Pop-Up Tissue Retraction Mechanism for Endoscopic Surgery

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Chapter 1

Introduction

1.1 Motivation

Current trends in surgical procedures have focused on minimally invasive surgery (MIS) with the end goal of shortening recovery time and improving patient outcomes. Since their development in the 1960s, flexible and steerable endoscopes have become the standard approach for diagnostic and therapeutic procedures in the gastrointestinal (GI) tract [1].

Although endoscopic diagnostic procedures performed are well-established and routine, many challenges exist when using endoscopes for therapeutic procedures, such as excising or ablating cancerous sites or other lesions. These challenges include distal tip instability, a lack of control for fine distal positioning, and the low amount of force that can be exerted by the endoscope tip without causing deflection of the endoscope itself [2]. Techniques such as endoscopic submucosal dissection (ESD) have been developed [3] to help address these shortcomings, but they require extensive training to successfully perform. Endoscopic mucosal resection (EMR) is another procedure for removing small lesions (< 25 mm) in the GI tract, but is challenged by the lack of endoscope distal tip dexterity [3]. Additional research has included the development of endoscopic add-ons to supplement the existing capabilities of conventional endoscopes [4–8], but these are similarly hampered by the inherent flexibility of the endoscope, as well as the coupling of the en-

doscope and device. Although this flexibility is crucial for navigating the curving GI tract to reach the surgical site, such flexibility also limits the capabilities of therapeutic endoscopic procedures [2, 9]. Similarly, the inevitable coupling between the mechanisms and the endoscope itself which leads to instability, limited manipulation, and counter-intuitiveness for manipulation [1]. Proposed solutions of anchoring the endoscope are numerous in the literature, with examples including inflatable balloons, pop-up structures, and adhesives [10–13]. Work has also been done to enhance distal tip dexterity with a highly-controllable means of steering the endoscope tools, minimizing the need to move the endoscope itself [4].

1.2 System Overview

In this thesis, I address the limitations of current resection- and ablation-based surgical procedures targeting early colorectal cancer (ECC) lesions in the lower GI tract performed with conventional flexible endoscopes. In order to fit within the current work-flow of therapeutic endoscopic procedures, the proposed tissue retraction device can be introduced into the body along the outside of the distal end of an endoscope and encased within a retractable flexible overtube (Fig. 3-1).

1.3 Impact

By automating the act of placing tissue under tension and decoupling this action from the motion of the endoscope tip, the integrated device presented here has the potential to expand surgeons' capabilities and increase the number of surgeons capable of performing these types of procedures.

1.4 Outline

In Ch. 2, I thoroughly describe relevant prior work and surgical techniques to the development of the proposed device. In Ch. 3, I describe the design and fabri-

cation process of each constituent component of the integrated device, including the introduction of a fabrication scheme for embedding rigid disks in TPE bellows actuators with planar manufacturing techniques to improve upon prior work [14]. I also present a means of integrating an expandable structure, inflatable bellows actuators, and a vacuum gripper into a device capable of tissue retraction. The expandable structure is based upon the pop-up book MEMS fabrication methodology [15]. Pop-up book MEMS has been used successfully for the development of medical devices in the literature [16]. The concept of integrating soft, inflatable devices with expandable rigid structures to constrain the inflation of the actuator has also been previously proposed [8] [17]. The integrated device and its components are tested with presented protocols and the results of these experiments are presented in Ch. 4. Implications of this thesis as well as opportunities for future work are discussed in Ch. 5.1

Chapter 2

Background Research

2.1 Prior Art

Endoscopy is a well-established field of medicine, with numerous recent innovations in endoscopic tools at the academic research level, where there is a substantial basis of work using pop-up MEMS fabrication techniques to fabricate surgical devices. Different strategies have been proposed for augmenting the therapeutic capabilities of endoscopes by developing multitasking endoscopic platforms [18, 19] or add-ons to the endoscope. Additional research has included the development of endoscopic add-ons to supplement the existing capabilities of conventional endoscopes [4–8]. However all these systems still struggle to be adopted mainly due to the inevitable coupling between the mechanisms and the endoscope itself which leads to instability, limited manipulation, and counter-intuitiveness for manipulation [1].

2.1.1 Pop-up MEMS

“MEMS” conventionally refers to “micro-electromechanical systems” and typically includes fabrication methods that have sub-millimeter features or smaller, often produced with methodologies like soft lithography, similar to those used in printed circuit board (PCB) fabrication. Frequently, etchings are performed to cre-

ate relatively planar features with small aspect ratios, where aspect ratio defines the depth of cut relative to its width. Thus, the traditional MEMS design methodology utilizes large shallow cuts or depressions, as they are easier to form than narrow, deep grooves would be. The meso-scale (micrometers to centimeters) offers a new range of problems and design opportunities, as conventional mechanisms like hinges and roller bearings experience greater inefficiencies and difficulty in manufacturing at sufficient tolerances. “Pop-up book MEMS,” alternatively “pop-up MEMS,” describes a design and fabrication methodology in which thin layers of material are machined individually and selectively laminated together with adhesive and flexible layers, allowing a “flat” structure to expand into a 3-dimensional one [15]. Although unproven commercially, pop-up MEMS is a popular topic in academic research, with work in the literature describing many medical device applications, including force-sensing graspers for surgery [20], endoscope stabilization [14], and fine positioning of endoscope tools [4]. Pop-up MEMS is well suited the development of medical devices because of the range of materials possible, allowing for the selection of biocompatible materials and precise manufacturing tolerances, as well as the large expansion ratio of initial to expanded states. Examples are presented below.

Pop-Up Endoscope 3 DOF Arm

Pop-up MEMS design techniques have been coupled with fluid-filled inflatable chambers actuating geometric structures to create a 3 DOF (Degree of Freedom) robotic arm for use at the distal tip of an endoscope [8], as shown in Fig. 2-1.

Pop-Up Endoscope Distal Tip Dexterity Mechanism

Similar fabrication techniques have been used to manufacture an expandable endoscope “wrist” mechanism, which is precisely controlled with Shape-Memory Alloy actuators (coiled wires that contract with applied current), and capable of steering endoscopy tools inserted through the working channel [4], as shown in

Figure 2-1: This pop-up arm is fabricated with pop-up MEMS techniques and could be used on an endoscope to enhance tissue grasping or tool maneuverability.

Fig. 2-2.

Figure 2-2: This endoscope add-on can precisely control the motion of the electrocautery tool inserted through the endoscope working channel and held firmly by the distal sheet of the device.

Pop-Up Endoscope Stabilization

Laminar fabrication techniques have also been used to create inflatable actuators compatible with pop-up MEMS structures to stabilize an endoscope in the GI tract [14]. Once inflated, the collapsible features would press against the walls of the GI tract and help allow the endoscope distal tip to avoid deflection when applying forces. These devices are shown in Fig. 2-3.

Figure 2-3: Various pop-up endoscope stabilization mechanisms shown, intended to brace against the GI tract to anchor the endoscope in place.

2.1.2 Actuators

There are a variety of actuation options available that are compatible with pop-up MEMS fabrication processes; an overview of several common soft actuation methods are presented here to justify the design decisions made in this thesis. Other types of actuation ruled out for complexity or unsuitability to the design requirements of this project include Shape Memory Alloy (SMA) actuators comprised of special materials that contract or deform when heated, as well as piezoelectric actuators which can oscillate very rapidly (several thousand Hertz) and can require very high voltages (several hundred Volts) to operate.

For actuators with large stroke capabilities that are relatively benign within a living system, pneumatic or hydraulic options are preferable, as their failure modes are unlikely to cause harm. These can be broadly described as flexible bladders that can be inflated from a thin initial height to achieve a substantial inflated height, or to use this inflation to change their geometry. They generally can exert high forces, inflate over the course of one to several seconds, and are generally compatible with the pop-up fabrication scheme due to their planar fabrication nature.

Soft Fluidic Micro Actuators (SFMAAs)

Soft Fluidic Micro Actuators (SFMAAs) are a class of actuator in which small inflatable chambers are made by spin-coating uncured silicone elastomers into thin, uniform sheets. These can then be bonded together to form sealed chambers into which fluids can be injected to deform the chamber into a spherical shape. These

designs are robust and well-characterized, although they have certain design limitations due to the size scale in which they are relevant [8]. The chamber is ordinarily only expanded to the diameter of the balloon before the elastomer begins to stretch and strain, followed by bursting. As such, these balloons are usually < 5 mm in diameter, limiting the total possible stroke of the actuator. By encasing this balloon such that it pushes against a structural element, force can be transmitted effectively and expand these small motions to larger displacements.

Figure 2-4: Various Soft Fluidic Micro Actuator (SFMA) designs shown, each capable of interfacing with and manipulating joints of pop-up structures.

Pouch Motors

Pouch motors are fabricated using heat-sealable membranes with inlet tubing to allow for inflation. As a fluid is injected into the flexible bladder, it deforms, causing a change in shape of the pouch motor chamber. A thorough design scheme has been developed to print pouch motors and incorporate them into other designs [21].

