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A Sterilizable Force-Sensing Instrument for Laparoscopic Surgery*

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Abstract— **Although some technologies have been developed to measure tool–tissue interaction forces during minimally invasive surgery (MIS), none of these technologies have been approved for use in humans. The primary factor preventing the use of sensorized instruments in humans is their inability to withstand the stringent conditions present during cleaning and sterilization. This paper presents a series of experiments that were performed to develop a sterilizable instrument capable of measuring tool–tissue interaction forces in three degrees of freedom using strain gauges. The experiments provided an appropriate choice of cables and connectors, as well as an optimal combination of strain gauge adhesives and coatings that allow the sensors to withstand autoclave sterilization. A prototype of the sensorized instruments was developed and tested. The final prototype was able to withstand a sterilization cycle with excellent results (0.10–0.21 N accuracy, 0.05–0.20 N repeatability and 0.06–0.21 N hysteresis depending on the measurement direction). This work shows that autoclave sterilization is possible for a strain-gauge instrumented device.**

I. Introduction

The advantages of entering the patient's body through small incisions in a minimally invasive manner have been widely presented in the literature, justifying how minimally invasive surgery (MIS) has changed the face of surgery over the past 20 years. Unfortunately, minimally invasive access creates significant limitations for the surgeon, who must deal with compromised instrument movement and a limited ability to feel tissue interaction forces (haptic feedback).

Several technologies have been developed in an attempt to provide haptic feel during MIS procedures with some success [1]. In some medical applications, sensing remotely from the operative site is possible; however, in MIS there are significant forces and torques that act at the incision point, such that forces measured from outside of the patient's body are not a good representation of the forces that act on the tissue. Although research to date has yielded instruments capable of sensing forces from inside the patient's body [2], these are not currently available for clinical use. The primary limitation that is preventing the use of these instruments in humans is their inability to withstand the stringent conditions required for proper cleaning and sterilization.

The objective of this work is to develop and test a sterilizable version of surgical instruments that can measure tool–tissue interaction forces during MIS.

A. Reprocessing of Medical Devices

All medical devices that are not disposable need to follow certain procedures to ensure that they are safe to use in clinical applications [3]. Tools and devices that come into contact with patients during surgical and therapeutic procedures must go through disassembly, cleaning, sterilization, drying, reassembly, and functional testing. It is up to the equipment manufacturer to outline how to disassemble, clean, and reprocess the equipment and devices. They must provide evidence that the cleaning and sterilization process is effective and has been validated.

Of the required processing steps, cleaning and sterilization are the most challenging to accommodate. Specifically, these steps involve:

- Cleaning: Physically removes all debris from the devices. It involves washing with soap and water, and using detergents and enzymatic cleaners.
- Sterilization: Eliminates all microorganisms that could cause disease. Although different methods of sterilization exist, steam sterilization in an autoclave is the preferred method. A typical autoclave cycle exposes the instrument to 121° Celsius at 207 kPa and 100% humidity for 30 minutes.

Some commercially available force sensors have been designed to withstand alcohol, ethylene oxide or formaldehyde sterilization [1]. However, they are much too large to be integrated within an MIS device.

The selection of proper materials for a sterilizable prototype is presented in the following sections.

B. Force-Sensing MIS Instruments

Several research groups have focused on developing sensorized instruments for surgical applications. A summary of force sensing technologies was presented in [1]. Of these technologies, it is important to recognize those that measure forces at the tip of the instruments, such that the forces applied by the trocar and the abdominal wall do not have an effect on force measurement. Some of these technologies successfully integrate strain gauges to sense grasping forces during microsurgery [4] and for large organ manipulation

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[5]. Other systems also use strain gauges to measure forces in 3-degrees of freedom (DOF) [6, 7] or 6-DOF [8]. The issues of sterilization and biocompatibility were not addressed in the design of these instruments.

