Shape Deposition Manufacturing of a Soft, Atraumatic, Deployable Surgical Grasper

Joshua Gafford*,1, Ye Ding*,1, Andrew Harris[1], Terrence McKenna[1], Panagiotis Polygerinos[1], Donal Holland[3], Dr. Arthur Moser[4], Conor Walsh[1,2]
[1]Harvard School of Engineering and Applied Sciences
[2]Wyss Institute for Biologically-Inspired Engineering
[3]Trinity College Dublin, Ireland
[4] Beth Israel Deaconess Medical Center

1 Background

Laparoscopic pancreaticoduodenectomy (also known as the Whipple procedure) is a highly-complex minimally-invasive surgical (MIS) procedure used to remove cancer from the head of the pancreas. While mortality rates of the MIS approach are comparable with those of open procedures, morbidity rates remain high due to the delicate nature of the pancreatic tissue, proximity of high-pressure vasculature, and the number of complex anastomoses required [1]. The sharp, rigid nature of the tools and forceps used to manipulate these structures, coupled with lack of haptic feedback, can result in leakage or hemorrhage, which can obfuscate the surgeon's view and force the surgeon to convert to an open procedure.

We present a deployable atraumatic grasper with on-board pressure sensing, allowing a surgeon to grasp and manipulate soft tissue during laparoscopic pancreatic surgery. Created using shape deposition manufacturing, with pressure sensors embedded in each finger enabling real-time grip force monitoring, the device offers the potential to reduce the risk of intraoperative hemorrhage by providing the surgeon with a soft, compliant interface between delicate pancreatic tissue structures and metal laparoscopic forceps that are currently used to manipulate and retract these structures on an ad-hoc basis. Initial manipulation tasks in a simulated environment have demonstrated that the device can be deployed though a 15mm trocar and develop a stable grasp on a pancreas analog using Intuitive Surgical's daVinci robotic end-effectors.

2 Device Design

Functional requirements of the system were informed by interviews with physicians and procedural observations. A photograph of the deployable manipulator prototype is shown in Figure 1. The manipulator consists of: (1) multi-jointed, cable-actuated fingers, (2) the quick-release handle, and (3) the sensing system with visual-haptic feedback.

A three-finger design where fingers mutually oppose each-other at a 120 degree angle was selected that allows for a high surface area for each finger to better distribute grasping force and enable a grasped object to be completely constrained. This configuration also has the advantage of maximizing the surface area of each finger given a 15mm diameter size constraint as imposed by the port size.

The fingers were designed deterministically using a combination of analytical and experimental tools, as shown in

* Shared first author

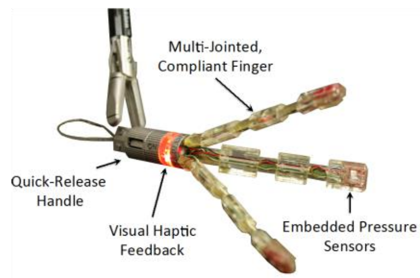

Figure 1. Deployable manipulator prototype

Figure 2. An analytical model was built in MATLAB (Natick, MA) to assist in parametric optimization via brute-force methods. Once optimum finger parameters were short-listed, empirical finger models were fabricated using shape deposition manufacturing. A series of tests were performed wherein fingers were evaluated according to their transmission ratio and 'jamming score' (i.e. the ability of the finger to geometrically 'trap' material within its distal joint). Thus, a finger with three joints, and proportionally-decreasing joint stiffness (from proximal to distal joint) was chosen.

The handle design features a 'reversible' ratcheting mechanism, as illustrated in Figure 3. The surgeon, using manual or robotic forceps, pulls on a cable to engage a ratchet with a cantilevered pawl, thus establishing maintaining tension in the cable to close the grasper. To release the grasper, the surgeon rotates the handle by 45 degrees to disengage the ratchet and pawl, and a compressive spring returns the ratchet to its original position, relieving tension in the fingers and allowing the grasper to be removed.

The distal segment of each finger has a rubber-encapsulated MEMS pressure sensor (TakkTile LLC) directly integrated into it, enabling real-time monitoring of the grasping force. Force information is relayed to the surgeon via

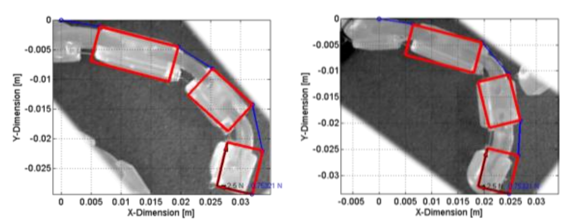

Figure 2. Overlay of analytical and empirical finger model showing agreement for a 2N tensioning force