Inflatable Bellows Actuators

Inflatable actuators fabricated with heat- and pressure-bonded Thermoplastic Elastomer, TPE (Fiber Glast, USA) with Polytetrafluoroethylene (PTFE, a non-stick material commonly sold under the brand name Teflon®) mask layers have been previously developed. These actuators exert meaningful forces on the order of Newtons and have been well characterized, but are noted to exert limited retractive forces

Figure 2-5: Pouch motors change their geometry when inflated. This change in length of angle can be used to move a structure.

due to the tendency of bellows chambers to buckle inwards when vacuum is applied, rather than solely contracting axially [14].

Figure 2-6: Inflatable TPE actuators can expand from low-profile starting configurations to relatively large displacements.

2.1.3 Vacuum Grippers

Applied vacuum pressure has been established as a means of interacting with tissue on the benchtop and during Minimally Invasive Procedures (MIS). Such grippers can take various forms, but generally include a chamber through which negative pressure is applied to tissue, and a means of connecting this chamber to the vacuum source.

Soft Grippers

Soft vacuum grippers previously described in the literature have been cast from silicone elastomers. The scale of these designs varies from 5 mm - 10 mm in diam-

eter.

The grippers shown in Fig/ 2-7 are intended for integration into the pop-up 3 DOF arm described previously [22]. Other vacuum grippers in the literature

Figure 2-7: The vacuum grippers shown here are 5 mm diameter and feature an internal chamber that can compress against tissue.

are less complex in their design, but sacrifice footprint and overall size for this decrease in design complexity. An example of work exploring cylindrical gripper design with and without membranes shielding negative pressure from directly contacting tissue are shown in Fig. 2-8 [23].

Figure 2-8: The vacuum grippers shown here are 10 mm diameter and are a simpler cylindrical design.

Hard Grippers

Other vacuum grippers have been developed for use in laproscopic surgical procedures. This work demonstrated the effective use of negative pressure to manipulate tissue, and also categorized ecchymoses, or burst blood vessels beneath the top layer of tissue, similar to bruises, that resulted. These were deemed benign and suggests that the use of vacuum grippers is unlikely to cause harm to the GI tract during procedures [24].

Figure 2-9: The vacuum gripper designs shown here are fabricated from stainless steel 10 mm diameter and do not deform like the soft grippers discussed previously.

2.1.4 Surgical Techniques

A general scheme for endoscopies is shown in Fig. 2-10. This shows many of the major systems and tools in use for endoscopic procedures [25], during which a wide variety of techniques such as polypectomy, ESD, and EMR may be used.

Polypectomy

Polypectomy is a well-established endoscopic technique that can encompass the use of forceps, snares, submucosal injection, and the use of mechanical clips and loops applied to polyps [26]. A representative example of a polypectomy procedure using a snare is shown below.

Figure 2-10: A steerable, flexible endoscope can be navigated through the upper or lower GI tract, with a camera feed to observe otherwise inaccessible areas.

Figure 2-11: A wire polypectomy snare is inserted through the endoscope working channel, maneuvered around a protruding polyp, and this loop is then tightened until the polyp is resected.

Endoscopic Mucosal Resection (EMR) & Endoscopic Submucosal Dissection (ESD)

In Endoscopic Mucosal Resection (EMR) & Endoscopic Submucosal Dissection (ESD) procedures, fluid is injected with a syringe inserted through the endoscope working channel between layers of tissue of the GI tract lining. This injection causes the uppermost mucosal layer to rise. An electrocautery tool is then inserted through the endoscope working channel and manipulated to burn through the separated layer of tissue. This cycle is repeated as needed until the entire lesion is resected [3]. The primary difference between ESD and EMR is the depth at which the injection and therefore the tissue resection is made.

Figure 2-12: Fluid is injected under the inner surface of the GI tract, and then electrocautery tools are used to burn through the tissue surrounding the lesion.

2.2 Area of Opportunity

Although a basis of work exists in applying pop-up MEMS design and fabrication techniques to the challenges of endoscope stabilization, distal tip dexterity, and articulated arms for tool manipulation, little focus has been given to simplifying the task of placing tissue under tension or decoupling devices from endoscope motion. Surgical techniques like ESD and EMR require significant surgeon training to be used effectively, with minimal development in devices to assist in placing tissue under tension. As such, opportunity exists for a device that does not impede the visual field of the camera at the distal tip of the endoscope, anchors itself to apply and maintain tension to the endoluminal tissue while remaining decoupled from the endoscope tip. This decoupling would allow for increased maneuverability of the endoscope tip for visual evaluation and better alignment of surgical tools to the area undergoing biopsy. Since multiple surgical techniques exist for tumors in excess of 25 mm, this device could be used to target relatively small, flat lesions of the sub-20 mm size range, not polyps which are sufficiently addressed by conventional polypectomy techniques. Such a device would expand surgeons' capabilities and reduce the rigorous training requirements for these limited methods. This thesis aims to fulfill these requirements by developing a biocompatible medical device suitable for deployment from an endoscope capable of anchoring itself to and retracting tissue. The device is to be compatible with current endoscopic techniques and evaluated on simulations of actual surgical procedures using tissue facsimiles

and *ex vivo* specimens. This thesis aims to improve upon the current standards for surgical procedures removing instances of early colorectal cancer lesions by developing an active, semi-autonomous tissue retraction mechanism decoupled from the endoscope tip and end-effectors.

2.3 Functional Requirements

The functional requirements of the device are drawn from metrics that will allow compatibility with conventional endoscopy techniques and methods of fabrication, and are defined in Table 2.1. The diameter of the tissue area to be retracted is intended to place the device as a suitable option for small, relatively flat lesions in the GI tract, like those indicative of Early Colorectal Cancer (ECC). The flat dimensions of the structure come from the dimensions and constraints of the Olympus CF-100L endoscope used for testing of the device, and are selected for compatibility with commercially available overtube sizes. The desired expanded height of the structure as well as the measure of tool access are intended to result in a design that can retract tissue to a sufficient height for access by electrocautery tools maneuvered with limited dexterity from the endoscope tip. The specified vacuum gripper force requirement is intended to create actuators that exert similar forces to those presented in the literature, and an estimate is made for the force required to retract tissue to the specified height, with consideration given to the inherently limited force the vacuum gripper can exert before detaching from tissue.

Table 2.1: Functional Requirements

Requirement	Desired Qty.
Diameter of tissue area to be retracted	5-8 mm
Structure Flat Dimensions	25 mm
Structure Expanded Height	10-13 mm
Endoscope Tool Access to Retracted Tissue	8 mm
Vacuum Gripper Force Applied	1 N
Bellows Actuator Force Produced (each)	1 N

Chapter 3

Design

3.1 Design Overview

Figure 3-1: Illustration of usage case of the proposed device and the workflow for deployment and tissue retraction: (a) collapsed device affixed to endoscope within hollow overtube, (b) deployment by retracting the overtube to expose the device, (c) positioning of the device with forceps over the targeted lesion, and (d) mechanism retracting tissue, allowing conventional tools to be used to excise the lesion with electro-cautery.

The proposed device can be affixed to the outside surface of the distal end of an endoscope and constrained within an overtube to shield the device from contacting tissue, as shown in Fig. 3-1 (a). Upon reaching the surgical site, the overtube

is then retracted to expose the device (Fig. 3-1 (b)). Forceps deployed through the endoscope working channel are used by the surgeon to position the device atop a lesion, with visual guidance and confirmation from the illuminated distal camera (Fig. 3-1 (c)). Although the device is shown on a horizontal section of tissue here, it can be adjusted using forceps and placed on lesions in the GI tract regardless of orientation to horizontal. Once properly positioned, negative pressure is applied to the vacuum gripper at the center of the device, adhering the device to the lesion site while negative pressure is sustained. The dual bellows actuators are inflated, expanding the pop-up structure and retracting the grasped tissue. The surgeon can then use conventional endoscopy tools such as electro-cautery probes inserted through the endoscope working channel to cut through the mucosa and muscularis layers beneath the lesion site, as shown in Fig. 3-1 (d). The dissected tissue is still held by the device's vacuum gripper and can be grasped with forceps for removal from the body for pathology analysis. The device is rapidly collapsed by venting pressure from the bellows actuators. To excise larger lesions, the device is repeatedly expanded, collapsed, and repositioned with forceps delivered through the endoscope working channel to adjust vacuum gripper location between rounds of electro-cautery. To remove the device from the body upon completion of a procedure, negative pressure is applied to the bellows actuators to keep them in a deflated state, the overtube is advanced, and forceps are used to maneuver the device back into the overtube while the endoscope is retracted. The thickness of the device before inflation adds less than 10 mm to the endoscope diameter to maintain compatibility with commercially available overtube sizes. The device must retract tissue to a height of 10 mm in order to offer sufficient access to the endoscope end-effectors, which means the device must expand to 13 mm or more since several some tissue will deform into the vacuum gripper, which will have a height of several millimeters.

To meet the specifications and be compatible with the outlined process outlined, the device needs to possess three basic components: a structure that controls deployment and actuation; expandable actuators capable of exerting sustained

Figure 3-2: Several subsystems are integrated together in the final device: (a) A four-stage TPE bellows actuator with rigid internal disks (shown in various stages of expansion), to expand the device (b) A silicone elastomer vacuum gripper, to grip the tissue to be retracted (c) The pop-up MEMS structure comprised of structural, flexural, and adhesive layers laminated together to create the final device (d) Integrated device in undeployed state (e) Integrated device fully expanded by inflated bellows actuators.

forces; and a means of gripping tissue. These subsystems are presented below.