An instrument capable of measuring forces in 6 DOF is presented in [9]. Although it is recognized that sterilization is needed, it is not clear how the portion with strain gauge sensing was made sterilizable and no performance results after sterilization are presented. The commercial version of this instrument is not currently sterilizable [10].

Other systems have successfully implemented optical sensors for force sensing [11–13]. The advantage of optical sensors is that the electronics can be located distally from the tip of the instrument, making sterilization easier. The limitations of using optical sensors as opposed to strain gauges are that the optical fibers themselves make it difficult to achieve high bending radii [14], and the interrogator required for accurate sensing is expensive.

In our previous work, we developed the SIMIS instruments, a set of sensorized instruments capable of measuring tool–tissue interaction forces while maintaining the size and weight of standard laparoscopic instruments [2,15]. Force measurement is provided using strain gauges to measure forces in 5 DOF, of which three have been found to be the most valuable and reliable: the forces acting perpendicular to the shaft in two directions and the actuation force applied when cutting or grasping an object.

These instruments were developed for use in a training environment in order to evaluate the usefulness of force information for skills-assessment [16]. Hence, it was not a requirement of the previous version that the instruments be sterilizable. Nevertheless, these previous instruments were built using metal and plastic capable of withstanding any sterilization procedure. What prevented them from surviving a complete procedure of cleaning and sterilization was that they were not fully sealed, as would be needed to prevent moisture or debris from entering the inside of the instrument, the cables and wires used on the instruments were not selected to withstand the cleaning and sterilization process, and the adhesives and coatings used to attach the strain gauges were not selected to withstand an autoclave environment nor was their toxicity considered.

This paper describes the work that was done to develop a sterilizable prototype of the SIMIS instruments. It also provides guidelines for cleaning and outlines future work.

II. Development of a Sterilizable Prototype

To develop an autoclaveable version of the SIMIS instruments, three main areas of concern were identified for improvement. These are described in the following sections.

A. Selection of Adequate Cables and Connectors

Cables are required to wire the strain gauges within the instruments. A total of 12 individual wires (four wires for each of the three bridges) need to be properly routed and protected from tangling and breakage. The specifications of the cables were determined as follows: i) made from medical-grade materials, ii) multi-conductor with at least 4 coated conductors, iii) covered with a protective outer sheath with a maximum outer diameter of 1 mm for every 4 conductors, iv) very flexible to allow them to wrap around the inner shaft, and v) able to withstand temperatures of over 121° Celsius.

The cables that were found to meet the requirements were from Cooner Wire [17]. These are teflon coated, multi-stranded bare copper conductors, with a gold-plated copper-braided shield. The selected model (CZ-1223-4) has 4 conductors (size AWG 38) with a nominal outer diameter of 0.82 mm. The cables are rated to 200° Celsius.

B. Selection of Adequate Connectors

In addition to the cables, a properly sealed connector is required so that the instrument can be unplugged from the electronics and placed in an autoclave for sterilization. The specifications for the connectors were the following: i) fully sealed to moisture, ii) must withstand 121° Celsius, iii) provide a minimum of 12 pins: 4 for each of the three bridges in order to ensure equal lead resistances in all of the bridge arms, and iv) accommodate miniature cables.

The connector that was found to be adequate for this application is a 19-pin connector from the Fischer Core Series [18] (part number 1031A019-130 for the connector and K1031A019-130 for the corresponding receptacle). These are high performance connectors, hermetically sealed for use underwater, in high-pressure conditions and corrosion resistant. They are rated to up to 200° Celsius.

C. Selection of Materials for Strain Gauge Installation

The most significant limitation with the previous SIMIS prototype, regarding sterilizability, was that the sensorized elements would not be able to withstand an autoclave cycle. An experimental evaluation was performed to determine the best combination of strain gauge adhesives and coatings to allow for sterilization of the SIMIS instruments.

A search was performed to identify adhesives and coatings that could withstand temperatures higher than 121° Celsius, that would not be weakened by exposure to high humidity, and that did not contain toxic chemicals. Table I shows the materials that were found to be suitable.

