

Monolithic Fabrication of Millimeter-Scale Surgical Devices with Integrated Sensing

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1 Background

The advent of minimally-invasive surgery (MIS) has cultivated a paradigm shift wherein open surgical procedures can now be performed through a number of small, millimeter-sized ports which can be quickly sutured closed, thus reducing patient morbidity and recovery time. The small scale of these procedures presents significant challenges to developing robust, smart, and dexterous tools for manipulating millimeter and submillimeter anatomical structures (e.g. vessels or nerves) and surgical equipment (e.g. sutures or staples).

To meet the demand for next-generation medical end-effectors, we are developing a versatile fabrication process, based on printed circuit board manufacturing techniques, to create monolithic, kinematically complex, three-dimensional machines in parallel at the millimeter to centimeter scales.

This paper describes an application of this manufacturing process in the creation of a microsurgical grasper with integrated force sensing, capable of manipulating objects and resolving gripping forces with 5 mN resolution.

2 Electromechanical Design

A grasper with integrated force sensing was manufactured for an example microsurgery application [1]. The grasping area must be 1×10 mm, fabricated from biocompatible materials. The sensing system must resolve forces up to 1 N with a high degree of resolution (< 10 mN). Finally, the sensor must be robust to anatomically-relevant temperature swings (negligible thermal drift over 20 C).

The mechanical actuation of the gripper is shown in Figure 1. All motion is permitted by flexure-based kinematics, using Kapton polyimide as the flexure layer. Two jaws are brought together by pulling at the midpoint of an internal Sarrus linkage as shown. An in-plane steel serpentine flexure deforms upon actuation, thus providing a restoring force which passively opens the grasper once the actuation force is removed. This flexure also supplies a counter-torque about the Sarrus linkage to close the jaws in a ‘pinching’ motion. The closure kinematics can be arbitrarily selected by adjusting the distance between the flexure attachment point and the location of the internal Sarrus linkage. Two external linkages act as rotary bearings to constrain any transverse motion between the jaws.

The sensor is a custom-designed serpentine-style strain gage reminiscent of commercial off-the-shelf (COTS) thin film strain gages. In order to achieve thermal stability, a half-bridge must be completed on the structure of the gripper itself such that the force-sensitive gage is biased by an identical gage placed in a location that experiences no mechanical

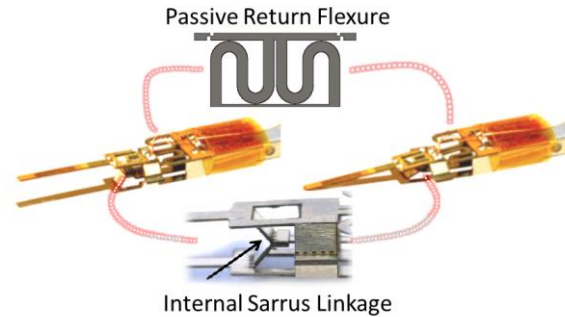


Figure 1. Grasper actuation showing return spring and internal Sarrus linkage detail

loading, but experiences the same thermal expansion. Thus the geometric footprint of the sensor is constrained so that two gages can be placed on the grasper surface. Analytical modeling was used to design a gage with a footprint of 1mm x 3mm and a nominal gage resistance of 120 Ω .

3 Manufacturing

The grasper was manufactured using a fabrication process inspired by printed-circuit board manufacturing (also known as Pop-Up Book MEMS). During lamination, precisely aligned material layers are combined in different ways to create functional layers that serve a specific purpose, including structural layers, flexure layers that enable rotary joints and articulated structures, printed circuit board (PCB) layers, electrically insulating layers, adhesive layers, or metal spring layers. Finally, various functional layers combine to create multi-structure, multi-material, quasi-2D laminates capable of folding into complex 3D structures.

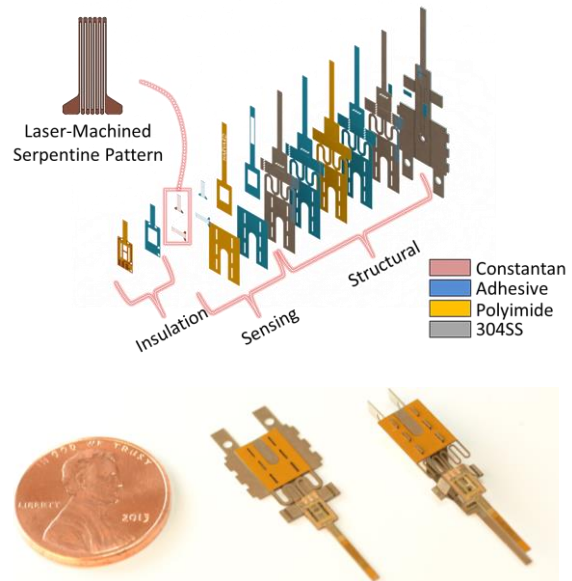


Figure 2. (top) Layer-by-layer composite manufacturing of gripper, incorporating structural, sensing and encapsulation sub-laminates, (bottom) integrated force-sensing grasper, (middle) post-release (flat) and (right) ‘popped-up’ with US penny for scale