3.2 Pop-up Structure

Pop-up book MEMS is a design and fabrication methodology in which thin layers of material are machined individually and selectively laminated together with adhesive and flexible layers, allowing a flat structure to expand into a 3-dimensional device based on flexure joints [15]. The pop-up structure presented here is designed to accommodate the incorporation of a vacuum gripper and expandable housing for dual bellows actuators while resisting substantial deformation during use. These requirements aligned well with pop-up MEMS capabilities. Other design options were considered, including using inextensible soft materials for the structure, but the challenges of the conformable nature and lack of rigidity inherent to such a structure were expected to overshadow the potential benefits. The pop-up MEMS design scheme allows for precise alignment of small components difficult to accurately place unassisted, and can allow for parallelization to produce

multiple pop-up structures at one time.

As such, the pop-up structure was constructed with the following materials: 381 μm thick fiberglass-epoxy laminate sheets as structural material (Garolite G-10/FR4), 25 μm thick polyimide film as flexure layers, and pressure-sensitive 3M[®] 9877 sheet adhesive. Each layer is individually machined using a diode-pumped solid state (DPSS) laser (Oxford Lasers, Inc., USA), and aligned using dowel pins on a precision-machined aluminum plate. The resulting laminate is laser machined to release the final device structure from the bulk substrate before integration of the vacuum gripper. This finished pop-up structure is shown in Fig. 3-2 (c). The design of the pop-up structure depends upon the deployment method of the device, in which it is affixed to the outer diameter of the endoscope within a flexible overtube. As such, the pop-up structure is designed to minimize the marginal increase in endoscope diameter before the device is deployed, as this increased effective diameter scales up as the width and height of the device increase, as shown in Fig. 3-3. A basic pop-up structure prototype is shown in Fig. 3-4. Although the

Figure 3-3: As the device dimensions increase, the diameter of the overtube needed to envelop it also increases. Design choices were made carefully to ensure the device remained compatible with standard overtube diameters.

geometry of subsequent iterations could be adjusted to a certain extent, the final length of a device with this basic design that met the other functional requirements for tool access and open space for housing a vacuum gripper suggested it would exceed the maximum specified device length when flat. This posed a problem, as maximum length was specified to preserve the possible bend radius of the endoscope distal tip while maneuvering through the GI tract, and exceeding this limit could negatively impact endoscope capabilities.

One means of shortening the overall device length is to shift from a single-stage

Figure 3-4: Proof-of-concept paper prototype suggests that this design could be successful, but is potentially too long to preserve the endoscope's possible bend radius. Cured silicone elastomer sample used to keep mechanism expanded and demonstrate functionality.

expansion mechanism to a two-stage mechanism. A partially functional two-stage expansion mechanism is shown in Fig. 3-5. The functional principle is the same as that of Fig. 3-4, but the horizontal distance required to house a flat mechanism capable of reaching a certain expanded height is less than that comprised of a single-stage mechanism. However, since adding an additional stage to the expansion mechanism required five additional layers (three adhesive layers and two structural layers), this came at the expense of design and fabrication simplicity and speed.

Figure 3-5: Prototype almost fully delaminated, but principle of mechanism is visible here. Cured silicone elastomer sample used to keep mechanism partially expanded and demonstrate functionality.

The prototype presented in Fig. 3-6 (a) uses similar expansion geometries to those in Fig. 3-4, but they are oriented perpendicularly to the long axis of the mechanism. By orienting these expansion geometries in this way, the overall length of the mechanism could be reduced, which is a beneficial change. As seen in Fig. 3-6 (b), this geometry could conform favorably around a cylindrical shape (such as an endoscope). Although preliminary, this prototype showed promising results

and encouraged continued development of this general design.

Figure 3-6: Prototype with perpendicular single-stage expansion chambers. (a) Tweezers are used to manipulate the mechanism and demonstrate expansion capabilities (b) The mechanism can fold such that it could conform to a cylindrical endoscope.

Using cardstock to produce prototypes was a useful exercise in allowing rapid iteration cycles. To create the final device, the pop-up structure was redesigned with adjusted dimensions for using fiberglass-epoxy (FR4) sheets as the structural layers, and to accommodate a more precise alignment routine.

3.3 Bellows Actuators Design and Improvements

Heat- and pressure-bonded Thermoplastic Elastomer, TPE (Fiber Glast, USA) bellows actuators with Polytetrafluoroethylene (PTFE, a non-stick material commonly sold under the brand name Teflon[®]) mask layers have previously been developed. These bellows actuators demonstrate a linear relationship between blocked force and input pressure at low displacement heights, but exert limited retractive forces due to the tendency of bellows chambers to buckle inwards rather than move axially when vacuum is applied [14].

Here I propose the introduction of rigid PTFE disks within the enclosed chambers of the soft bellows actuators at the same scale. The planar fabrication method of combining subunits to form complete bellows chambers enables the inclusion of additional bellows chambers and thus customizable inflation height. This thesis

will focus on bellows actuators with a diameter of 9 mm and four bellows chambers. These dimensions were selected for suitability for integration into the tissue retraction device and the limits imposed on device size to allow deployment into the GI tract.

Initial attempts to fabricate bellows actuators followed the fabrication workflow specified in the literature [14] exactly, with multiple batches producing failed actuators with various causes of failure. In order to isolate and resolve individual problems, the actuator design was simplified and the established scheme was continually modified until the process consistently fabricated functional actuators. The general workflow can be described as follows:

1. TPE and PTFE layers are individually cut with a laser-cutter.
2. TPE and PTFE layers are selectively placed into an oven at elevated temperatures under pressure to cause the TPE to bond to itself, with PTFE serving as a mask.
3. By repeating this process, multiple bellows chambers can be connected.

3.3.1 Bellows Actuator Final Fabrication Workflow

The first sub-unit of the soft bellows actuator is fabricated with two adjacent layers of 38 μm thick TPE following the process shown in Fig. 3-7. This double layer of TPE enhances robustness of the material when undergoing deformation during heating, as this deformation is required to accommodate internal disks of sufficient thickness to resist buckling under applied negative pressure. This would represent a novel design improvement and potentially allow inflatable bellows actuators to be integrated into new types of mechanisms where exerting larger retractive forces would be desirable.

Different layers of TPE are cut with a CO_2 laser cutter and alternated with laser-cut 254 μm and 76.2 μm PTFE layers to act as masks and forms. Layers of TPE and PTFE are aligned using precision dowel pins and stacked manually. The layers of

Figure 3-7: Fabrication workflow for the proposed bellows actuators with internal rigid disks: (a) Interface layer between adjacent bellows chambers (b) Additional mold layers with the result of the previous step, creating pocket for enclosed disk (c) Final bonding of top TPE layer and input tubing (d) Enclosed disk dimensions.

TPE in the first two steps of the process are bonded at 180°C for one hour under 0.07 MPa pressure, as shown in Fig. 3-7. The 76.2 μm PTFE layers serve in the first step to mask the TPE and allow only desired areas to bond (Fig. 3-7 (a)). This first step produces the layer that interfaces between two bellows chambers. The 254 μm PTFE also serves as a mask to the TPE but also as a form to create sufficient vertical space while the TPE is heated to encase rigid PTFE disks within the bellows chambers.

During the second step of the process (Fig. 3-7 (b)), multiple subunits resulting from the first step may be added, serving to customize expanded height of the finished actuator. Additional intermittent 254 μm PTFE mold layers are added to transmit the vertically applied force of 0.07 MPa to the areas of TPE being bonded. In this step, the bonds around the outer diameter of all bellows chambers except that with the inlet tubing are formed.

Following heat- and pressure-bonding, the top layers of this laminate are manually removed, and additional 254 μm PTFE layers are added as forms to create bonds that will enclose the last bellows chamber with its inlet tubing. A tube with internal diameter of 0.64 mm (Micro Renathane Catheter Tubing, Braintree Scien-

tific, USA) is inserted and a drop of Loctite[®] Vinyl, Fabric & Plastic Flexible Adhesive is added before the top sheet of TPE and an upper PTFE mold layer are added. The resulting laminate is heated at 145°C for one hour under 0.06 MPa pressure, as shown in Fig. 3-7 (c). The external PTFE layers are manually cut away before the laminate has cooled, and the inlet tubing is trimmed, producing bellows actuators like those shown in Fig. 3-2 (a).

3.3.2 Bellows Actuator Modeling

The output force of an actuator produced from this process can be modeled by the simple $F = P \times A$ relationship, where F is the force produced, P is the input pressure, and A is the area of the circular bellows chamber when flat, as determined by the 254 μm PTFE layers that transmit the applied force during heating in Fig. 3-7 (b) and (c). This relationship holds true when expanding from flat, with decreased force output as the overall height increases and the TPE begins to strain. However, as this outputted force magnitude diminishes, $\Delta F = \Delta P \times A$ is a better description. The rate at which force output increases with an increase in pressure will be relatively constant and dependent upon the area of a bellows chamber, and is detailed in Ch. 3.