This table shows that two of the adhesives and two of the coatings are compliant with the International Organization for Standardization (ISO) 10993 series [19]. This series of standards regulates the biocompatibility of medical devices and is considered a critical condition that must be met for new devices to be approved for clinical trials. The details of the evaluation that was performed to assess the best combination of adhesive and coating are presented below.

III. Experimental Methods

A series of experiments was performed to identify the best combination of adhesives and coatings that would allow the strain gauges to withstand more sterilization cycles while maintaining excellent sensing performance. An evaluation was designed as a full-factorial test with two factors (adhesive and coating) at three levels each (3^2 design) for a total of 9 different combinations. The experiment was designed with 11 replicates to ensure sufficient power and to account for the learning curve in strain gauge installation.

Stainless steel bars of the same material as the instruments (Stainless Steel 316) were used to perform the assessment. EA-06-031-CE-350 strain gauges (Vishay Precision Group Inc.) were installed. To ensure consistency, all 9 combinations of strain gauges would be installed on the same stainless steel bar. All 9 strain gauge combinations were placed on the 11 bars in a random order.

To evaluate the performance of the gauges, the bars were held in cantilever, while weights of increasing mass were used as a load. To ensure consistency, the bars were built with a series of equally spaced holes that allowed them to be mounted in a loading jig in such a way that the distance between the mounting point and the strain gauge was the same for each gauge, see Fig. 1. Similarly, holes on the other end of the bar allowed the weights to be applied at the same distance from each strain gauge.

A. Strain Gauge Installation

All combinations of the coatings and adhesives were used for each stainless steel bar, for a total of 9 strain gauges per bar. The laying of the gauges was done in blocks based on the adhesive. Gauges requiring M-Bond 610 were placed first, as curing this adhesive required a complex procedure.

TABLE I. SPECIFICATIONS OF THE ADHESIVES AND COATINGS TESTED.

No.	Material	Specifications
Adhesives		
1.	M-Bond 610, Vishay	Operating temperature between -269° and 175° C. Curing requires a three-step process at different temperatures in an oven. Contains toxic substances in the liquid state but is not toxic once cured.
2.	Loctite M-3981 Henkel	ISO 10993 certified—further strengthens in an autoclave environment. Designed for medical applications. Must be oven cured.
3.	SILASTIC Type A Medical Adhesive, Dow Corning	Operating temperature of up to 150° C. Designed specifically for medical applications. ISO 10993 certified.
Coatings		
4.	M-Coat C, Vishay	Reasonable moisture protection, operating temperature -60° to 260° C. Contains toxic substances in the liquid state but is not toxic once cured.
5.	Loctite M-31CL, Henkel	ISO 10993 certified, 150° C operating temperature. Not recommended for products that will see more than 3 sterilization cycles.
6.	Loctite M-11FL, Henkel	-60° to 250° C operating temperature, ISO 10993 Certified. Not recommended for products that will see more than 3 sterilization cycles. Must be oven cured.

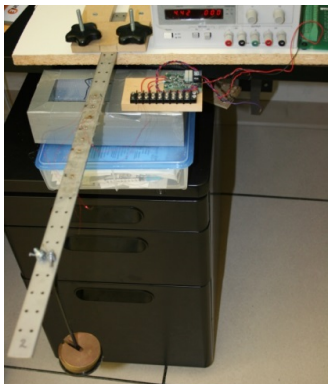

Figure 1. Experimental jig with stainless steel bar in cantilever.

The gauges attached with the Loctite adhesive were done second, also cured in an oven, followed by the gauges using the Silastic adhesive. The installation guidelines for each adhesive and coating, including surface preparation, were followed to ensure consistent results. Several gauges fastened with the Silastic product had to be refastened. The gauges were soldered and coated in a continuous fashion.

B. Performance Evaluation

For performance evaluation, the strain gauges were directly connected to an amplifier in a Type I quarter bridge configuration. A strain gauge amplifier (Quanser Consulting, Inc.) was used to read the information from the strain gauges. The other components included a dual output power supply (Agilent Technologies, model E3620A) and a data acquisition card (Keithley Instruments, model KPCI-3108). Custom software was used to read and filter the data from the gauges, perform the calibration and record the results.

