Communications

Integration of a Miniaturised Triaxial Force Sensor in a Minimally Invasive Surgical Tool

Pietro Valdastri*, Kanako Harada, Arianna Menciassi,
Lucia Beccai, Cesare Stefanini, Masakatsu Fujie, and Paolo Dario

***Abstract*—This paper reports preliminary results on design and fabrication of a cutting tool with an integrated triaxial force sensor to be applied in fetal surgery procedures. The outer diameter of the proposed device is 7.4 mm, but a scaled down design can be easily achieved. Linearity and hysteresis tests have been performed for both normal and tangential loadings. A linear transformation relating the sensor output to the external applied force is introduced and discussed. The typical working range for the conceived instrument is around 0.3 N, while 20 N and 1 N are, respectively, maximum normal and tangential forces for which the device robustness has been assessed.**

***Index Terms*—Fetal surgery, minimal invasive surgery, "smart" surgical tool, triaxial force sensor.**

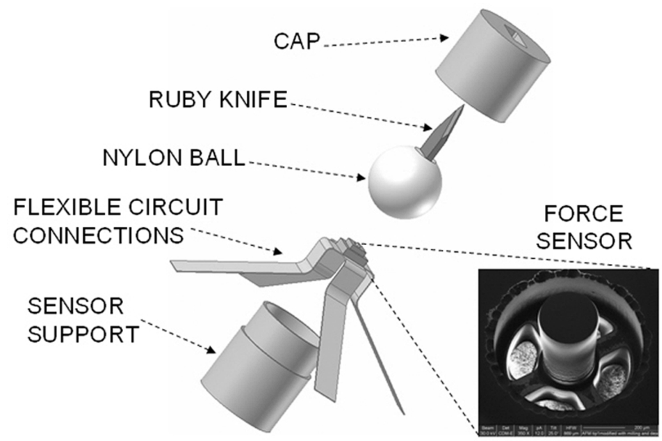

Fig. 1. Exploded drawing of the proposed surgical tool. Inset: Focused Ion Beam image of the silicon triaxial force sensor.

I. Introduction

In emerging fetal surgery procedures, the accuracy and miniaturization of surgical tools are dramatically important in order to avoid damage to both the fetus and the future mother. In [1], a novel surgical robotic system for intrauterine fetal surgery under open magnetic resonance imaging (MRI) is presented. The target disease, unfortunately quite common, is *spina bifida* or myelomeningocele, that is the incomplete closure in the spinal column. In the proposed surgical process, both the abdominal and uterine walls would not be heavily incised, but rather surgical instruments are inserted through small holes in these walls to perform minimally invasive surgery (MIS). Damage to the uterus and fetus could cause premature delivery or lead to the need for Caesarean section. A surgical knife embedding a force sensor and designed to operate during cutting of the very delicate and soft fetal skin would give the surgeon force feedback and valuable information about the orientation of the knife on the tissue. Several instruments (scalpel, forceps, etc.) equipped with force sensors have been introduced in MIS, as reported in [2]–[4]. On the other hand they cannot be easily scaled down to the size requested for the integration on the tip of a bending manipulator as the one reported in [1]. In addition, they do not meet the specifications for MR safety as defined in [5].

The device presented in this paper applies a MEMS-based triaxial force sensor to the blade of a cutting tool and demonstrates the feasibility of accurate force sensing capabilities integrated into the tip of a bending manipulator for fetal surgery.

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*P. Valdastri is with CRIM Lab, Scuola Superiore Sant'Anna, Pisa 56025, Italy (e-mail: p.valdastri@crim.sssup.it).

