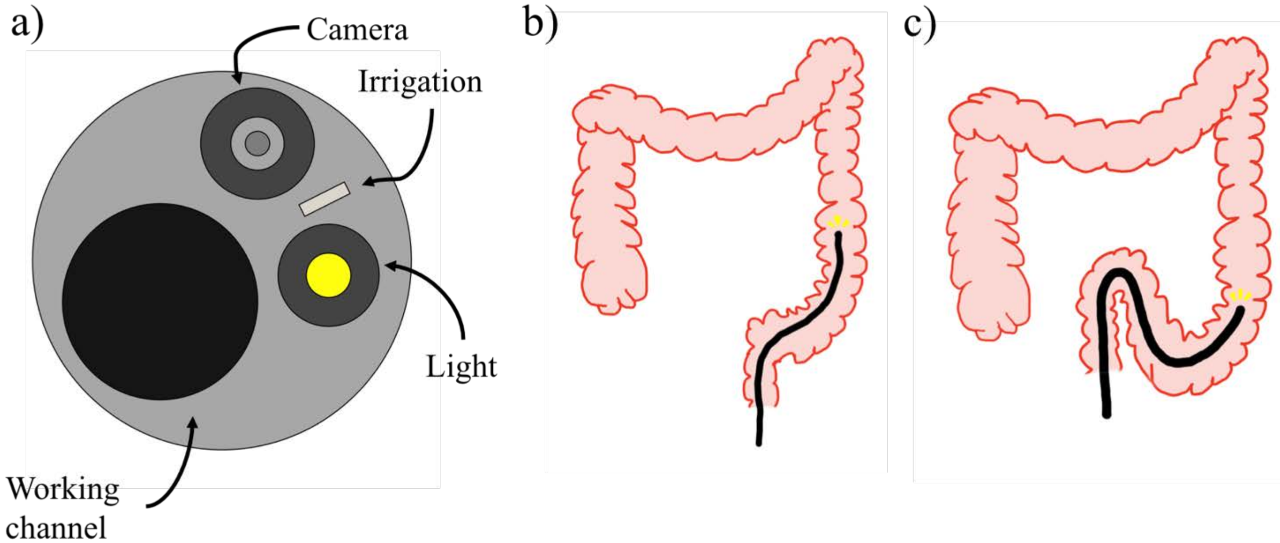


Figure 1. (a) Detailed diagram of tip of colonoscope, showing working channel, light, camera, and irrigation; (b) Colonoscopy procedure without looping; (c) N-loop forming during colonoscopy.

2. MATERIALS AND METHODS

2.1 Prototype design and proof of concept

Polyvinylidene fluoride (PVDF) is a piezoelectric material that creates voltage in response to an applied force, while providing the geometric flexibility needed for this application. To fit inside the 2.8 mm diameter of the working channel of the colonoscope, 0.08 mm thick PVDF strips are used in our prototypes to detect the change in voltage when a force compresses the device. To detect this voltage response, conductive tape (copper or aluminum) is attached to both sides of a strip of PVDF and standard 8-gauge wire is soldered to the conductive tape. Then, the PVDF strip is placed in a 3D-printed mold and coated with polydimethylsiloxane (PDMS), a flexible, insulating silicone polymer. Building on and modifying the prior experiments of Seghir *et al*[10] and Johnston *et al*[11], three different ratios (5:1, 10:1, and 20:1) of base to curing agent were tested in order to determine which ratio would work the best for the device. Based on the experiment below, a ratio of 20:1 PDMS base to curing agent was used for the prototype that was tested. The mold is then placed in a vacuum chamber at –0.8 bar for 30 minutes and cured in an oven at 60 degrees Celsius for 45 minutes. After 45 minutes, the PDMS had hardened in the oven, showing that a shorter curing period and lower temperature than those described by Seghir *et al* and Johnston *et al* were sufficient to cure the PDMS. After the PDMS hardened and cooled, the prototype was removed from the 3D printed mold. Two molds were created: a cylindrical mold and a flat mold (Fig. 2a-b). The cylindrical prototype represents the final device that is placed in the working channel of the colonoscope. The flat prototype is a proof of concept on which tests were conducted to determine the relationship between an applied force and the voltage response of the PVDF material. For each mold, three strips of PVDF were embedded within the PDMS. Since each PVDF strip can generate voltage, this triple-sensor arrangement allows for increased resolution at the site of the applied force (Fig. 2c).