To evaluate the performance of the gauges and the effect of autoclaving, the following steps were performed:

1. Each bar was mounted in cantilever such that the distances from the mounting point to the gauge and from the gauge to the weight location were always the same.
2. Each gauge was calibrated by applying weights from 0 to 1 kg in 0.1 kg increments. All calibrations were performed at a standard voltage of 5.26 V, although some gauges required a higher voltage to register a signal after autoclaving.
3. Data were recorded for 10 s when no forces were being applied to evaluate noise and drift.
4. Data were then recorded while applying weights at 0 kg, 0.5 kg, 1 kg, 0.5 kg and 0 kg again.
5. Finally, the performance was assessed by computing the following measures: (a) Accuracy was measured by comparing the measured values to the theoretical values. (b) Hysteresis was assessed by comparing the values at 0 kg and at 0.5 kg when increasing and decreasing the applied load. (c) Noise was measured by comparing the maximum and minimum values of the data when no forces were being applied. (d) Drift was computed by comparing the average of the first 500 samples and the average of the last 500 samples when no forces were being applied. A final performance measure was computed by adding the above error measures (a lower value indicates better performance).

Once the calibration and assessment were completed for all 99 gauges, the bars were placed in an autoclave (Getinge Castle 500LS series steam sterilizer) for a complete standard cycle. After the bars were dry and had returned to their normal environmental temperature, the calibration and assessment procedure was repeated. The autoclave /assessment cycle was performed a total of five times.

IV. RESULTS

A preliminary evaluation was performed to assess the performance of the 99 original strain gauges after installation, as presented below.

A. Original Performance

Due to errors in installation, only 51 of the 99 strain gauges provided a valid force measurement after installation,

as presented in Table II. The results of the preliminary evaluation are presented in Table III. As the gauges within each combination had similar performance, one combination was selected as being representative of the whole set.

In summary, there were 22 working gauges with Adhesive 1, 14 working gauges with Adhesive 2, and 16 working gauges with Adhesive 3. Similarly, there were 12 working gauges with Coating 4, 24 working gauges with Coating 5, and 16 working gauges with Coating 6.

It is apparent from these values which adhesives and coatings made the installation process more difficult. For example, the starting performance of the gauges adhered with Adhesive 3 is much poorer than the performance of the other gauges. A steeper learning curve might be involved in the application of some of these substances.

A. Performance after Autoclaving

Sample results of gauge performance following sterilization are presented in Table IV. For simplicity, only the best-performing gauge is presented. A summary of the overall results is presented in Table V, showing the average of all the gauges tested at each combination. It is clear from this table that Coating 6 was the only one able to protect the gauges well enough for any gauge to survive all 5 cycles.

TABLE II. WORKING STRAIN GAUGES FOR EACH COMBINATION OF ADHESIVE AND COATING, AND THEIR POSITION ON THE BAR.

Adhesive/coating	Working gauges	Position on the bar
1/4	3	1,3,7
1/5	10	9,9,6,4,7,5,2,4,6,7
1/6	9	9,4,3,8,6,1,5,1,8
2/4	4	4,6,1,2
2/5	8	3,5,2,7,1,9,6,4
2/6	2	1,6
3/4	5	3,6,2,9,3
3/5	6	7,4,1,5,1,7
3/6	5	8,5,9,3,9

TABLE III. SAMPLE RESULTS OF THE PRELIMINARY EVALUATION (ALL VALUES IN N).