K. Harada and M. Fujie are with Waseda University, Tokyo 169-8050, Japan.

A. Menciassi, L. Beccai, C. Stefanini, and P. Dario are with CRIM Lab, Scuola Superiore Sant'Anna, Pisa 56025, Italy.

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II. System Design and Fabrication

The core component of the device presented in this paper is a silicon based triaxial force sensor. Its design and performances are reported in [6]. It is composed of two silicon chips, connected together by flip-chip bonding: a sensing part, represented in the inset of Fig. 1, and a support part that has the function of a carrier chip. While the sensing chip is $1.5\ \mathrm{mm} \times 1.5\ \mathrm{mm} \times 0.5\ \mathrm{mm}$, the overall dimension of the sensor, composed of the two silicon parts, is $2.3\ \mathrm{mm} \times 2.3\ \mathrm{mm} \times 1.3\ \mathrm{mm}$. As regards the principle of operation of the force sensor, the central cylindrical pillar is sustained by four cross shaped tethers, having each a p-type piezoresistor implanted. The three components of an external applied force can be obtained from the four fractional changes in resistance of the piezoresistors.

Several issues must be considered in order to select adequate packaging materials and to design the instrumented device, so that it can be properly integrated onto the tip of a bending manipulator working safely in an MRI environment:

- depending on the very delicate application, a trade-off between maximum loads and sensitivity must be considered;
- a flexible and reliable wiring connection must be implemented;
- because of the presence of conductive and ionic body liquids in the operative site, sealing must be seriously considered;
- all the employed materials must be MR safe and meet biocompatibility standards.

By considering these issues, a mechanical interface with the purpose of reliably transmitting the force applied on the knife to the mesa of the MEMS sensor has been designed. A flexible wiring connection has been used to connect the four piezoresistors to the external acquisition electronics. A flexible circuit has been obtained from LF9150R Pyralux (DuPont, USA). High-resolution copper tracks have been shaped by using MicroPosit S1813 photoresist (Shipley, USA) in a photolithographic process. The force sensor has been glued onto the flexible circuit and its pads have been connected to the copper tracks by wire bonding. This step defines the inner diameter of the device, because

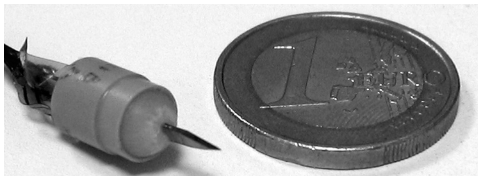

Fig. 2. Picture of the developed force sensing device without the covering cap.

wire bonding connections require additional space to the one needed for the silicon sensor. Since the final target of miniaturization should be pursued, in future prototypes the sensing chip $(1.5\ \mathrm{mm} \times 1.5\ \mathrm{mm} \times 0.5\ \mathrm{mm})$, that has electrical connection pads on the lower side would be directly bonded to the flexible circuit by using conductive glue or similar techniques. Thus, the same design can be scaled down to a diameter of 2.3 mm and fetal surgery applications could be then addressed. A cylindrical sensor support has been fabricated in Polyether Ether Ketone (PEEK), by using a 5-axis CNC machining center. The external diameter is 7.4 mm, while the internal one is 6.33 mm, which is the smallest dimension that can host the force sensor connected to the flexible circuit through wire bonding. Four holes at the bottom supporting part allow the circuit to exit and to be connected to an external acquisition system. A Nylon ball, with a diameter that is equal to the inner one of the sensor support, is mechanically connected to the force sensor through soft polyurethane (Poly 74-45, PolyTek, USA). A ruby blade has been chosen as tip, in order to accomplish a sharp incision of biological tissues. The ruby knife is 5.5 mm long, 2 mm wide, and 500 μm thick. It has been attached to the ball by cyanoacrylate glue. The surface where the ruby knife is glued has been machined using abrasive paper, in order to have a better adhesion between the two parts. An exploded view of the conceived device is represented in Fig. 1.