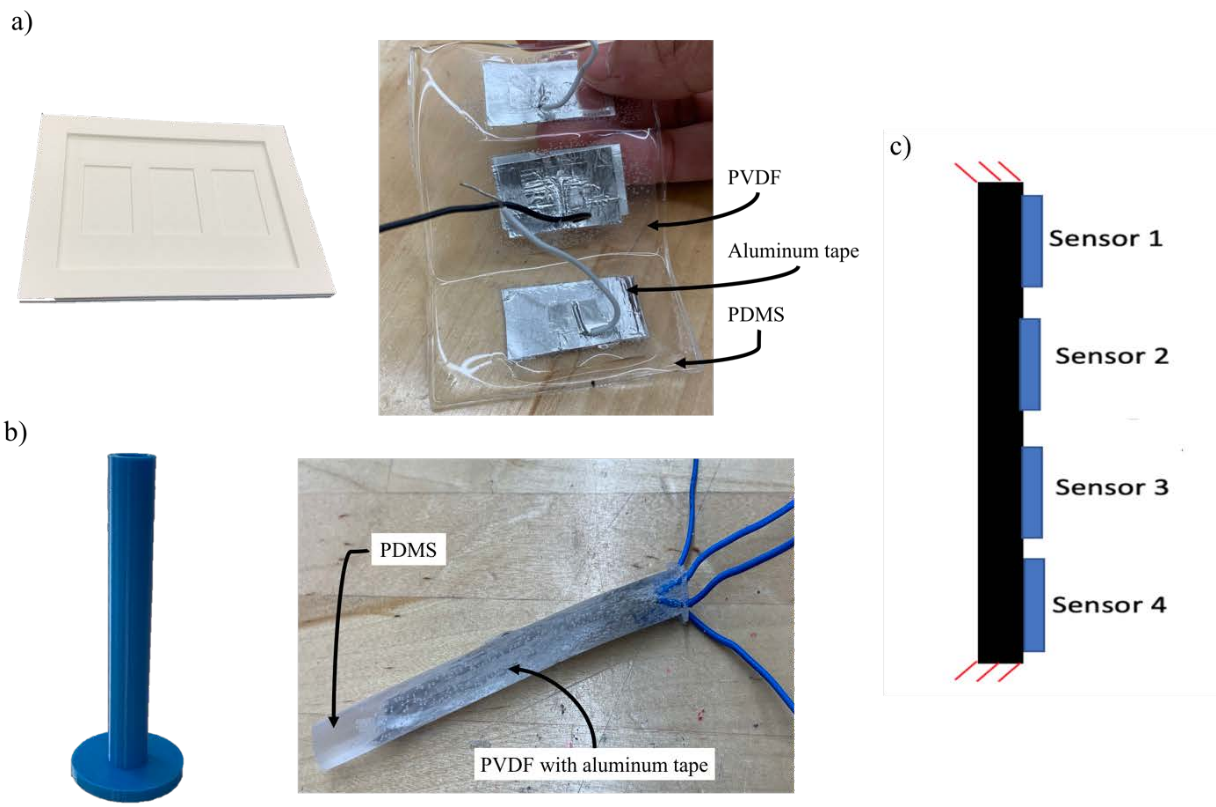


Figure 2. (a) 3D printed flat mold (left) and flat proof-of-concept prototype (right); (b) 3D printed cylindrical mold (left) and cylindrical prototype (right); (c) Schematic of multi-sensor design for final piezoelectric device.