Adhesive /coating	RMS error	Repeatability	RMS hysteresis	Noise	Drift	Total
1/4	0.03	0.04	0.05	0.17	0.02	0.31
1/5	0.06	0.07	0.04	0.23	0.03	0.43
1/6	0.04	0.04	0.12	0.15	0.00	0.35
2/4	0.08	0.05	0.20	0.19	0.02	0.54
2/5	0.13	0.09	0.21	0.21	0.07	0.71
2/6	0.05	0.05	0.04	0.18	0.03	0.35
3/4	1.64	0.44	1.48	0.93	0.09	4.58
3/5	0.25	0.08	0.17	0.34	0.04	0.88
3/6	2.32	0.87	1.43	1.31	0.45	6.38

TABLE IV. OVERALL PERFORMANCE (IN N) OF THE BEST PERFORMING GAUGES IN EACH COMBINATION, AS CALCULATED BY ADDING THE ERRORS OF ACCURACY, HYSTERESIS, NOISE AND DRIFT.

Adhesive /coating	Original	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5
1/4	0.319	1.474	–	–	–	–
2/4	0.420	0.319	0.422	1.618	–	–
3/4	3.28	–	–	–	–	–
1/5	0.356	0.724	1.307	–	–	–
2/5	0.182	0.434	0.621	1.300	–	–
3/5	0.888	29.40	9.051	–	–	–
1/6	0.348	0.334	0.544	0.459	0.380	0.406
2/6	0.602	0.680	0.764	0.808	1.365	0.992
3/6	4.627	5.508	10.34	7.494	8.185	8.712

B. Summary of Experiment 1

The results presented above show that the only gauges that survived all 5 cycles were those installed with Coating 6. Although Adhesive 1 had one gauge that survived all 5 cycles with this coating, it was the only one out of 9 that survived any autoclaving. Almost all of the gauges properly installed with Adhesives 2 and 3 and Coating 6 survived all 5 cycles. It might be possible that the low number of working gauges with the 2/6 combination and the poor gauge performance with the 3/6 combination was caused by inexperience in the installation process. It was therefore decided to examine these two combinations further.

C. Experiment 2

Based on the results obtained from the first evaluation, a total of 4 additional gauges were installed with Coating 6, two with Adhesive 2 and two with Adhesive 3 in order to perform one last comparison and tune the installation process. The installation process was modified slightly to ensure an even distribution of the adhesive over the entire gauge. All four gauges worked properly from the start. The results of the performance evaluation after autoclaving are shown in Table VI. These results clearly show that Loctite M-3981 (Adhesive 2) had much better performance and all gauges survived more cycles.

V. PROTOTYPE ASSEMBLY AND EVALUATION

Based on the results from the previous section, a sterilizable prototype of the SIMIS instruments was constructed, capable of measuring forces in 3 DOFs: perpendicular to the shaft in *x* and *y* and the grasping forces.

TABLE V. SUMMARY OF RESULTS SHOWING AVERAGE PERFORMANCE FOR ALL GAUGES IN EACH COMBINATION AND OVERALL COMMENTS.

Adhesive /coating	Average total error (N)	Autoclave survival
1/4	1.28 ± 1.26	Poor results, only one gauge survived one cycle.
2/4	3.85 ± 7.14	2 out of 5 survived after 1st cycle, only one survived Cycles 2 and 3.
3/4	4.57 ± 1.26	No gauges survived Cycle 1.
1/5	0.57 ± 0.40	Good performance. Out of 10 gauges, none survived more than 2 cycles.
2/5	0.57 ± 0.30	Good performance, but out of 8 gauges, none survived more than 3 cycles.
3/5	8.10 ± 9.24	Out of 6 gauges, none survived more than 2 cycles. Poor performance.
1/6	0.38 ± 0.11	Only one gauge out of 9 survived cycle 1 and continued to work until the end.
2/6	0.77 ± 0.38	Difficult to apply, only 2 were working from the start. The ones that did survive had excellent performance and survived 3 cycles or more.
3/6	7.46 ± 4.50	Almost all survived but original performance was very poor. Initial performance might improve with a better installation process.

TABLE VI. RESULTS OF THE EVALUATION WITH ADHESIVES 2 AND 3.