All used materials, e.g., ruby, Nylon, PEEK, copper, and polyurethane, are MR safe. In addition, polyurethane is also commonly used to embed electronics components and it highly increases the robustness of the silicon sensor by penetrating into the empty cavities and acting as a mechanical soft stop in case of overloading. The use of a spherical interface between the support of the blade and the sensor ensures an isotropic transmission of the force, thanks to its symmetry. All the packaging components have been designed so that, during a pure tangential loading, the Nylon ball rotates around its center.

The assembly procedure involves the following steps.

- The sensor, connected to the flexible circuit, is glued onto the sensor support.
- An abundant polyurethane quantity is poured on the top of the force sensor.
- The ball is placed on the polyurethane.
- A cap is used to close the device so that the machined surface of the Nylon ball contacts the top inner surface of the cap. The cap has been purposely designed to impose a desired distance D, between the sensor mesa and the sphere by following the next two process steps.
- All exceeding polyurethane is pushed out from the vias, in the lower part of the sensor support, where the flexible connections pass through. In this step, it is possible to guarantee proper sealing of the device inner space and the achievement of the desired distance D.
- After polymerization the cap is removed, the blade is glued to the flat surface of the ball (Fig. 2), and the cap is placed in its final position.

The main drawback of using a soft polyurethane filling is a loss in sensitivity and linearity of the sensor response; thus, a trade-off must be found in specifying the distance D. In fact, when this distance is small, the mechanical compliance of the transmission is low, and consequently large forces can be transmitted to the sensor, thus resulting in high fidelity, but also in low robustness. On the other hand, with large distance, the compliance between blade support and sensor is high, thus protecting the silicon structure from large forces, but also decreasing the sensitivity and amplifying the hysteresis, due to the polymeric material. In order to have the desired robustness and sensor performance for forces in the range of 0.3 N (typical values required to perforate tissue layers during bypass grafting [7]), the optimal value of D has been experimentally determined to be 1.5 mm. Therefore, the amount of polyurethane in the inner cavity of the device is around 40 mm^3.

Tangential loads applied to the device are more critical than normal loads: when tangential forces are applied, the detachment of the Nylon ball from the polyurethane filling can occur. Thus, a mechanical stop for the lateral blade movement has been conceived through a proper design of the slot placed on the top part of the cap. Hence, by modeling the tangential loading of the blade with an elastic constant, derived from experiments, it is possible to design the slot in order to stop the lateral blade movement as soon as the maximum force is reached.

III. Experimental Results

The test bench used to validate and characterize the device has been described in [8], where it has been used for the bare silicon sensor characterization. This allows a more straightforward comparison between the results obtained from the final device and those from the force sensor without packaging. All the following data have been acquired at a sampling rate of 100 samples per second and then denoised using SWT De-Noising 1-D (Wavelet Toolbox 2.2, Matlab, The Mathworks, Inc., Natick, MA) applying a 5-level Haar wavelet decomposition, considering an unscaled white noise structure and using a fixed form soft threshold method, where the threshold is assumed 3.5% of the full scale range.

A. Linearity and Hysteresis

A first set of tests has been performed in order to measure the system linearity and quantify the hysteresis during normal and tangential loadings. In particular, the following three loading schemes have been investigated.

- Normal loading (Z axis).
- Tangential loading along the $R_3 \rightarrow R_1$ direction (X axis).
- Tangential loading along the $R_2 \rightarrow R_4$ direction (Y axis).

These three loading configurations are linearly independent and allow, in case of linearity, to build a calibration matrix originating from the acquired data.

During normal tests, a load increasing from 0 N up to 1 N has been applied at a translational constant speed of 70 $\mu\mathrm{ms}^{-1}$. Sensor outputs, in terms of fractional change in resistance $\Delta R/R$ versus normal loading force, are plotted in Fig. 3.

A normal hysteresis cycle, obtained when an applied force increases up to 0.9 N and decrease back to zero at a loading frequency of 0.1 Hz, is represented in Fig. 4. By defining the *hysteresis ratio* $\hbar$ as

$$\hbar = \frac{\mathrm{Loop\ Area}}{\frac{\mathrm{Max\ (Loading\ Force)} \times \mathrm{Max\ (\Delta R/R)}}{2}} \tag{1}$$

the result is $\hbar = 0.144$. The coefficient of determination, considering both the loading and the unloading parts of the cycle, is found to be around 0.96 for all the piezoresistors.