2.2 Data Visualization

When a loop begins to form, voltages greater than 20 mV (yellow in Fig. 3a) are generated by our piezoelectric device. As the colonoscope continues to bend and the loops continue to form, increasing voltages on the order of 100 mV (red in Fig. 3a) are recorded. Once the exact relationship is determined, the cylindrical model will be bent in the shape of different loops (e.g. n-loop, alpha-loop, and u-loop) and this data will be catalogued to identify later what type of loop is forming. Then these data can be used to create a real-time imaging program to alert the endoscopist of potential loop formation (Fig. 3b). In order to determine the relationship between voltage response and applied force, a test in which the force applied on the device varied and the resulting voltages were measured was conducted. For this experiment, one sensor from the flat prototype was hooked to a Digilent Analog Discovery 2 oscilloscope. Then, to generate different forces, a 20-gram mass was dropped from four different heights (10 cm, 20 cm, 40 cm, and 80 cm) onto the center of the flat prototype (Fig. 4). Ten trials were conducted for each height and data was excluded when the mass made significant contact with the plastic tube on its descent. In order to ensure that the force was applied to the same location for each trial, a plastic tube 1-2 cm was placed above the center of the flat prototype, held in place by a clamp. The 20-gram mass was dropped from the top of the tube for each trial and the resulting voltage response was recorded on the WaveForms application (Digilent Inc. Seattle, WA, USA). Each trial was filmed for analysis in the Logger Pro (Vernier Software & Technology, Beaverton, OR, USA) application. After the position of the bottom of the 20-gram mass was manually recorded, Logger Pro calculated the velocity of the mass at each point. A ruler was used in the video to calibrate the Logger Pro application. Since PVDF creates a negative voltage when a force is applied and a positive voltage once that force is released,[12] the duration of impact, as determined from downward peak to upward peak in the velocity data, could be calculated. The force applied to the piezoelectric device was calculated by the following formula:

!""""#$%& ()*+% (,) = ./OO)1 2%$3h5 (63)* [89:;<=>? @/(A) B> >=C9 ;D =CEB<>-89:;<=>? @/(A) B> G>BH>] / [I=C9 (G) B> JEKBHL E9BM-I=C9 (G) B> L;KNKBHL E9BM]   (1)

Since the 20-gram mass was dropped with an initial velocity of 0 m/s, this formula can be simplified to:

!""""#$%& ()*+% (,) = 0.02 (12)* [456789:; </(=) >: :9?5 7@ 9?A>8:] / [B9?5 (C) >: DAE>FG A5>H-B9?5 C(>:) G7EJE>FG A5>H].   (2)

From this data, the relationship between an applied force and the voltage response generated by our piezoelectric device is able to be determined, which is necessary to create a real-time, 3-dimensional representation of the position of the colonoscope within the colon.

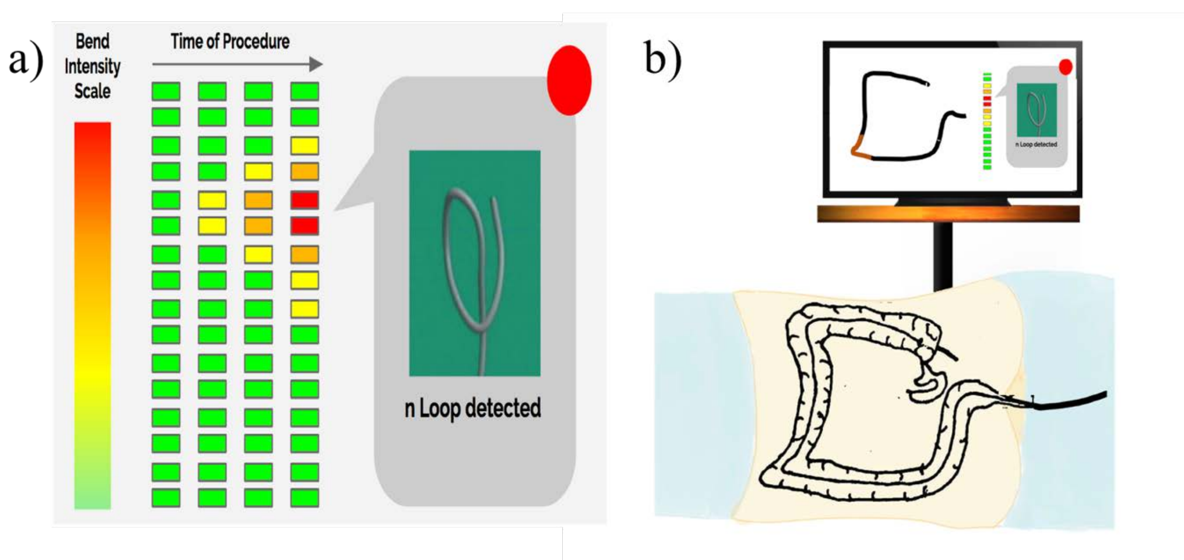


Figure 3. (a) User interface showing force data and alert of the formation of an n loop; (b) Scenario of piezoelectric device predicting a loop forming during a colonoscopy.