Previous iterations of soft bellows actuators fabricated with a 76.2 μm PTFE film disk encased in each bellows chamber (solely to mask the TPE layers from bonding in the chamber) were susceptible to bending and then buckling when under applied negative pressure, limiting the pulling force output to 0.50 N [14]. When this occurs, the TPE shell of the bellows chambers tries to reach a smaller final volume, and this force can be sufficient to cause buckling of the internal 76.2 μm PTFE disk, allowing this volumetric decrease to occur. As such, it was hypothesized that the incorporation of a thicker, more rigid PTFE disk would minimize these effects by preventing the volumetric change and encouraging axial movement of the rigid disks to thereby improve actuator retraction performance. Modeling the system as a disk under uniform radial compression, which the TPE

would apply to the disk under applied negative pressure, as discussed in Eqn. 3.1, supports this hypothesis.

I modeled the enclosed disk as a circular plate with a concentric hole under uniform radial compression on its outer edge, with a being outside diameter of the disk, b being the inner diameter of the disk as shown in Fig. 3-7 (d), t being thickness of the disk, E being Young's modulus, ν being Poisson's ratio, and σ' being critical unit compressive stress. Because the ratio of diameter to thickness $\frac{a}{t}$ is greater than 10, this model holds and we can say that:

$$\sigma' = K \left(\frac{E}{1 - \nu^2} \right)^2 \left(\frac{t}{a} \right)^2 \quad (3.1)$$

where K is a tabulated value dependent upon $\frac{b}{a}$ and equal to a linearly interpolated value of 0.285 from [27], thus $\sigma' \propto t^2$.

Therefore, increasing the thickness of the internal PTFE disks from 76.2 μm (solely to mask the TPE) to a thicker sheet (to provide rigidity as well as to act as a mask) suggests that the bending stiffness of a chamber of the bellows actuator would increase by $(t_{thick}/t_{thin})^2$. Thus, when increasing disk thickness from 76.2 μm to 254 μm , this results in increased resistance to buckling by a factor of 3.3^2 , or 10.89.

This assumes both versions are subjected to the same radial compression, as both are tested under equal vacuum line pressure applied to actuators that are identical other than thickness of their enclosed disks. A thicker internal disk, then, will allow individual bellows actuator chambers to resist subsequent buckling under vacuum and therefore allows higher retractive forces to be achieved.

3.3.3 Laser Cutting Challenges

The first fabrication step was laser-cutting. In general when making a cut, the speed of cut and power of cut are the two primary variables that are controlled. Furthermore, it is desirable to select laser-cutter settings such that the laser will cut through the selected materials, but leave the underlying surface unscathed. Both

aspects of this step initially presented challenges.

First, when using a small VersaLaser unit, it was difficult to get clean, smooth cuts of either the TPE or the PTFE materials. Upon switching to a larger VersaLaser machine and testing dozens of combinations of speed and power of the cut, satisfactory results were achieved.

Second, after optimizing the settings to cut the TPE and PTFE, selecting the material for the underlying surface presented another point of difficulty. Typically, masking tape is used to affix a sheet of TPE or PTFE onto an immobile substrate to keep the material flat during laser cutting. However, with too high of a power setting, residue from the combustion of the substrate layer can foul the edges of the TPE and PTFE with an undesirable charred residue. A trial-and-error process eventually determined an optimal cardstock to be used as a substrate. Using a disposable substrate layer was ideal, as it allowed for the reuse of the substrate several times before incremental damage merited its replacement.

Following consistent, clean results from the laser cutting process, heat, pressure, and time settings were varied to achieve optimal results. The baseline settings for TPE bonding were 180°C and 0.7 MPa, but these were varied across a wide range to realize bonding of the TPE layers without excess melting of the material and sufficient pressure to cause good contact between layers without squeezing molten TPE out of the mold, as shown in Fig. 3-8.

Figure 3-8: Malleable TPE squeezed out during heat- and pressure-bonding is visible as darker green around the edges of the TPE sheet.

3.3.4 Pin Alignment

One strategy proposed at the start of the project but not ultimately implemented was the use of a central alignment pin in addition to those at the four corners of each actuator. Conceptually, the central pin seemed like an ideal means of eliminating the need for manual adjustment of the location of small bellows components, particularly the alignment of the PTFE disks enclosed within each bellows chamber. The central alignment pin would have been concentric with the bellows chambers, and been used for all but the very top and bottom sheets of TPE forming the top and bottom of the bellows actuator. However, this plan was discarded upon realization that the standard aluminum pin-alignment plates (shown in Fig. 3-9 with a bellows actuator mid-fabrication) in use by the Harvard Microrobotics Lab do not have such holes machined into them, as this was not a consideration when they were originally designed for use with pop-up devices. The high cost

Figure 3-9: The dowel pins inserted through the corners of the actuator align with the hole pattern of the aluminum plate. An upper and lower set of plates are used throughout fabrication.

of precision machining with the necessary tolerances prohibited the possibility of creating additional holes in the existing plates. Therefore, the decision was made to continue without the central pin, and to reevaluate the need for new alignment plates if disk misalignment proved to be a common source of actuator failure. With careful attention paid to the placement of enclosed PTFE disks in each fabrication cycle, and fine adjustments made with precision dental picks to nudge the disks

within the proper preformed pocket in the TPE after the addition of each subsequent layer, this was not a substantial problem. However, for fabrication of larger quantities of bellows actuators, or if new alignment plates were to be fabricated, the inclusion of these central alignment holes could prove helpful and convenient without substantially increasing the manufacturing complexity or associated costs.

3.3.5 Inclusion of Rigid Internal Disks

One goal of this thesis was to improve upon shortcomings in the design of existing fabricated actuators. The existing bellows actuator design was limited in the forces it could output when under applied negative (vacuum) pressure, as the bellows chambers tended to buckle inwards, as shown in Fig. 4-4 (a) in Ch. 4. This suggested there was room for improvement in the design and fabrication of inflatable bellows actuators. In order to combat this tendency to buckle, instead of using 76.2 μm PTFE film, the prototyping plan used thicker, and therefore more rigid, sheets of PTFE. The justification for this design choice is discussed further in Section 3.3.2.

The first attempt of this design failed to consider that there was not a one-to-one swap between material thickness (going from 76.2 μm to 793.75 μm PTFE), and therefore did not anticipate the necessary change in the design of the bellows actuator cross-section. Instead, the entire bellows actuator molding process needed to be redesigned to create a pocket of sufficient depth inside each chamber to accommodate these thicker enclosed disks.

As part of the re-design, the TPE layers decreased in complexity and therefore in cutting time. With this simplified design, only two different TPE layers were needed, rather than the more stylized prior versions which had five different types. With these changes, and thinner (254 μm and 381 μm) sheets of PTFE and acetal in use, bellows prototyping moved forward. Acetal (Delrin[®]) is a non-stick thermoplastic commonly used for its low-friction properties and smooth surface finish. Given these properties, it seemed like a useful material to use in the molds

Figure 3-10: Mask acetal layers sometimes melted at the heat-bonding temperature of 180°C. This is visible as reflective white material bulging from bottom of bellows fabrication stack.

for bellows actuators during heat- and pressure-bonding. However, the melting point of acetal was too close to the temperatures used for bonding TPE, resulting in occasional melting of the acetal layers, as shown in Fig. 3-10.

FR4 (fiberglass-epoxy laminate), which is much more rigid than PTFE as a thin sheet (Young's modulus E of 18.8 - 18.9GPa [28] vs. 1.5 - 1.6GPa for PTFE [29]), was also used in a batch of prototypes, since a thinner FR4 sheet could be as rigid as a much thicker PTFE layer. Since prior testing had shown that TPE bonds fairly strongly to FR4 upon heating to this range of temperatures, the FR4 was laminated together with 76.2 μm PTFE to create a non-stick surface atop a rigid substrate. This would have allowed different thicknesses of FR4 to be used to achieve close tolerances of thickness for these non-stick layers. However, the adhesive sheet used to bond the FR4 to the PTFE melted at the elevated temperature of 180°C used to achieve TPE bonding. The molten adhesive reacting with the TPE, as well as the rough edges of the FR4 puncturing the TPE, rendered this design a failure, as shown in Fig. 3-11.

Realizing the shortcomings of acetal and PTFE-laminated-FR4, a variety of thicknesses of PTFE were ordered from McMaster-Carr and tested for use as both the mold layers and the internal rigid disks. Following dozens of failed batches of bellows actuators, an ideal combination of 254 μm mold thicknesses and 254 μm internal disk thicknesses were found. This yielded some success, but small holes in the bellows actuators often appeared especially where the TPE was in contact

Figure 3-11: Mask layers were fabricated from FR4 and PTFE laminated together with adhesive sheet. This design failed for multiple reasons.

with laser-cut edges of PTFE sheets. Upon closer examination, the rough nature of laser-cut PTFE edges was apparent, as shown in Fig. 3-12. At elevated temperatures, where the TPE was in a more pliable state, the rough and irregular features of these cuts were enough to puncture the TPE and cause it to tear rather than deform smoothly around the PTFE mold forms. Therefore, care was taken to further refine the laser-cutter speed and power percentage settings to create cleaner edges, as well as manually using 1200-grit sandpaper on every laser-cut PTFE edge that would contact TPE.

Figure 3-12: The cut finish resulting from laser-cutting yields a rough edge. This can be partially remedied with setting adjustments, but still requires manually smoothing with sandpaper.

