MINIATURIZED MAGNETIC FORCE SENSOR ON A CATHETER TIP

G. Chatzipirpiridis[1], S. Gervasoni[1], F. Berlinger[1], S. Blaž[2], O. Ergeneman [1], S. Pané[1] and B. J. Nelson[1]
[1]Multi-Scale Robotics Lab, Institute of Robotics and Intelligent Systems, ETH Zurich, Zurich, Switzerland
[2]RLS merilna tehnika d. o. o., Komenda, Slovenia

ABSTRACT

This paper reports the smallest magnetic force sensor integrated on a catheter tip. The sensor is capable of high sensitivity and robust force measurements suitable for *in-vivo* applications. It utilizes a magnet mounted on a flexible membrane encapsulating the catheter and a Hall sensor to detect the magnetic field generated by the magnet. The proposed device can be used in many applications of minimally invasive surgery (MIS) to detect forces applied on tissue during procedures or to characterize different types of tissue for diagnosis.

KEYWORDS

Catheter, permanent magnet, magnetic sensor, Hall sensor, tissue characterization

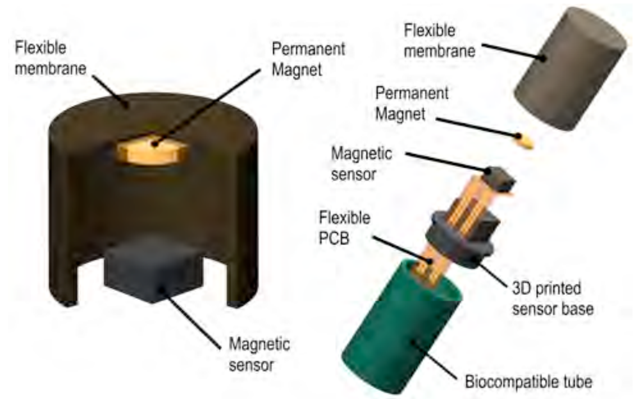

Figure 1: On the left the magnetic force sensor and on the right the assembly on a catheter tip.

INTRODUCTION

Motivation

The last decade has seen conventional surgical procedures increasingly being replaced by minimally invasive surgery **(**MIS) methods such as hypodermic injection, percutaneous surgery, angioplasty, or coronary catheterization. MIS has not only aided surgeons in delicate interventions, but also provided more comfort to patients by reducing pain, blood loss, and hospitalization [1]. Despite the benefits of MIS, surgeons still face several technical challenges such as restricted ergonomics, difficulties reaching certain organs or tissues, or inaccuracy in estimating the forces exerted at the operating site. During open surgery, surgeons rely on tactile sensations to guide tissue manipulation and examination [2]. Studies have demonstrated that tumors can be distinguished through the stiffness variation in the tissue [3,4]. Analogous examination becomes difficult with MIS. Yokoyama et al. first reported the important relationship between catheter/tissue contact force and lesion size in a preclinical study. In a recent publication it was shown that sensing the contact forces between catheter and tissue reduces the risk of steam pop and thrombus [5]. While miniaturized catheter sensors using fiber optic sensors have been demonstrated [6], there is strong interest to further scale down these devices and improve robustness.

Concept

In this paper we propose a miniaturized force sensor integrated on a catheter tip for MIS applications. The device utilizes a magnetic Hall sensor and miniature permanent magnet mounted on flexible encapsulation acting as the sensing membrane. Figure 1 illustrates the sensor system on a catheter tip. When an external force is applied to the force sensor, the membrane deflects causing the permanent magnet to change its position. This leads to a variation of the distance between the Hall sensor and the permanent magnet and to an increase in the magnetic field strength read by the sensor. This increase of the magnetic field induces a voltage change in the Hall sensor. Figures 2 and 3 show the 3D deformation plot and deflection versus applied force plot, respectively, obtained by finite element analysis (FEA) simulations when a force is applied to the catheter. Three different flexible membrane thicknesses were simulated: t = 250 µm, t = 500 µm, and t = 750 µm.