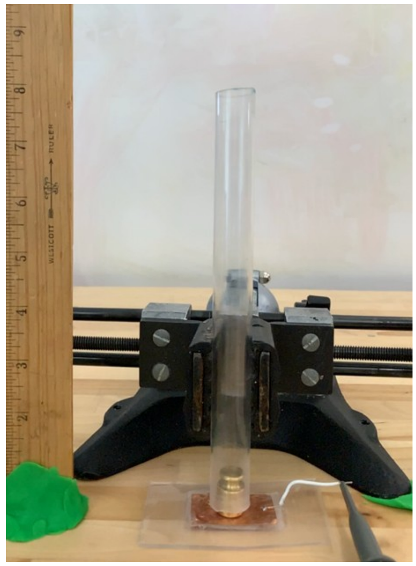


Figure 4. Experimental set up for test to determine relationship between applied force and voltage response in piezoelectric device.

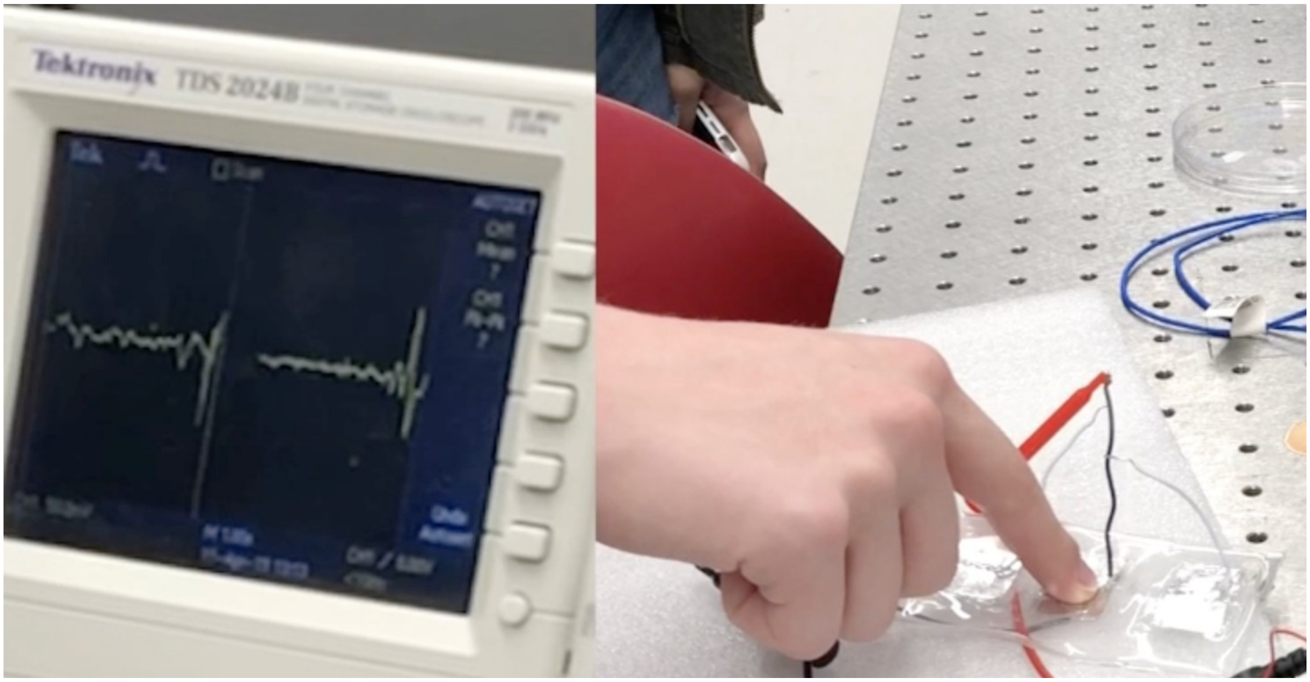
3. RESULTS AND DISCUSSIONS

3.1 Prototype design and proof of concept

While designing our flat proof of concept prototype (Fig. 2a), we experimented with the flexibility of our device. As the ratio increased, the stiffness and sensitivity of the device increased, suggesting that a ratio of 20:1 base to curing agent would be most suitable for the prototype. We also wanted to determine the best method of curing the PDMS. Two different methods were tried. First, the PDMS was cured in an oven at 60 degrees Celsius for 45 minutes. Second, the PDMS was allowed to cure at room temperature for 48 hours. There was no observable difference between the two prototypes after they were removed from their molds. However, after curing at 60 degrees Celsius, the 3D printed mold was deformed and could only be used to make one prototype. The air in the mold expanded when placed in the oven. This was not the case when the PDMS was cured at room temperature. We will continue to develop our final cylindrical prototype, including by using a PDMS spin-coater which can create a layer of PDMS fewer than 5 μm in thickness.[13] A thin layer of PDMS will be necessary for our final prototype to fit in the working channel of an colonoscope, which is only 2.8 mm in diameter.

3.2 Data Visualization

In order to create a real-time representation of the position of the colonoscope within the colon and to categorize the type of loop that is forming, there was the need to determine the relationship between the applied force on the piezoelectric device and the resulting voltage response. Initial testing of the