3.3.6 Two-Ply TPE

In addition to manually smoothing each cut edge of the PTFE layers, the lay-up scheme was modified to include extra TPE layers for increased resilience to point defects. TPE is difficult to purchase in small quantities, and it usually sold on large

rolls containing several hundred square meters of the material. Additionally, the material is conventionally used to form barriers on goods like grocery foods and produce, where the thin, stretchable nature of the TPE at elevated temperatures is desirable. Therefore, seeking thicker TPE was both cost- and supplier-prohibitive. Instead, two layers of 38 μm TPE were used. These two layers of 38 μm TPE were included with the intent of reinforcing the previously delicate TPE shell, such that a point defect would only damage one of the two TPE layers. This increased resilience of the actuators and likely contributed to the comparatively higher forces produced compared to past versions of the actuators. To create these two-ply TPE layers, initially, one TPE layer was manually placed with tweezers over the four alignment pins (one in each corner). However, this method was time-consuming and difficult due to mild static adhesion between adjacent TPE layers and because including two TPE layers instead of one doubled the time required to cut the TPE. To overcome this challenge, TPE was doubled over on itself before laser cutting, and TPE sheets for actuators were produced in large batches of several hundred layers at a time. Conventional posterboard was used as the substrate for the laser-cutting of TPE, and laser settings were refined to cut through both layers of TPE without cutting through the backing posterboard. Due to the heat produced by the laser cutter, an imperfect but functional bond was formed between TPE layers along the entire cut edge. This allowed for each two-ply layer of TPE to be removed intact with tweezers from the backing substrate and deposited into a container for future use. This batch fabrication, and the ability to pick-and-place each two-ply layer as an intact component helped to facilitate the many rounds of bellows actuator prototyping.

3.3.7 Sealing Challenges

Once the mold layer material selection and thickness, temperature, and pressure setting were optimized, the consistent sealing of the inlet tubing to the TPE layers remained a problem to be solved. The prior sealing process had consisted of using

76.2 μm PTFE film to mask a thin channel of TPE from bonding to itself. Shortly after removal from the oven at 180°C, the PTFE mold layers were removed with tweezers before the TPE cooled. The micro-catheter tubing was then to be inserted with a rigid internal wire temporarily inserted into the tubing to give it sufficient rigidity to force it into the TPE channel. A length of heat-shrink tubing (about 10 - 15 mm) was then placed over the inlet channel and placed within an aluminum block with a central hole. The aluminum block was intended to conduct heat from a programmable heated plate and transmit heat radially to cause the radial contraction of the heat-shrink tubing, which would contract the TPE channel tightly against the micro-catheter tubing and form an airtight seal. The heat-shrink tubing could then be left in place to provide mechanical reinforcement of the seal, or trimmed away with precision surgical scissors to make a lower-profile actuator with more flexible inlet tubing.

However, after the changes already implemented, this process proved challenging and results inconsistent. Bellows actuators resulting from some of these tests are shown in Fig. 3-14. Multiple types of heat-shrink tubing were tested using the above process, including conventional tubing with different shrink ratios (one example of which is shown in Fig. 3-14 (a)), meaning that for the same starting diameter, some will contract more than others, as well as moisture-seal heat-shrink tubing (shown in Fig. 3-14 (b)), which contains a concentric inner layer of adhesive that melts upon heating and is intended to fill small holes and gaps and form a water-resistant seal. To activate these types of heat-shrink tubing, a heat gun with adjustable temperature settings was used. However, the contraction temperature of the heat-shrink tubing was close to the melting point of the TPE, such that care needed to be taken to shield the TPE bellows from the heat gun and to direct the heated airflow away from the main body of the actuator. Even with this precaution, the TPE deformed and curled as it was affected by the applied heat, as shown in Fig. 3-13.

Bellows actuators fabricated with moisture-resistant heat-shrink tubing often had only small leaks, and were capable of inflation to full or near-full heights,

Figure 3-13: The TPE edges near the heat-shrink tubing were susceptible to the heat applied to shrink the tubing.

but could not sustain these inflation heights without continuous injection of air. Bellows actuators were evaluated by submersion in a clear glass beaker of room-temperature tap water and inflated with a 60 mL syringe. The release of bubbles from even tiny holes or punctures in the TPE bellows shell manifested themselves here. It was easy to identify where the failure occurred on the actuator, and therefore at which step in the fabrication process the problem was introduced.

Many batches of actuators were fabricated along these lines, with minor variations. For instance, some batches were fabricated with varied temperature cycles applied to the heat-shrink tubing, or with manually squeezing the heated heat-shrink tubing with tweezers to extrude the molten adhesive out both ends of the contracted tubing, with the intent of creating a complete, air-tight seal. However, errors and leaks continued to manifest. Following technical discussions with Daniel Vogt of the Wyss Institute, two suggestions were made for consistent sealing of the bellows actuators: Flex Seal® “Liquid Rubber in a Can” and Loctite® Vinyl, Fabric & Plastic Flexible Adhesive.

Flex Seal® is a liquid rubber product that is sold in its uncured state but cures to a flexible, waterproof seal in under an hour at room temperature. This material was applied as a sealing material at the interface of the micro-catheter tubing with the TPE both by itself and in conjunction with heat-shrink tubing. However, due to the viscous nature of the Flex Seal® rubber, it did not flow well enough into small gaps, and therefore produced inconsistent sealing results with numerous small leaks. A bellows actuator with this material added in an attempt to seal gaps

left by applied moisture-resistant heat-shrink tubing is shown in Fig. 3-14 (c).

The Loctite[®] Vinyl, Fabric & Plastic Flexible Adhesive proved more successful. It has been used previously in similar work with TPE on a larger scale, as it reacts with TPE and causes it to become malleable and form strong bonds to itself until the adhesive dries after a few minutes. In order to couple the functionality of the Loctite[®] Vinyl, Fabric & Plastic Flexible Adhesive with the existing success of the heat- and pressure-bonding process for sealing all but the inlet tubing, Loctite[®] Vinyl, Fabric & Plastic Flexible Adhesive was added to the TPE immediately before introduction of the final enclosed PTFE disk and inlet tubing. A narrow channel was included in the mold layers to accommodate the inlet tubing, with the thickness of the channel being equal to one half of the outer circumference of the inlet tubing. Upon making the TPE malleable with the addition of Loctite[®] Vinyl, Fabric & Plastic Flexible Adhesive and heat, a tight seal was formed between the tubing and the TPE. This process, as shown in Fig. 3-7, proved effective at forming the final seal of the bellows actuator, forming robust seals. A bellows actuator resulting from this process is shown in Fig. 3-14 (d).

Figure 3-14: Various means of sealing bellows actuator inlet tubing are shown here: (a) conventional heat-shrink tubing (b) water-resistant heat-shrink tubing (c) water-resistant heat-shrink tubing with Flex Seal[®] “Liquid Rubber in a Can” (d) Loctite[®] Vinyl, Fabric & Plastic Flexible Adhesive

This final step is performed at a lower temperature (145°C) because at the same temperature of the prior steps (180°C), the TPE deformed into the central hole of the PTFE disks and resulted in small punctures, as shown in Fig. 3-15. To com-

but this, several batches were fabricated with the alignment plates flipped upside down before being placed into the oven. This same problem also resulted on the opposite outermost bellows chamber. This problem could have potentially been resolved by using internal PTFE disks without internal holes, or with one smaller central hole or a series of small holes. However, this center hole was deliberately included to promote uniform inflation from an un-inflated state, when the bulk of the added air flows through this central hole to reach upper bellows chambers. Thus, the lowering of the oven temperature to still cause uniform TPE bonding without causing unnecessary malleability and deformation was a desirable compromise.

Figure 3-15: Without PTFE supporting the malleable TPE over the internal disk's hole during heating, the distortion tends to tear through and leave a small hole, visible as the bright white spot at the bellows center.

3.3.8 Fabrication Cycles

Each batch of bellows actuators took several hours to complete. The exact fabrication time varied with the number of bellows chambers, and therefore the final inflated height, of the actuators. However, for a basic approximation of batch cycle time, multiple batches of Step 1 (shown in Fig. 3-7) were required to produce sufficient inter-chamber layers, each requiring 60 minutes in the oven, and about fifteen minutes each of set-up and removal time. To optimize the fabrication process, Step 1 was performed in continuous batches on two sets of precision alignment plates, so that one was ready to be placed in the oven to bond immediately after the other plate set was removed. In this way, a continuous flow of TPE intra-bellows layers

could be bonded.

The bellows actuators were laid-up layer-by-layer to reach the desired height, taking about thirty to forty-five minutes to lay-up a batch of 8 actuators. This was then placed into the oven for one hour before removal of the top few mold layers. Alternate and additional mold layers were then inserted, as well as drops of Loctite[®] Vinyl, Fabric & Plastic Flexible Adhesive, lengths of micro-catheter tubing, and finally mold layers on the top. This was all then placed back into the oven under pressure. This final step needed to happen quickly, as the Loctite[®] began to react with the TPE immediately, and heat was needed to make the TPE deformable and pliable enough to form an air-tight seal. Following an additional hour in the oven, the actuators were individually removed from their mold layers and the PTFE layers cut away with precision surgical scissors. From start to finish, each batch of actuators took six to seven hours. Approximately thirty batches of actuators were fabricated to various stages of fabrication cycle completion before the design and process parameters yielded consistently sealed, functional actuators fabricated en masse. The final process parameters described in Fig. 3-7 produce reliable results, with typical yield of 6 or 7 functional actuators out of each batch of 8. The final successful bellows actuator fabrication workflow is presented below.