FABRICATION

General arrangement

The catheter is composed of six main components. Figure 1 shows these components and their arrangement. Starting from the bottom, a biocompatible tube, acts as the main support for the entire system. Inside the biocompatible tube a flexible printed circuit board (PCB) is mounted to transmit the data from the Hall sensor to an external device. The tip arrangement is based on a 3D printed part shaped as a rectangular pillar. The rectangular pillar is arranged in a way that the flexible PCB is attached to one of the lateral faces and bent at the top forming an L-shape. The end of the flexible PCB is attached to the top face of the rectangular pillar and holds the Hall sensor. To complete the system a flexible membrane is attached to the rectangular 3D printed part. A small spacing is left between the Hall sensor and the internal surface of the membrane, where a NdFeB permanent magnet is installed.

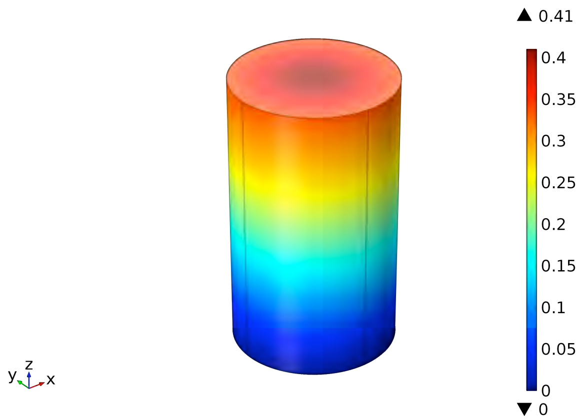

Figure 2: FEA simulation of the deflection of the flexible membrane when a force is applied on the top surface. Based on FEA simulations the range and sensitivity of the sensor can be adjusted by changing the geometry and material of the membrane. The used flexible membrane has an outer diameter of 2 mm, inner diameter of 1 mm, membrane thickness of 500 μm, and a height of 3.5 mm. It is made of silicon rubber.

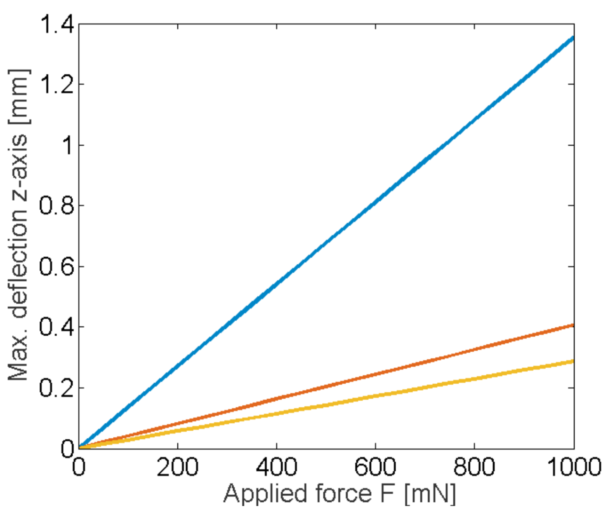

Figure 3: The displacement of the membrane plotted as a function of the applied force. The three lines starting from the top correspond to membranes with thicknesses of 250 μm (blue), 500 μm (red), and 750 μm (orange), respectively. Linear behavior is observed in the range of interest of forces.