The sensor outputs for an applied tangential load along the X axis are plotted in Fig. 5. In this configuration, the sphere transmits the applied force to the polyurethane filling and then to the force sensor; in this way R_3 and R_1 exhibit an opposite behavior, while R_2 and R_4 are not significantly influenced. The coefficients of determination are 0.964

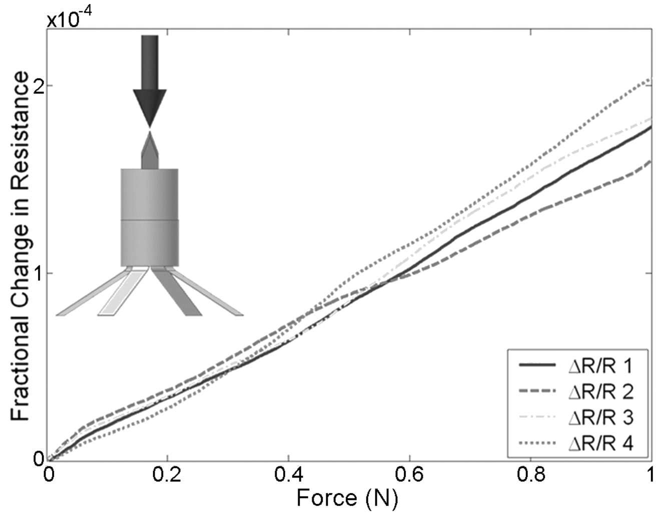

Fig. 3. Sensor response to a normal loading.

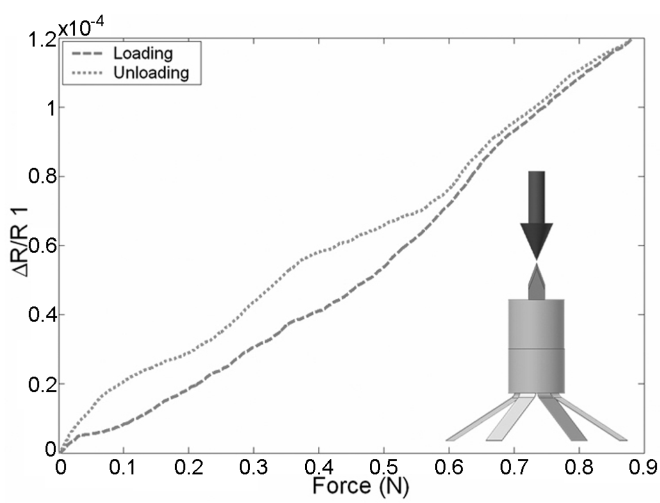

Fig. 4. Hysteresis cycle for normal loading.

for $\Delta R/R1$ and 0.97 for $\Delta R/R3$. The same applies to the results of a pure tangential loading along the Y axis. In this case, the coefficients of determination are 0.97 for $\Delta R/R2$ and 0.98 for $\Delta R/R4$. For tangential loading the *hysteresis ratio*, defined in (1), is $\hbar = 0.131$.

Standard deviation of calibration data, evaluated on 20 trials, is lower than 2% of the signal full scale range. The calibration reported in this paper has been performed at thermal equilibrium at room temperature without temperature compensation. For microsurgical use, the effects of thermal variation on the piezoresistor output should be precisely characterized via calibration experiments in a thermal chamber. The resulting data would enable compensation of the sensor output for the effects of thermal variation. Force resolution, limited by sensor noise performances, is about 3 mN for tangential loadings and 20 mN for normal loadings.

