Flexure-based multi-degrees-of-freedom in-vivo force sensors for medical instruments

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Abstract
This paper presents novel multi-degrees-of-freedom force sensors based on flexures used as mecano-optical transducers (named flexure body) and white light interferometers used as opto-electrical transducers. Together, these transducers make up a load cell exploiting the nanometric accuracy of Fabry-Pérot interferometric measurement to reach milli-Newton force accuracy. The design focuses on the flexure body composed of three sections: a base (attached to the measuring device), a compliant section which deforms under applied forces and a pointed rigid section whose tip touches tissues during surgery. The fiber interferometer measures the distal displacement with respect to the base using one 125 µm diameter optical fiber for each load cell DOF. The key advantages of this design are: compact design (1 to 4 mm diameter shaft), simple optical alignment during assembly, scalability from Newton down to milli-Newton force levels, insensitivity to electrical charge and compatibility with sterilization procedure. These properties satisfy the requirements of in-vivo force measurements during surgery. The paper presents analytical stiffness estimation of 1 DOF flexure bodies and finite element stiffness analysis of multiple-DOF structures followed by the design, manufacturing and assembly process. The realized sensors are then characterized experimentally on a specifically designed motorized test-bench, which allows application of calibrated forces from various directions onto the sensor tip. A specific calibration strategy was developed improving measurement accuracy of the sensor.

Keywords:
In-vivo force measurement, compliant mechanisms, Fabry-Pérot interferometry, optical fiber, heart surgery, ear surgery.

1. Introduction
Force measurement provides quantitative feedback between medical tools and patient tissue during surgery. It is valuable for handheld instruments and catheters, as well as for robotic surgical systems. Feedback increases the information obtainable by a surgeon’s hand alone. Sensor miniaturization can provide force information below human sensory threshold as with instruments proposed by He [1]. Force sensing instruments for Minimally Invasive Surgery (MIS) provide information on tissues compliance, something previously possible only during traditional open surgery. Thanks to contact force sensing catheters, tactile information can be extracted from areas not accessible with other tools, thereby increasing the efficiency of ablation, as reported by Kuck [2].

Medical interventions such as MIS lack visual feedback so require alternative imaging methods, Magnetic Resonance Imaging (MRI) being a leading option. However, this introduces magnetic fields to the operating room which, along with electrically powered instruments such as coagulators, can generate high noise for electrical force sensors. It is therefore preferable to use optical sensors which are insensitive to such perturbations. There are two leading optical force sensing technologies. One is based on the Fiber Bragg Grating (FBG) and the other, the focus of this study, uses Fabry-Pérot interferometry. The problem with FBG sensors is a lower sensitivity in the principal tool axis, thus requiring higher tool complexity leading to a greater volume. On the other hand, Fabry-Pérot sensors can provide uniform force sensitivity in all three orthogonal directions using single body force-to-displacement transducers, the intellectual property advance has been protected by Sensoptic SA [3]. Core of the Fabry-Pérot interferometer consist of two partially reflective surfaces spaced micrometers apart. Light ray transmitted through such geometry is split and generates interferometric pattern, with constructive interference when all the beams are in phase. This paper can be considered as an introduction to the systematic development of sensors taking advantage of this advance.

Figure 1. a) Force sensing instrument, b) Flexure body, c) Cross section showing the fiber locations A, B and C, d) Fabry-Pérot cavity
2. Load cells

Our load cells consist of a single mecano-optical transducer which we call the flexure body and one or more opto-electrical transducers based on white light Fabry-Pérot interferometry. The article focuses on the design and development of the flexure body, while using commercially available opto-electrical transducers.

2.1. Mecano-optical transducer: converting force into displacement

Figure 1a shows a typical force sensing medical instrument with the coordinate system at the point of force application. Figure 1b shows a detailed section of the flexure body: the base, considered to be a rigid body, is connected to the handle. On the other side is the pointed rigid section with tip adapted to tissue palpation. The compliant mechanism forming the mecano-optical transducer links the tip to the base. It defines force measuring parameters such as force range and number of DOFs. Different topologies of this compliant structure are proposed below.