Hall sensor

A Hall sensor die is used to ensure maximum miniaturization and sensitivity to the external field from the magnet. The dye is wire bonded on the thin flexible PCB before being integrated on the catheter. Figure 4 shows the Hall sensor wire bonded on the flexible PCB placed on a fingertip. The Hall sensor outputs an analog signal and only requires four lines for operation. Two lines are used for biasing the device by applying a current and the other two are used to measure the Hall voltage corresponding to

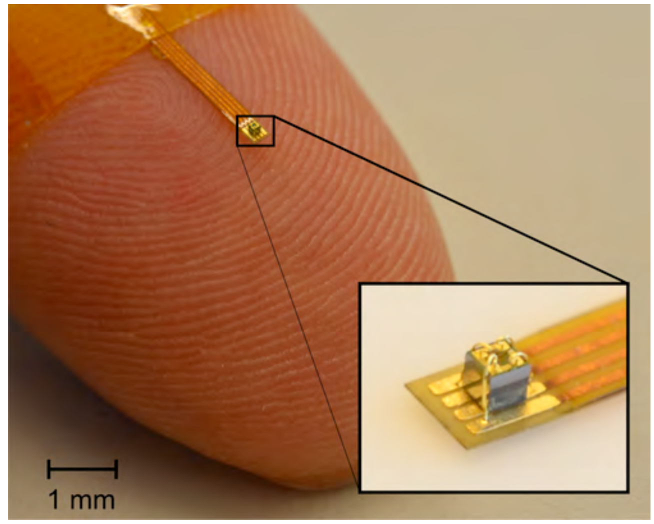

Figure 4: The Hall sensor wire bonded on the flexible PCB placed on a fingertip. Prior to wire bonding the Hall sensor die is glued with a biocompatible epoxy to the flexible PCB. The flexible PCB serves as the connection between the Hall sensor and the external readout circuit.

the magnetic flux density. To ensure mechanical stability the dye is glued with a biocompatible epoxy on the flexible PCB before wire bonding. A readout circuit is designed and implemented to measure the magnetic field values. The flexible PCB provides the connection to the external readout circuit via the catheter. The readout circuit makes the A/D conversion and sends the final reading to a computer for further processing.

Flexible membrane

The flexible encapsulation membrane is prepared by molding silicon in a 3D-printed mold. The molding is conducted in a vacuum chamber using a room temperature **v**ulcanizing silicone compound. This procedure ensures a smooth, bubble-free membrane with isotropic mechanical properties. This is especially important to ensure reliable reading of the membrane deflection under different bending angles. In addition, the silicone compound is not toxic and suitable for medical use. It has very high resistance to chemicals for example acidic solutions allowing the catheter to operate in harsh environments like the stomach.

The membrane with the magnet and the flexible PCB are incorporated in a biocompatible tube resulting in a catheter with a diameter of 2mm. The magnet is fully integrated in the silicone membrane during the molding process. This process guarantees good adhesion to the membrane and allows large deformations. This is extremely important for the reliability of the entire system. The flexible silicon membrane is strongly attached to the biocompatible tube forming a perfect seal. This seal provides isolation from the surroundings and protects the inner components from tissues and bodily fluids. Figure 5(a) shows the assembled catheter next to a coin. Figure 5(b) shows an exploded view of the catheter components.