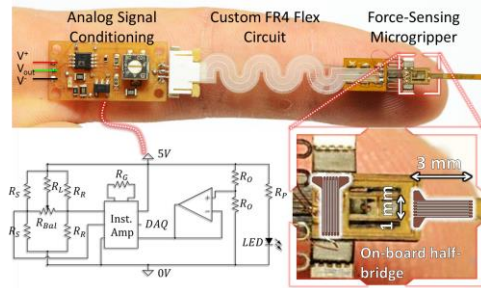


Figure 3. Sensorized grasper implementation, showing detail of signal conditioning and on-board half-bridge

An exploded view of the top layer, showing different functional sublaminates, is shown in Figure 2 (top). 304 Stainless Steel was chosen as the structural layer, with Kapton™ polyimide acting as the flexible layer which enables kinematic motion. Constantan (45% Cu/55% Ni) was chosen as the sensing layer as its thermal expansion properties are very similar to 304SS. Subsequent layers were joined using Pyralux FR1500 sheet adhesive (duPont).

The details of the manufacturing process, which are left out for brevity, are described in [2]. After release cuts are made and the grasper is ‘popped-up’ (Figure 2 (bottom)), the entire structure can then be coated in a 30 μm thick layer of Parylene which makes the device completely biocompatible.

A custom-designed flexible circuit featuring a manually-tunable Wheatstone bridge with adjustable gain (set at 500 for this application) was fabricated, along with a serpentine flexible circuit with traces to connect the gripper to the signal conditioning circuit via a Molex connector. The full implementation (grasper, wiring, and signal conditioning) is shown in Figure 3.

4 Testing Results

The sensor was calibrated by hanging discrete weights of known mass from the distal end of the grasper jaw and recording the resulting voltage. The sensor sensitivity was found to be roughly 4.8 V/N. The RMS noise of the sensor, measured by numerically integrating the power spectral density of a null signal measured over one minute, is roughly 23mV (corresponding to a force of 5 mN).

A demonstration platform was built wherein the gripper is actuated by a trigger, and a real-time force reading is displayed by an LED bar graph where each bar represents 10 mN of force. This platform is shown in Figure 4. In addition, force data is output to a serial port via an Arduino Nano microcontroller at a sample rate of 50Hz for real-time 10-bit analog force display and data post-processing.

To demonstrate the efficacy of the device in an anatomical scenario, a simulated task was performed wherein the gripper manipulated a 19mm long, 1.5-gauge (m) straight-taper suture needle and drove it through a block of Ecoflex-0010 (Smooth-On) which acts as a tissue analog. The resulting force profile generated from this task is shown in Figure 5 (both raw and filtered with a 2nd order zero-phase Butterworth with a cutoff frequency of $\pi/2$ rad/sample). The results show that the force sensor is able to detect forces with high resolution, and the differentiation between null force, grasping force and driving force is evident.

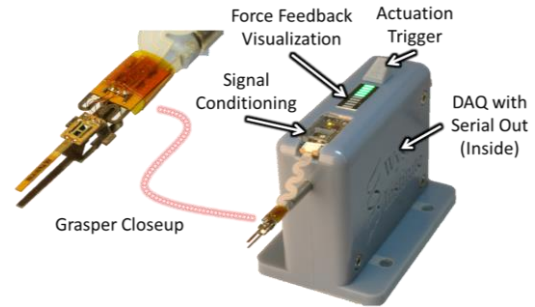


Figure 4. Demonstration platform used for testing

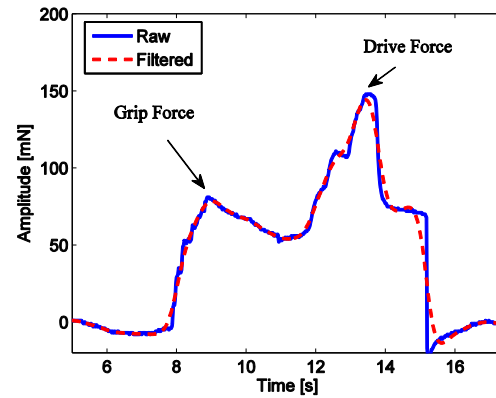


Figure 5. Force profile recorded from a simulated suture needle driving task.

5 Conclusions and Future Work

We have presented a novel surgical grasper prototype with embedded strain sensing, fabricated entirely using a one-step composite lamination manufacturing approach. The grasper was experimentally shown to detect distal loads with a resolution of 5 mN and a sensitivity of 4.8 V/N. Simple manipulation tasks show that the grasper can reliably differentiate between different loading conditions.

Future efforts will focus on integrating tactile sensing to decouple force localization and magnitude measurements. Integrating multiple sensing modalities with miniature mechanical end-effectors offers the potential to create smart surgical tools that provide physicians with information that enables them to perform more effective and safe procedures when using minimally invasive tools.

Acknowledgments

The authors would like to acknowledge the Wyss Institute and the Harvard School of Engineering and Applied Sciences for their support of this work.

References

- [1] Hammond et al., “Soft Tactile Sensor Arrays for Micromanipulation.” IEEE IROS, Vilamoura, Portugal, 2012
- [2] Gafford, J., Kesner, S., Wood, R., Walsh, C., "Surgical Devices by Pop-Up Book MEMS," ASME IDETC, Portland, Oregon, 2013.