piezoelectric sensor verified the voltage response. Video 1 shows the real-time voltage response due to an applied force, in this case pressing down on the sensor. Further testing (Fig. 4) was conducted to find the relationship between applied force and voltage response. When the mass initially hits the piezoelectric sensor, a downward spike in velocity is measured. When the mass bounces back up and leaves the sensor, an upward spike is measured (Fig. 5). The applied force was calculated using both the final velocity of the mass as it impacted the sensor and the total duration of the impact (Equation 2). Individual data points initially show a rough linear trend for both the negative response and the positive response. After the average voltage response and force were calculated for each height, a line of best fit was plotted in Microsoft Excel 2017 (Fig. 6). The negative voltages were fit to the line $y = -0.0449x - 0.0499$ with an r-squared value of 0.89892. The positive voltages were fit to the line $y = 0.0231x - 0.018$ with an r-squared value of 0.44187. This result suggests that the negative voltage peak due to the initial impact of the mass has a linear relationship with the applied force. The positive voltage does not appear to have as strong a correlation to the applied force. However, more testing is required to refine these results. The relationship between applied force and voltage response will form the basis of a program that can convert a voltage response into an indication of bending or looping to aid the clinician.



Video 1. “Initial Voltage Response Testing” shows the real-time generation of voltage when a force is applied to the piezoelectric sensor http://dx.doi.org/10.1117/12.2548873 .

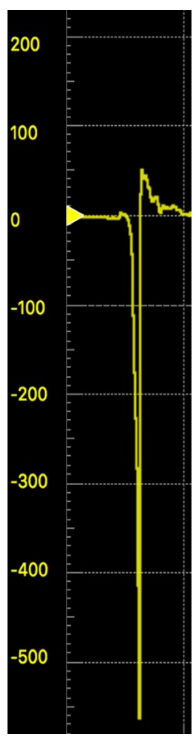
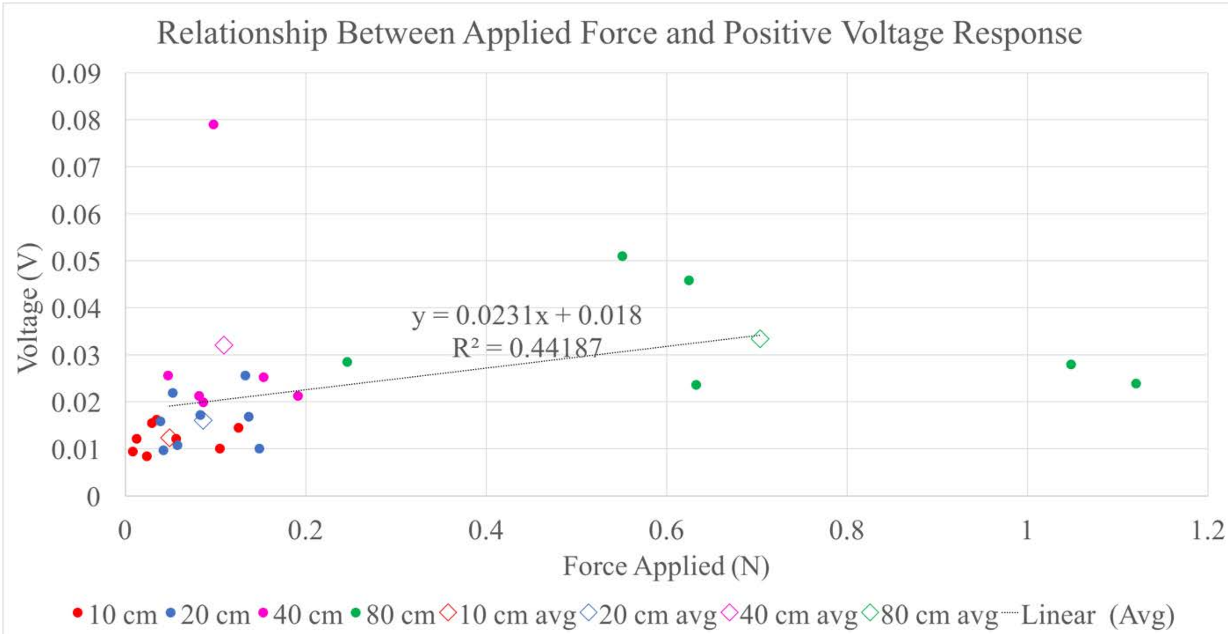