Adhesive /coating	Average performance (N)	Autoclave survival
2/6	0.26 ± 0.14	Survived all 5 cycles
2/6	0.23 ± 0.11	Survived all 5 cycles
3/6	1.11 ± 0.96	Survived all 5 cycles
3/6	1.35 ± 0.62	Survived only 3 cycles

A. Strain Gauge Installation

Four gauges were laid in a full bridge configuration on the inner shaft that connects the handle to the tip in order to actuate the grasper. These gauges measure grasping forces. To measure the forces acting perpendicular to the shaft, two half bridges were placed on the main shaft. The strain gauges were installed using Loctite M-3981. As this adhesive required curing in an oven, the gauges were placed and clamped to ensure an even distribution of the adhesive.

After installation, the gauges were coated using Loctite M-11FL. Several layers were required to ensure full coverage without dripping around the sides of the shaft.

B. Wiring and Assembly

Once the gauges were installed and the coating was dry, the instrument needed to be wired such that the cables were protected and the connector could withstand sterilization. The cables were soldered to the female side of the 1031A019 connector. All of the cables were covered in shrink wrap and the base of the connector was filled with silicone. The male side of the connector was connected to a standard 19-pin connector wired to three strain gauge amplifiers powered by a Universal Power Module (Quanser Consulting Inc., model UPM-1503). A Q8 Hardware-in-the-Loop board (Quanser Consulting Inc.) was used to capture the signals from the amplifiers. Custom software running on a Dell Vostro 420 workstation with an Intel Core 2 Quad Q8200 2.33 GHz processor served to capture, process and record the the strain gauge data. The final prototype is shown in Fig. 2.

C. Calibration and Performance Assessment

To assess the performance of the sterilizable instrument, the instrument was connected and allowed to stabilize for 1 hour. To establish the relationship between the measured voltages and the forces acting on the instrument, the instrument was calibrated using a custom calibration jig and software. The following steps were performed:

a) The instrument was first placed in cantilever as shown in Fig. 3 to calibrate the x and y moments. The instrument was aligned such that the application of weights to the tip would only create a change in one of the signals. Weights were applied at the tip from 0 kg to 0.5 kg. The instrument was then repositioned to calibrate the orthogonal direction.

b) To calibrate the inner forces, a small force/torque sensor was used (ATI Industrial Automation, model Nano-17), as shown in Fig. 3. Several values were recorded from the sensor and the instrument as the grasping force was gradually increased using a clamp on the instrument handle.

Experiments were then conducted to evaluate the performance of the force sensors. To assess accuracy for the x and y directions, the instrument was placed in the calibration test bed while the weight at the tip was increased from 0 to 0.5 kg in 0.1 kg increments. This process was repeated 3 times. The accuracy was calculated as the root mean square (RMS) of the error between the measured forces and the theoretical forces. For the grasping force, the instrument was placed in the calibration test bed and a total of 6 values were collected when varying the grasping force between 0 and 17 N. This process was also repeated 3 times. Repeatability in the x and y directions was determined by calculating the maximum standard deviation observed. For the grasping force, repeatability is presented as the total standard deviation of all 18 measurements.

3. Hysteresis: To assess the effect of hysteresis in the x and y directions, weights were applied in each direction from 0 to 0.5 kg and back to 0 in 0.1 kg increments. The values at each weight level were then compared and the RMS error was calculated. It was not possible to compute hysteresis on the grasping force as it was not possible to accurately control the closing of the graspers to a particular force value.

Upon completion of the initial performance assessment, the instruments were placed in an autoclave for one full cycle. After almost 40 hours, performance was reassessed. The results of the performance assessment before and after autoclaving are presented in Table VII. These results show that the gauges installed with the chosen combination of adhesive and coating are capable of measuring forces with good accuracy, repeatability and low hysteresis. The results also show that the measurement of forces in the y direction and the grasping forces improved after sterilization, with a small decrease in performance in the x direction.