The stiffness associated with blade movement during tangential loading has been experimentally evaluated. As discussed in Section II, this value is useful for designing a proper housing for the blade in the device cap. Considering the tangential load applied as in the previously introduced configurations, the stiffness that relates the blade lateral

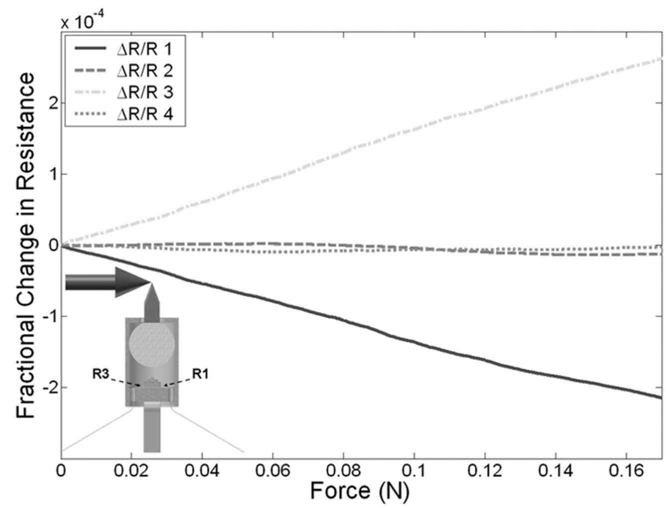

Fig. 5. Sensor response to a tangential loading along $R_3 \rightarrow R_1$ direction.

displacement to the applied force is $k = 0.7\ (\mathrm{N/mm})$ for both the X and Y directions. Such a value must be scaled through a trigonometric transformation in order to relate the applied force to the movement at the blade base, that is where the cap slot would act like a mechanical stop. The trigonometric transformation can be applied since the center of rotation of the Nylon ball is coincident with its center. Thus, it results $k' = 1.8\ (\mathrm{N/mm})$.

Finally, maximum loading force ranges have been evaluated through experiments. Regarding normal loadings, the device overloading limit increases from 3 N of the bare silicon sensor up to 20 N thanks to the polyurethane filling that absorbs the applied compression. While for tangential forces, if the covering cap is removed, the detachment of the Nylon ball from the polyurethane filling occurs at around 1 N.

B. Sensitivity Matrix

Once the linearity and the low hysteresis of the device have been assessed, a linear transformation from the four values of fractional changes in resistance (vector $\overline{\Delta R}/R$) to the values of the three components of the force (vector $\overline{F}$) can be used. As introduced in [8], the linear transformation K applies

$$\overline{F} = K\frac{\overline{\Delta R}}{R}. \tag{2}$$

In order to assess how the force sensor performances are influenced by the packaging process, the K matrix has been previously evaluated on the bare silicon force sensor before its embedding, thus obtaining

$$K^{\text{bare}} = \begin{pmatrix} 4.92 & 0 & -4.86 & 0 \\ 0 & -5.3 & 0 & 4.6 \\ 6.65 & 5.62 & 4.73 & 5.89 \end{pmatrix} \mathrm{N}. \tag{3}$$

The experimental sensitivity matrix S_E^{bare}, which is the Moore-Penrose pseudoinverse of matrix K^{bare}, is

$$S_E^{\text{bare}} = \begin{pmatrix} 0.094 & 0 & 0.043 \\ 0 & -0.1 & 0.04 \\ -0.11 & 0 & 0.043 \\ 0 & 0.096 & 0.047 \end{pmatrix} \mathrm{N}^{-1}. \tag{4}$$

The sensitivities of the force sensor, defined as in [8], are

$$\begin{aligned} S_x^{\mathrm{bare}} &= 0.11\ \mathrm{N}^{-1} \\ S_y^{\mathrm{bare}} &= 0.1\ \mathrm{N}^{-1} \\ S_z^{\mathrm{bare}} &= 0.047\ \mathrm{N}^{-1} \end{aligned}.$$