3.4 Vacuum Gripper

The efficacy of vacuum pressure as a means of gripping soft tissue is well-documented in the literature [22] [23], with novel design approaches including the creation of biomimetic systems based upon octopus suckers [30]. In this thesis, simpler gripper designs were explored.

3.4.1 Final Vacuum Gripper Fabrication Scheme

In order to readily integrate the vacuum gripper into the laminar fabrication methodology of the pop-up structure, the mold is designed to yield a flat sheet of cast elastomer at the top of the vacuum gripper which could be mechanically constrained between two structural sheets with a pass-through for the tubing through which negative pressure is applied. Molds are 3D-printed on an SLA Form 2 printer (Formlabs, Somerville, MA, USA). A silicone elastomer, DragonSkin[®] 20 (Smooth-On, Macungie, PA, USA), is cast into the molds and placed into a vacuum chamber until all trapped air escapes after about ten minutes before being cured at 60°C for 60 minutes. Individual vacuum grippers are cut apart from the larger array in which they are cast, and a small hole is poked through the top of the cured vacuum gripper. Tubing with internal diameter of 0.64 mm (Micro Renathane Cather Tubing, Braintree Scientific, MA, USA) is inserted and the connection is sealed with additional uncured DragonSkin[®] 20 applied on the interior side of the seal with the vacuum gripper, as shown in Fig. 3-2 (b).

3.4.2 Vacuum Gripper Fabrication Overview

Leveraging the fast iteration cycles possible with 3D-printing, a series of molds were designed in CAD using Solidworks[®]. After 3D-printing, they were cured under UV - light and baked in a convection oven for 24 hours before liquid silicone elastomers were cast into the molds and cured. The casting silicone elastomers begins with a 1:1 mass ratio of uncured parts 'A' and 'B' being measured on a balance before being manually mixed and then placed into a centrifuge for 60 seconds. This mixed elastomer has a working time on the order of fifteen minutes before it begins to cure, so it is quickly poured into the 3D-printed mold and placed into a vacuum chamber. "De-gassing" is a commonly-used step in the casting of silicone elastomers. By placing the uncured elastomer under high vacuum pressure, trapped air will rise to the top and no longer remain trapped within the cast elastomer. If this step is not included, inclusions of small bubbles can occur

and compromise the uniformity of the finished cast, as shown in Fig. 3-16.

Initially, a Stratasys Dimension FDM printer (Stratasys, Eden Prairie, MN, USA) was used to print the molds, but the resolution of the printer proved inadequate when sub-millimeter features including rounded fillets were desired on the vacuum grippers. Printing of the molds was then completed on a Form 2 (Formlabs, Somerville, MA, USA) with 25 μm layer resolution, greatly improving the final quality of the finished parts.

The first few batches of molds were designed as hollow “cones” or “domes” of elastomer. In order to produce these as “positives” of the silicone elastomer, “negatives” were required, and to generate the necessary mold geometries, a 2-part mold was necessary. This introduced undesirable complexity into the casting process, and complicated the use of the vacuum chamber to effectively de-gas the cast grippers. This is evident in Fig. 3-16, where trapped air bubbles are visible that were not removed by de-gassing because the 2-part mold blocked them from rising to the surface.

Figure 3-16: Close-up of poor-quality cast silicone elastomer grippers, showing trapped air bubbles.

These 2-part molds consisted of a lower plate with an array of indented pockets that would form the outer side of the vacuum grippers and into which the uncured silicone elastomer would be poured, and an upper piece with protruding parts corresponding to each indentation, forming the inner surface of each vacuum gripper. The upper and lower mold plates were aligned with four 4-40 screws, and screwed together to press the two mold parts tightly together during curing. To expedite the curing process, the mold was placed into a convection oven at 60°C

for 60 minutes.

The initial molds shown in Fig. 3-17 were valuable in qualitatively determining an appropriate size range for vacuum grippers that could be incorporated into the final integrated device.

Figure 3-17: Refinement of 3D-printed vacuum gripper molds included adjustments in gripper size and geometry. The 2-part molds limited potential for degassing and added complexity.

3.4.3 Integration into Device

After the shortfalls of the 3D-printed molds made using the Stratasys[®] Dimension printer, focus was given to simplifying mold design and including features that would allow the vacuum grippers to be readily integrated into the overall device. Because of the laminar nature of the pop-up MEMS fabrication methodology, one ideal means for the integration was determined to be mechanically constraining a thin sheet of cast elastomer between structural layers of FR4. Other methods under consideration included using adhesive to affix the top surface of a cast actuator to a structural layer. However, this was rapidly ruled out because of the incompatibility of silicone elastomers with many conventional adhesives that can affect its material properties and which do not offer substantial resistance to applied tension. Prior testing was conducted by the author that attempted to bond DragonSkin[®] 20, a common silicone elastomer, to acrylic sheet using cyanoacrylate glue and silicone adhesive without success. In prior unpublished work by the author while working in the Harvard Biorobotics Laboratory, a means of mechanically constraining cast silicone elastomeric actuators between two rigid plates

connected with screws was developed. This method proved very effective and adaptable to different pneumatic actuator designs and inspired the thought that a similar approach could be applied to a similar scenario on this smaller scale.

3.4.4 Updated Vacuum Gripper Molds

As such, a new mold array was designed to vary vacuum gripper diameter and height, while keeping gripper wall thickness at a constant 2 mm. This 2 mm value was deemed an acceptable thickness based upon the material properties of the selected silicone elastomer DragonSkin20 after experimental casting of various designs. Fortuitously, the inclusion of this thin elastomeric sheet at the top of the vacuum gripper aligned well with the transition away from complex 2-part molds. An improved mold design is shown in Fig. 3-18. It consists of a negative cylindrical shell into which uncured elastomer will be poured, as well as an indented portion at the top that will create a sheet of elastomer upon casting. A completed vacuum gripper fabricated in this manner and cut apart from the rest of the array is shown in Fig. 3-19.

Figure 3-18: The final 3D-printed vacuum gripper mold is shown above. (a) shows the cavity for the thin elastomeric sheet atop the negative cylinder, (b) shows the array of gripper designs fabricated concurrently.

Design is always a matter of compromise between functional requirements and functionality. Given the basic relationship that $Force = Pressure \times Area$, it follows that for a given vacuum pressure, a larger surface area over which to apply that pressure would generate larger forces. With this information applied to the cylin-

Figure 3-19: Subset of the cast vacuum gripper array shown with inlet tubing inserted and adhered for two grippers. Cast surface finish is smooth with few defects. Grippers can then be cut apart from the array; individual gripper also shown.

drical style of vacuum gripper described above, this suggests that grippers with the largest diameter would be the most desirable. However, this may also merit an increase in the wall thickness in order to maintain similar levels of rigidity. Also, when varying the vacuum gripper height, a taller height would mean that tissue that deforms into the chamber of the vacuum gripper has a larger distance over which to do so before potentially clogging the tubing inlet through which negative pressure is applied. Thus, although the above suggests a tall, wide vacuum gripper could exert large forces upon tissue, these features are tempered by the need for the device to be deployable into the GI tract. Additional height and width of the vacuum gripper increases the viable diameter of overtube that could be used to encase the device during insertion. Because of the selected method of mechanically constraining the device, sufficient structural material to maintain rigidity needs to be extent on either side of the vacuum gripper. Furthermore, the device is currently intended to target small lesions in the GI tract, measuring around 10 mm diameter, so a substantially larger vacuum gripper is not needed. Ultimately, an outer vacuum gripper diameter of 8 mm outer diameter and 4 mm height was selected as the best fit for these competing priorities.

3.4.5 Testing Methods

A fixture was fabricated to reliably and consistently hold vacuum grippers on an Instron[®] machine so that they could be raised at controlled rates to evaluate the

mass of porcine stomach tissue they could retain. The fixture in place on the movable top plate of the Instron[®], with one vacuum gripper installed, lifting a 40 g sample of porcine stomach tissue, corresponding to an exerted force in excess of 0.40 N, is shown in Fig. 3-20.

Figure 3-20: 40 g of mass lifted by vacuum gripper adhering to porcine stomach tissue. Instron axis used to raise the vacuum gripper.

3.4.6 Inlet Tubing Attachment

Micro Renathane Cather Tubing from Braintree Scientific was selected for its compatibility with biological systems and its demonstrated prior use in similar devices [14] [22]. To insert the inlet tubing through which negative pressure is to be applied, the sharp tip of a pair of tweezers was used to manually puncture the top surface of the cast vacuum gripper. With the tweezer tip sticking through the layer of silicone elastomer, a length of micro-catheter tubing was forced over the tweezer tip, and it was rapidly retracted through the elastomer layer. This left the tubing inserted through a close-fitting hole in the elastomer, but still required further sealing to create a robust and leak-resistant seal. Initially, Sil-Poxy[®] Silicone Adhesive (Smooth-On[®], Macungie, PA, USA) was used to create this seal, with the silicone adhesive being applied with a toothpick on the top surface of the vacuum gripper

where the elastomer interfaces with the tubing. This connection was fairly robust, and functioned well in creating a leak-proof seal, but added several millimeters of height to the completed vacuum gripper, as shown in Fig. 3-21.