VI. Discussion and Conclusions

This paper presented the development and evaluation of a sterilizable version of an MIS instrument capable of measuring tool–tissue interaction forces in 3 DOFs. Apart from identifying cables and connectors capable of withstanding an autoclave cycle, a series of experiments was conducted to determine an ideal combination of biocompatible adhesives and coatings for gauge installation.

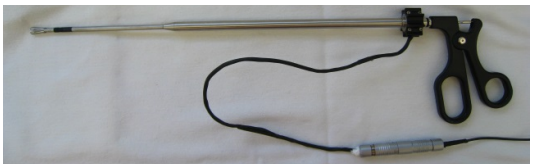

Figure 2. The sterilizable prototype.

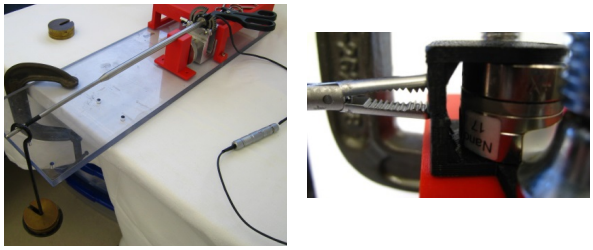

Figure 3. Instrument in test bed for calibrating forces in the x and y axes (*left*) and for calibrating the grasping force (*right*).

TABLE VII. PERFORMANCE OF THE FINAL PROTOTYPE BEFORE AND AFTER STERILIZATION (ALL VALUES IN N).

	RMS error	Repeatability	Hysteresis
Before Sterilization			
Actuation	0.40	0.35	–
x axis	0.08	0.04	0.09
y axis	0.14	0.11	0.18
After Sterilization			
Actuation	0.21	0.20	–
x axis	0.18	0.14	0.21
y axis	0.10	0.05	0.06

The results show that Loctite M-3981 adhesive in combination with Loctite M-11FL coating provides sufficient protection to allow the strain gauges to survive at least 5 sterilization cycles with excellent performance (even though the coating is only recommended for 3 cycles). Due to time constraints, additional cycles were not conducted.

Building on these results, a prototype of the instrument was constructed and put through an autoclave cycle. The performance of the sensors was measured before and after sterilization with comparable results (the results were slightly better in the *y* axis and grasping). The results show that strain gauges can be installed using biocompatible adhesives and coatings that can withstand the high temperatures, humidity and pressures required for autoclave sterilization.

Improved performance after sterilization was observed in the trials presented in Section IV and in the evaluation of the final prototype. As described in Table I, the Loctite adhesive strengthens further after autoclaving. We believe this to be the reason for the improved performance.

Although only one sterilization cycle has been performed on the current prototype, we anticipate that at least 5 cycles will be possible, based on the results of the trials presented in Section IV. Additional evaluations will be conducted as part of future work to determine the life of the instrument.

Additional work is required to determine the best way to seal and clean the instrument. The long narrow lumen of the instrument cannot be fully sealed to foreign substances due to the interchangeable tips and the nature of the actuation mechanism of the instruments. Methods for flushing the inside of this type of device have been implemented in the past for medical devices and a similar procedure is expected to be acceptable for this instrument as well. However, there are also mating surfaces between components that need to be sealed in order to ensure that debris does not enter these areas, as it would not be possible to properly flush them without full disassembly—a process that would expose sensitive parts of the instruments and should be avoided. Research into proper sealing materials is necessary.

Finally, the cleaning and disinfecting procedure required for medical devices will have to be properly outlined. Experiments need to be performed to find detergents and enzymatic cleaners that do not react with the sealing materials or with the adhesives and coatings selected above. This will also involve determining the required exposure times and validating that the instruments are fully disinfected prior to reassembly and sterilization.

An adequate method for calibrating the instruments once sterilized will also need to be outlined. It is not feasible to have the instruments calibrated using the current techniques if they have been sterilized for surgical use. The current calibration method is also time consuming and cumbersome. A more automated calibration method can be developed using a 6 DOF force/torque sensor as the basis for the calibration. These issues will be investigated in future work.

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