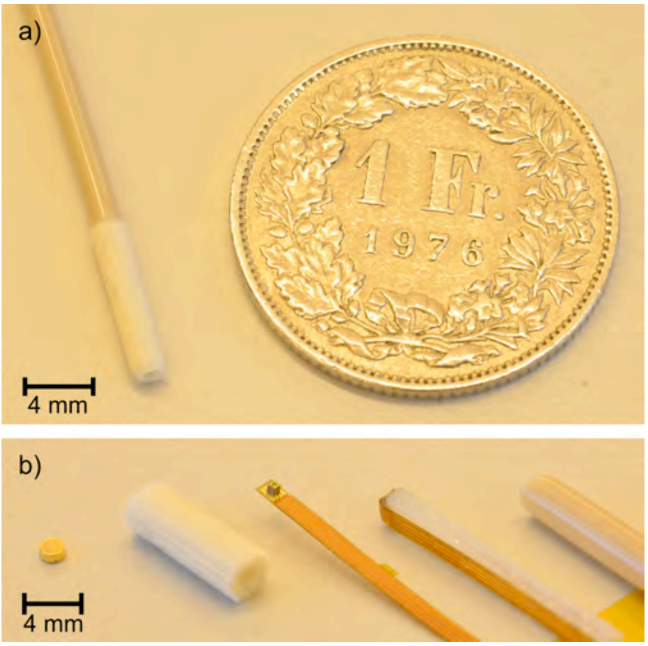

Figure 5: a) The assembled catheter next to a coin. b) Exploded view of the catheter components. From left: the permanent magnet, the flexible membrane, the flexible PCB with a wire bonded Hall sensor, the 3D printed base, and the biocompatible tube.

The components are as follows starting from left: the permanent magnet, the flexible membrane, the flexible PCB with a wire bonded Hall sensor, the 3D printed base, and the biocompatible tube.

RESULTS AND DISCUSSION

Device characterization

In order to convert the magnetic readings into a force reading, the flexible membrane bending has to be characterized and calibrated. First, the magnetic field change due to displacement of the magnet was characterized. The magnet was mounted on a micromanipulator and the magnetic field was measured by the Hall sensor as the magnet was moved away from the sensor. With the measured data, it was then possible to derive a look up table and the corresponding relation between magnetic field and displacement. Fig. 6 shows the experimental magnetic flux density variation with respect to distance to the sensor. Vertical displacement of zero corresponds to the surface of the magnet. The magnetic flux density drops rapidly going away from the magnet. This behavior is critical for the operation of the catheter. To maximize the sensitivity and have sufficient field strength, the magnetic Hall sensor should be mounted as close as possible to the magnet. By using the stiffness information of the membrane, the displacement measurements can be converted into force values. In this work FEA-based stiffness values are used to calculate the force. It was found that the force sensor has a displacement resolution of

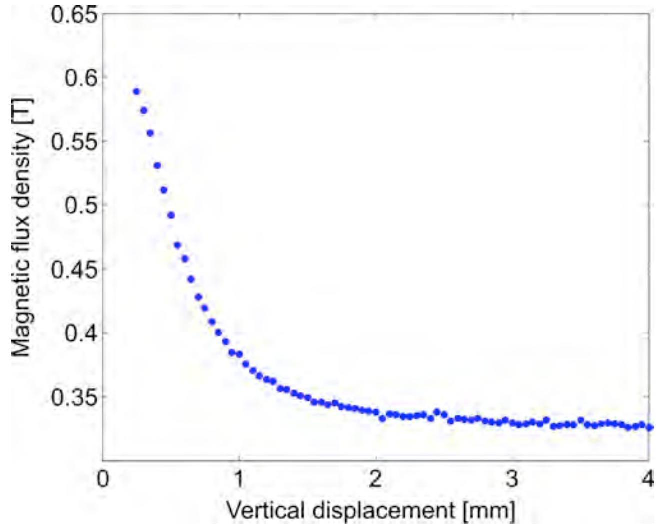

Figure 6: Magnetic flux density plotted from the surface of the magnet. The data is measured with the Hall sensor wire bonded on the flexible PCB. The magnet was moved by a SmarAct micromanipulator. Zero vertical displacement (x = 0) corresponds to the surface of the magnet.

50 µm and a range of 1 N, which is within the specifications required by clinical applications.

CONCLUSION

A miniaturized force sensor integrated on a catheter is demonstrated. The sensor is capable of high sensitivity and robust force measurements suitable for *in-vivo* biomedical applications. The proof of concept for force sensing utilizing a magnet mounted on a flexible membrane and a Hall sensor to detect the magnetic fields is shown.

The proposed device can be used in applications of minimally invasive surgery (MIS) to detect forces applied on tissue during procedures or to characterize different types of tissue for diagnosis.

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CONTACT

*G. Chatzipirpiridis, tel: +41-044-6323669;
chgeorge@ethz.ch