Figure 3-21: Sil-Poxy[®] Silicone Adhesive was used to seal the inlet tubing, which proved functional but bulky.

These concerns were alleviated by using additional silicone elastomer to create the seal on the interior of the vacuum gripper before trimming the inlet tubing close to the surface. Since the inlet tubing is never under tension during use, the seals created with this method were also sufficient, but with the added benefit of adding no additional height to the vacuum gripper. A vacuum gripper fabricated with this revised seal is shown in Fig. 3-2(b).

Performance of the vacuum gripper when integrated into the final device is described in Ch. 4.

3.5 Integrated System

3.5.1 Integrated Device V1

The first version of the integrated device is shown in Fig. 3-22. This device incorporated the pop-up structure, bellows actuators, and vacuum gripper. However, it was not optimized for conforming to an endoscope with deployment via an over-tube scheme; it was intended as a first-pass at combining these various discrete components and evaluating device performance on porcine stomach tissue. The device was placed onto porcine stomach tissue, negative pressure was applied via the vacuum gripper, and then the bellows actuators were inflated with positive air pressure. The integrated device was functional, retracting tissue to a height

of 9 mm. However, several areas for improvement were identified: subsequent iterations of the device needed to be deployable from the endoscope, the upper structure layers were prone to delamination due to the upper sheet of the cast vacuum gripper deforming the adjacent FR4 layers around itself, the bellows actuators needed to be better fixed in place to prevent movement during inflation, and manual trimming of the device structure was required for optimal functionality.

Figure 3-22: V1 of integrated device successfully retracting tissue. Thickness of elastomeric sheet relative to adhesive sheet is visible in the deformation of top FR4 sheet.

Each of these shortcomings was addressed in the second version of the integrated device shown in Figs. 3-2 and 3-23 and demonstrated in Ch. 4 . Resolution strategies are described below.

3.5.2 Endoscope Deployment

When Integrated Device V1 was placed against the outer diameter of the endoscope to evaluate how it conformed to the circular cross-section, it was apparent that the gap distances of the flexure joints were too small to allow for the requisite bending angles for the top and bottom layers. When refining the design for Integrated Device V2, this gap distance of the flexure joints was increased, and did allow for sufficient conformability to the endoscope for an overtube to fit over the device and endoscope. However, this is still an area for future refinement to best optimize the device design.

3.5.3 Vacuum Gripper Mechanical Constraint

Mechanically constraining the vacuum gripper was identified as an ideal means of keeping the vacuum gripper in place and firmly affixed to the top layers of the pop-up structure. However, due to the design of the vacuum gripper mold used to cast the gripper (Fig. 3-18), the elastomeric sheet included at the top of the vacuum gripper is much thicker than the adhesive layer joining the FR4 layers together. This thickness mismatch induces strain in the FR4 layers, causing the expedited delamination of the FR4 layers. In V2 of the integrated device, two main changes were made to help resolve this: spacer layers of FR4 and adhesive were added, and the thickness of the elastomeric sheet was reduced. The latter change allowed for a reduction in the bending of the adjacent FR4 sheets, compared to V1, but the addition of spacer layers eliminated this deformation completely. Alternating layers of FR4 and 3M[®] 9877 sheet adhesive were added until their thickness summed to that of the elastomeric sheet. A final FR4 layer was then bonded across the top of the device, encapsulating the vacuum gripper between it and the bottom layers of FR4.

3.5.4 Bellows Actuator Placement

In V1 of the integrated device, the bellows actuators were not firmly affixed to the top and bottom of the pop-up structure. An attempt was made to adhere the upper and lower TPE to the FR4 layer using Gel-Pak, a reusable adhesive sheet often used to hold sheet materials during laser micro-machining. However, the Gel-Pak did not bond strongly to the TPE, so a more robust bond was desired.

When conducting testing of individual bellows actuators to build a model correlating force output, inflation height, and input pressure, as described later in Eqns. 4.1 and 4.2, 3M[®] 9877 adhesive was identified as sufficient for bonding the top and bottom TPE layers of a bellows actuator to FR4 sheets for testing on an Instron[®] machine. This same technique was applied here, with the 9877 adhesive keeping the bellows actuators in place during device deployment, inflation, and

deflation in *ex vivo* testing.

3.5.5 V2 of Integrated Device

V2 of the Integrated system is constructed as follows: The bellows actuators with internal rigid PTFE disks and vacuum gripper are incorporated into the pop-up structure to complete the device, as shown in Fig. 3-2 (d) and (e). The vacuum gripper is mechanically constrained between two layers of fiberglass-epoxy laminate sheets. The bellows actuators are affixed on the top and bottom TPE layers with the same adhesive sheet. Input tubing lines for the bellows actuators are linked together by a tee-fitting to operate from a single input pressure line.

Figure 3-23: V2 of integrated device successfully retracting tissue, incorporating changes from V1.

Chapter 4

Testing & Results

All subsystems of the integrated device were tested and characterized individually before incorporation into the integrated device. The soft bellows actuators with rigid internal disks were characterized both in expansion and retraction, a working range of output forces by vacuum suckers was experimentally determined, and the pop-up structure was measured to ensure suitable geometry. *Ex vivo* tests using porcine stomach were performed to simulate the use of the integrated device in the GI tract. The device was also affixed to an endoscope and a proof-of-concept deployment method was demonstrated. The burst pressure of the actuators was measured by pressuring actuators to failure and was found to be 299 kPa.

Prototypes of the bellows actuators with internal rigid PTFE disks are shown in Fig. 3-2 (a). The deflated height of the four-stage bellows without rigid internal disks is 0.85 mm with an expanded height of 18 mm; the deflated height of the comparable actuator with internal disks is 1.8 mm with a comparable expanded height.

4.1 Bellows Actuators

A four-stage bellows actuator was tested on a materials testing machine (Instron®) by placing it between two flat rigid plates displaced from one another at various discrete heights. Dual syringe pumps provide controllable input pressure mea-

sured by a pressure gauge (BSP B010-EV002-A00A0B-S4, Balluff, USA), and force readings from the load cells (Instron[®] $\pm 10\text{N}$ Static Load Cell, Cat. No: 2530-428) were taken at regular pressure intervals. These values were compared to the theoretical model. The top and bottom layers of TPE were adhered to 254 μm fiberglass-epoxy laminate sheets with sheets of 3M[®] 9877 adhesive. This was done to cause a constant contact area of the TPE against the FR4, and therefore also the Instron[®] plate and load cell, regardless of actuator expansion height. Without this flat sheet, the contact area decreases as total expansion height increases, as the top bellows chamber does not deform sufficiently to press fully flat against the top plate.

Bellows actuators were also tested under applied negative pressure to determine the efficacy of the rigid PTFE disks contained within each chamber in resisting buckling and exerting forces under applied negative pressure. The top and bottom layers of TPE were adhered to 254 μm fiberglass-epoxy laminate sheets with sheets of 3M[®] 9877 adhesive, with attached acrylic fixtures to hold these plates in the Instron[®] jaws. The top and bottom plates were spaced 10 mm apart before negative pressure was applied. Negative pressure was measured using a pressure sensor manifold (MPX4115V, Motorola Freescale Semiconductor, Inc., USA) and the retractive force was measured by the load cell of the Instron[®]. This test was performed for bellows actuators with internal PTFE disks of 254 μm thickness and otherwise identical actuators with 76.2 μm internal PTFE disks.

4.1.1 Bellows Actuator Force Characterization (Extension)

In extension, four-stage bellows actuators could produce 10 N of force when expanding from fully flat. The relationship between pressure and area as $F = P \times A$ holds at low displacement heights, and can be better described as $\Delta F = \Delta P \times A$, with the rate of force increasing with a marginal increase in pressure remaining constant across various displacement heights. Regardless of total height, forces on the order of Newtons were produced. Based upon the $\Delta F = \Delta P \times A$ relationship, given the average slope of the plot in Fig. 4-2, the effective area is found to

be $41.7 \pm 8.46 \text{ mm}^2$. This yields an experimental result for diameter of 7.29 mm, which is 8.88% less than the diameter of the rigid PTFE disk (8 mm) and 19% less than that of the bellows chamber (9 mm).

4.1.2 Bellows Actuator Performance Modeling

The above slope data for calculating marginal force exerted with a change in pressure can be combined with displacement results shown in Fig. 4-1 to generate an expression for the observed behavior of the bellows actuator. To determine the force to be exerted at a particular height of an actuator with a 9 mm outer diameter and an 8 mm outer diameter embedded rigid disk, the required pressure value can be interpolated from Fig. 4-1, or approximated by a linear fit, with the linear change added to this fixed offset. This means that

$$F = (4.17 \times 10^{-5})(\Delta P) \quad (4.1)$$

where $\Delta P = P_{input} - P_{Disp}$, the difference between final input pressure and the displacement pressure required for the bellows actuator to reach a particular height. The slope here results from Fig. 4-2 and P_{Disp} is the interpolated pressure required for the bellows actuator to reach a particular height. P_{Disp} can be found with a linear model fitted to the displacement vs. pressure data, which holds with an R-square value of 0.990 at displacements greater than 6 mm. The linear model

$$H_{disp} = (4.78 \times 10^{-2})(P_{Disp}) + 5.41 \quad (4.2)$$

can be used in conjunction with Eqn. 4.1 to get an estimate of the forces these actuators can produce at large displacements, above 6 mm. Below this displacement, the simple $F = P \times A$ model described previously could be used to estimate the forces produced. The linear fit above 6 mm of displacement is sufficient for a device such as this, because we assume that the forces applied at large displacements (to sustain tissue retraction) are more important than those applied at small

Figure 4-1: Plot of displacement (mm) vs. pressure (kPa) during inflation of a four-stage bellows actuator with top and bottom TPE faces attached to 381 μm FR4 with 3M[®] 9877 sheet adhesive.

displacements. 2 mm of bellows actuator displacement is necessary for the base of the device to contact the tissue, due to the height of the vacuum gripper. This model is limited because the actuators deform when encountering resistance, but is presented as a useful way to estimate forces produced in a particular configuration.