2.2. Opto-electrical transducer: converting displacement into electrical signal

Figure 1d shows the Fabry-Pérot cavity whose length changes with the flexure body deformation. When force is applied, the initial distance between the optical fiber and mirror changes. A distal light source generates an initial ray through an optical fiber of 125 μm diameter. A portion of this ray is reflected back from the end of the fiber, while the remaining portion is reflected by the mirror and returns into the fiber. The interference between these two rays is detected by the interferometer. Displacements ranging from -5 μm to +5 μm from the rest position can be measured with 5 nm resolution and 50 Hz acquisition rate. Based on the measured displacement using the stiffness matrix of the flexure body.

3. Flexure body development procedure

3.1. Requirements

Consultation with clinicians provided specifications for the force range, number and type of DOFs, pointed tip shape, application dynamics, tool sterilization and other constraints.

3.2. Mechanical design

The design of the architecture of the compliant section followed guidelines developed by Simon Henein [4]. A significant advantage of this structure is the monolithic nature of the flexure structure allowing the decomposition of a 3D force into three parallel displacements measurable by individual fibers. Moreover, using flexures suppresses solid friction and the associated hysteresis. This ameliorates the resolution and lowers limit of the force measurement.

3.3. Analysis

Two methods were used: the first one is based on analytical calculations with classical beam theory, assuming the blades are of constant cross-section. The second method uses Finite Elements Analysis (FEA) with Comsyl Multiphysics, letting more complex shapes be treated.

3.4. Manufacturing

The flexure body transducers were made out of medical Grade 5 Titanium and manufactured using Wire-Electrical-Discharge Machining (Wire EDM) with a 100 μm diameter wire.

3.5. Characterization and calibration

Each manufactured transducer was tested by an automated characterization setup operating in two modes. First with the calibration mass attached to the tip of tested probe, then with a reference force sensor applying a load to the tested probe. In both cases, the tested probe was rotated with a 10’ raster covering a half-sphere of force directions either in relation to gravity or to the principal axis of the reference force sensor.

In order to determine the applied force vector from the interferometer readings, a mathematical model was constructed. This model introduces a stiffness matrix which defines the force components \(F_x, F_y, F_z\) in terms of the measured displacements \(d_1, d_2, d_3\). The matrix then acts as

\[
\vec{F} = \begin{bmatrix} F_x \\ F_y \\ F_z \end{bmatrix} = \begin{bmatrix} k_{11} & k_{12} & k_{13} \\ k_{21} & k_{22} & k_{23} \\ k_{31} & k_{32} & k_{33} \end{bmatrix} \begin{bmatrix} d_1 \\ d_2 \\ d_3 \end{bmatrix} - \begin{bmatrix} d_0^1 \\ d_0^2 \\ d_0^3 \end{bmatrix}
\]

where \(d_0^1, d_0^2, d_0^3\) are the interferometer offsets.

The correct evaluation of this matrix is crucial to obtain accurate force measurements. Prior to this research, the stiffness parameters were determined experimentally by applying three orthogonal sets of forces in the main directions. In the present work, we developed a new calibration procedure based on linear or quadratic regressions. This new procedure leads to a more accurate determination of the calibration matrix and interferometer offsets. This reduces the overall error, i.e. the standard deviation of the measurements. For an applied force of 1N on the PalpEar probe, the original measuring error of ±4.51% is reduced to ±0.69%.

4. Flexure body structures

<table>
<thead>
<tr>
<th>Flexure body and fiber location</th>
<th>DOF</th>
<th>Force range</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>X: ±2 N</td>
<td>4 mm</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Y: ±1 N</td>
<td>±1 N</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Z: ±1 N</td>
<td>2 mm</td>
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5. PalpEar

The particularly successful probe PalpEar was evaluated by a clinical study [5] validating its performance and advantage in the Ossicular Chain Mobility Measurement procedure.

6. Conclusion

Our work confirms the advantages of flexure-based multi-DOF force sensors and establishes analytical methods for their design and characterization. In life sciences presented sensors are used for in vivo tissue characterization. Based on this concept new tool could be foreseen allowing e.g. single cell manipulation, where tool-cell interaction force is monitored and controlled.

References