Evaluating the same quantities for the proposed surgical tool, the K matrix results

$$K = \begin{pmatrix} -343.1 & 0 & 375.49 & 0 \\ 0 & 395.19 & 0 & -341.68 \\ 1496.7 & 1353.3 & 1224.6 & 1437 \end{pmatrix} \mathrm{N} \tag{5}$$

and the experimental sensitivity matrix S_E is

$$S_E = \begin{pmatrix} -1.3 & 0 & 0.2 \\ 0 & 1.4 & 0.2 \\ 1.5 & 0 & 0.2 \\ 0 & -1.3 & 0.2 \end{pmatrix} \times 10^{-3}\ \mathrm{N}^{-1}. \tag{6}$$

Thus, the sensitivities are

$$\begin{aligned} S_x &= 1.5 \times 10^{-3}\ \mathrm{N}^{-1} \\ S_y &= 1.4 \times 10^{-3}\ \mathrm{N}^{-1} \\ S_z &= 0.2 \times 10^{-3}\ \mathrm{N}^{-1}. \end{aligned}$$

IV. DISCUSSION

Experimental results reported in the previous sections have been obtained with a device having a D of 1.5 mm. The lower this design parameter is kept, the more the device performances will be close to the bare force sensor ones.

The actual hysteresis level is still too high to enable accurate force sensing in a fetal surgery scenario. However, by reducing D, the hysteresis can be reduced as well, with the drawback of a decrease of the full loading range. Another way to further reduce the hysteresis effect is to use a filling material with different mechanical properties. By scaling down the design, as introduced in Section II, the space filled with soft polymer would also scale down, thus enabling a significant reduction of hysteresis levels.

Larger hysteresis in the sensor response occurs for normal rather than tangential loading. A possible explanation is that during normal loading the Nylon ball axially slides inside the cylindric housing, while, in tangential loading, rotation is small and there is a small displacement with respect to the housing. Thus, normal hysteresis is both caused by the material intrinsic viscoelasticity and by friction at the interface between the housing and the internal parts, while tangential hysteresis is mainly due to material nature.

The decrease in sensitivity due to the polyurethane filling is clearly evident, since $S_\bullet^{\mathrm{bare}}$ and $S_\bullet$ differ by two orders of magnitude. Comparing the K and the S_E matrices for the silicon sensor and for the final device, the mechanical effect of force inversion during tangential loadings becomes evident. In particular, K_{11}^{bare} is opposite in sign if compared to the same element of the K matrix, and the same applies for K_{13}^{bare}, K_{22}^{bare}, and K_{24}^{bare}. This is due to the spherical element in the force transmission path, which is responsible for the inversion in the direction of tangential loadings.

V. CONCLUSION

Feasibility of mounting a triaxial force sensor on the tip of a bending manipulator has been demonstrated in this paper. Even if dimensions of the reported prototype are still too large to allow practical fetal surgery procedures, scalability of the proposed device and approach has been discussed and it will be pursued in future works. Safety and sterilization issues must also be addressed. ac driving of the Wheatstone bridge or the use of an isolation amplifier (e.g., AD208 from Analog Devices) instead of a normal instrumentation amplifier are two strategies that can be adopted in order to improve safety. Techniques like Ethylene Oxide sterilization can be taken into account for the proposed device, since it does not impose a high temperature and pressure on the device, even if it could leave residues in the packaging. All materials that have been used to assembly the prototype are MRI safe. Thus, after a proper assessment, the device could be safely used inside a MRI room during time slots between two following MRI image acquisitions. In order to use the device also during MRI imaging, MRI compatibility assessment is needed and this issue will also be investigated in future work.

The same design principle may be used for other biomedical applications where three dimensional force sensing on the device distal part is required. Based on the different applications, the blade can be replaced by other kinds of probes. The same applies for the correct dimensioning of the distance D that must be tailored, depending on the required loading range and sensitivity.

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