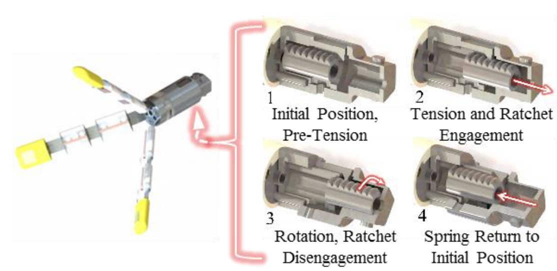

Figure 3. Handle operation, (1) Initial state, (2) cable tensioning and ratchet engagement, (3) collar rotation and disengagement, (4) spring return to initial state

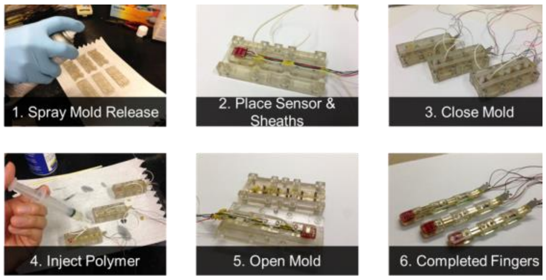

Figure 4. SDM of multi-jointed finger

a glowing RGB LED ring, which turns from green to red once a pre-defined pressure threshold is exceeded.

3 Manufacturing

The multi-jointed fingers were fabricated using a two-part shape deposition manufacturing (SDM) process [2]. SDM is beneficial for our application due to implicit encapsulation and isolation of wiring/cabling from the environment, and automatic strain relief, as the sensor, leads and wires are hard-molded into a stiff polymer.

In the first SDM process, steel-reinforced elastomer joints were molded out of PMC-780 urethane rubber compound (Smooth-On, Easton, PA). One-part, open-top molds were 3-D printed with alignment pins to locate precision laser-cut, 0.002” thick steel torsional reinforcement flexures. The steel flexures were placed in the mold, and the urethane compound was poured over each mold.

The second SDM process, shown in Figure 4, molds the stiff structural segment using pre-degassed Task-9 polyurethane elastomer (Smooth-On, Easton, PA), thus integrating the flexible joints, sensor, wiring, and actuation cable sheath to realize a fully-encapsulated, fully-functional three-jointed finger.

4 Validation and Future Work

The transmission ratio of our device was measured by actuating an individual finger and measuring the distal reaction force using an ATI Nano 6-axis force-torque sensor. The transmission ratio was found to be 23%, compared to a predicted ratio of 25%, as shown in Figure 5.

Our device was qualitatively evaluated in a simulated robotic procedure. An Intuitive daVinci^{TM} Surgical System (Intuitive Surgical, Sunnyvale, CA), equipped with one endoscope and two Prograsp^{TM} forceps, interfaced with our device to pick up and manipulate a 50g pancreas analog. The procedure was performed by an experienced robotic surgeon

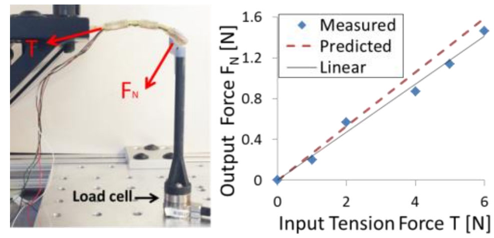

Figure 5. Analytical and measured transmission ratio

at Beth Israel Deaconess Medical Center in Boston, MA.

Overall, the results of the procedure are extremely promising. Screenshots of the simulated procedure are shown in Figure 6. The multi-jointed, compliant nature of the deployable manipulator allowed it to conform to the complicated geometry of the pancreas analog. The surgeon did not experience trouble in deftly manipulating the device and situating it onto the pancreas analog. The deployable grasper was able to maintain a stable grasp once rotated 90 degrees, to simulate cephalad retraction of the pancreas.

During the simulation, it was observed that, rather than pulling the cable tension loop axially to establish tension, the surgeon instead performed a twisting motion to tension the cable, which was much more controlled. Given this preference, we will devise a mechanism that leverages this motion to tension the cable in the next prototype.

Future iterations of the handle will not be made out of stainless steel but rather a biocompatible polymer to greatly reduce the overall weight. In addition, the ratchet design will be revisited such that only the necessary cable range-of-motion is enabled by the design to minimize wasted space.

Acknowledgments

This work was performed in ES 227, a course at the Harvard School of Engineering and Applied Sciences (SEAS) taught by one of the authors (CJW) with two of the authors (DH, PP) acting as support teaching staff. Funding was provided by SEAS, the Wyss Institute for Biologically Inspired Engineering and a Course and Program Grant from the National Collegiate Inventors and Innovators Alliance.

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Figure 6. daVinci simulation storyboard as seen through stereoscope (inset is external view): (left) device retrieval, (middle) device positioning around pancreas analog, cable tensioning, (right) cephalad retraction