Figure 5. Voltage graph (mV) showing a negative and positive voltage response when a 20-gram mass was dropped from 80cm.



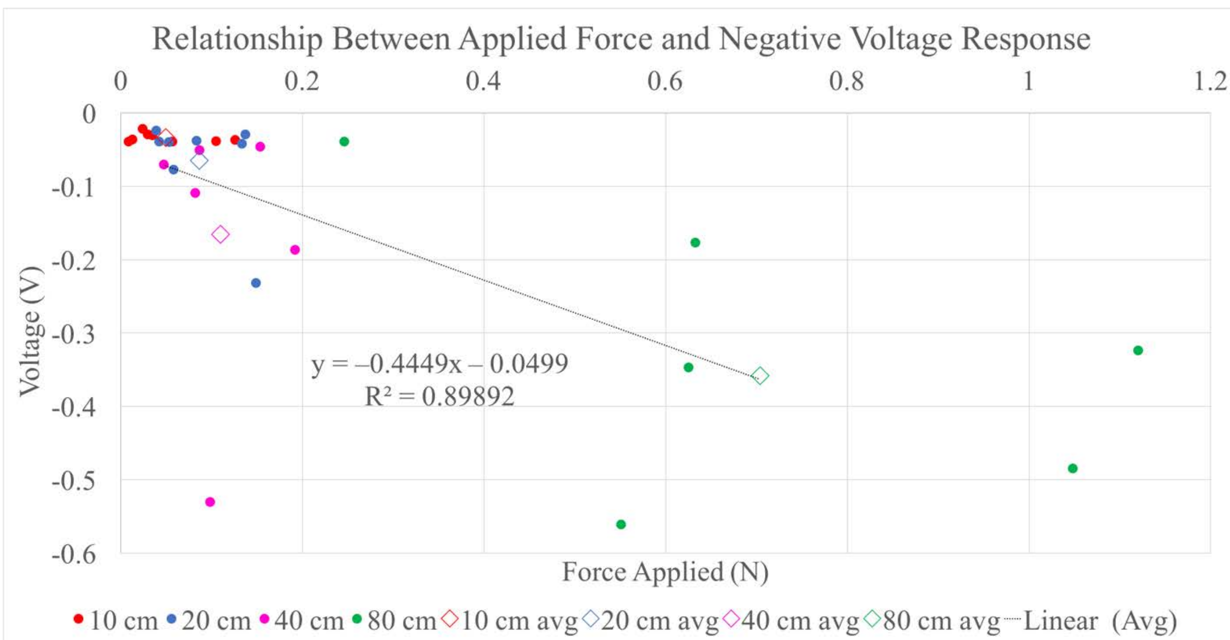


Figure 6. Graphs showing positive (top) and negative (bottom) voltage response vs. applied force.

4. CONCLUSIONS

This study reports the development of a customized flexible piezoelectric sensor and lab-bench validation studies aimed to determine the relationship between applied forces and the resulting voltage responses. Equipped with further experimental results, we plan to present, at the SPIE Medical Imaging 2020 meeting, how this piezoelectric device can accurately aid endoscopists during colonoscopies by providing a real-time image of the position of the colonoscope within the colon.

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