Figure 4-2: Plot of pressure vs. force for four-stage bellows actuators in extension at various displacement heights.

4.1.3 Bellows Actuator Force Characterization (Retraction)

When fixtured in an extended state with the top and bottom layers of the bellows constrained 10 mm apart, the maximum force outputted by a four-stage bellows actuator with rigid internal PTFE disks peaked at 3.096 N. The drop in force output after the peak value results from time-dependent behavior of the actuators as they continually buckle and compress inwards with sustained negative pressure. Internal disks of 254 μm thickness resulted in a peak force output of 3.10 N compared to 1.68 N for an otherwise identical actuator with 76.2 μm internal disks, as shown in Fig. 4-3. This represents a 1.8 - fold increase in applied force by bellows actuators in retraction, a substantial increase in force exerted compared to prior versions of these actuators with thinner TPE and PTFE layers [14], validating the prediction made from the model presented in Eqn. 3.1, where the increased resistance to buckling was expected to increase. The buckling of actuators with 76.2 μm internal disks is shown in Fig. 4-4 (a), and the resistance to buckling for actuators with 254 μm internal disks is visible in Fig. 4-4 (b).

Figure 4-3: Plot of pressure vs. force for four-stage bellows actuators in retraction, with and without rigid internal disks. Top and bottom TPE faces are bonded to FR4 sheets and fixed at 10 mm displacement.

Figure 4-4: (a) Bellows actuator with internal PTFE film undergoing buckling during retraction testing with applied vacuum. (b) Bellows actuator with rigid internal disks resisting buckling under applied vacuum.

4.2 Vacuum Grippers

Vacuum grippers cast from silicone elastomers in 3D-printed molds were fixtured in an FR4 and acrylic jig to firmly retain the gripper and affix it to the movable top plate of the Instron[®]. Vacuum was applied (92 kPa) once the base of the vacuum gripper was in contact with a sample of porcine stomach tissue. Once the gripper had retracted a portion of the porcine stomach tissue, the movable top plate of the Instron[®] was raised vertically at a rate of 20 mm/min. Incrementally larger masses of tissue were lifted until the vacuum gripper could no longer fully raise the tissue from its enclosing container without the tissue detaching from the gripper.

4.2.1 Vacuum Gripper Lifting Characterization

Vacuum grippers made from a cast silicon elastomer were successful in lifting 40 g masses of porcine stomach tissue, corresponding to exerted forces in excess of 0.40 N. This is comparable to those measured in the literature for similar grippers that produced up to 1.2 N [22,23].

4.3 Pop-up Structure Testing

Pop-up structures and their component material selections described in Ch. 3 and shown in Fig. 3-2 (d) and (e) were evaluated by comparing performance relative to desired expanded height, and desired stiffness of the overall structure. The flexure joints of the mechanism were also evaluated and manually flexed through their full

range of motion to ensure sufficient gap distance to prevent the fiberglass-epoxy laminate layers from pinching the joint or contacting one another. The pop-up structures were manually opened with precision tweezers and the deployed height of the structure was measured using digital calipers.

4.4 Integrated Device Testing

The integrated device was deployed from an Olympus CF-100L endoscope onto porcine stomach tissue samples using an FEP (Fluorinated Ethylene Propylene) tube to serve as an overtube to contain the integrated device, as described in Fig. 3-1 (a) and (b). This added diameter is comparable to commercially available endoscopes in common use, which have outside diameters ranging from 12.2 - 21 mm [31]. Placing the device with thickness of 4.70 mm and width of 10 mm tangential to the outer surface of the endoscope increases the effective endoscope diameter to 20 mm, but future work on geometric design changes could decrease this diameter to operate with a smaller overtube. Negative pressure (92 kPa) was applied through the vacuum gripper to anchor the device to the tissue before the two bellows actuators were concurrently inflated.

The structure of porcine stomach is comprised of mucosa and muscularis layers which together measure 2500 μm thick. This is thicker than reported thicknesses of human GI tract mucosa and muscularis layers of the intestinal wall, which vary from 495 - 1090 μm , thus making porcine stomach an acceptable substitute for benchtop *ex vivo* testing [32]. Using conventional endoscopy tools, the retracted porcine stomach tissue was successfully contacted by tools inserted through the endoscope working channel.

4.4.1 Integrated Device Retracting Tissue

The integrated device was placed inside an FEP overtube (23.81 mm outer diameter, 22.23 mm inner diameter) with the Olympus CF-100L endoscope (Fig. 4-6 (a)).

Following the scheme described in Fig. 3-1, the overtube was retracted from the endoscope to expose the device, as shown in Fig. 4-6 (b). This proof-of-concept demonstration of deployment validates the described workflow as a means of conducting the device to the site of a lesion. The vacuum gripper is then actuated with applied negative pressure, and inflation of the soft bellows actuators begins, retracting the porcine stomach tissue, as shown in Fig. 4-5. An end-effector is deployed through the working channel of the endoscope, which is capable of interacting with the retracted tissue with visual feedback provided by the distal illuminated camera of the endoscope, as shown in Fig. 4-6 (c).

Figure 4-5: Integrated device deployed on porcine stomach tissue. Tissue is retracted to height of 13.5 mm.

As shown in Fig. 4-6 (d), the tip of the endoscope is decoupled from the integrated tissue retraction device (linked only by flexible tubing for the vacuum gripper and soft bellows actuators). This is a major strength of the device, as once the device is deployed and retracting tissue, the surgeon is free to manipulate the endoscope to best approach the retracted tissue for electro-cautery and biopsy without significant resistance from the device or connections to the deployed device.

Although the integrated device successfully retracts tissue without causing damage to the surrounding area, one major limitation of pop-up MEMS devices deployed in living systems is the sharp, planar nature of the laser micro-machined layers. Future work could be done to minimize this shortcoming by changing the geometric design of the device and adding rounding the corners by adding fillets or encasing the structure in a layer of soft silicone elastomer.

Figure 4-6: (a) Integrated device encased in 23.81 mm outer diameter overtube (b) Integrated device during deployment and overtube retraction (c) View from endoscope distal camera, end-effector in foreground (d) Deployed device retracting tissue, endoscope with tool contacting tissue retracted by integrated device, as an electro-cautery tool would be used to ablate tissue.

4.5 Functional Requirements Evaluation

Table 4.1: Functional Requirements Evaluation

Requirement	Desired Qty.	Measured Qty.
Diameter of area to be retracted	5-8 mm	10 mm
Structure Flat Dimensions	25 mm	30 mm x 40 mm
Structure Expanded Height	10-13 mm	13 mm
Vacuum Gripper Force Applied	1 N	0.40 N
Bellows Actuator Force Produced (each)	1 N	10 N
Endoscope Tool Access to Retracted Tissue	8 mm	16 mm

Chapter 5

Conclusion

5.1 Conclusion

In this thesis, I present a device fabricated with pop-up book MEMS techniques to actively retract tissue in the GI tract while remaining decoupled from the endoscope tip. I introduce a layer-by-layer manufacturing method for using heat and pressure to bond TPE sheets to create pockets with sufficient depth to contain a rigid PTFE disk within each chamber of a larger bellows actuator, using PTFE forms to deform the TPE while at elevated temperatures. The manufacturing method allows for batch fabrication, as well as the inclusion of additional bellows chambers to customize the final actuator stroke. All proposed systems are characterized thoroughly and are fabricated with materials previously used in the fabrication of medical devices.

The inclusion of internal rigid planar disks expands the capabilities of soft TPE bellows actuators, increasing the potential use cases for a mostly-soft bidirectional actuator. On the millimeter-to-centimeter scale, soft TPE bellows offer a relatively large stroke and the ability to exert sustained forces in extension, as well as substantial retractive forces. Furthermore, the bellows actuator design offers the potential to exert proportionally larger forces at the centimeter-scale with similarly large flat-to-expanded ratios, if designed and fabricated with larger bellows chambers.

This theses also introduces a retraction device which can be deployed from conventionally used endoscopes to provide the necessary counteraction to ablate tissue, paving the way for applications in endoscopic removal of early stage cancers. The integrated tissue retraction device offers surgeons an additional method to simplify endoscopic procedures, potentially solving the issues of limited distal tip dexterity and lightening the extensive training requirements to perform these procedures.

5.2 Future Work

The next step in development of the integrated device following the successful *ex vivo* testing on porcine stomach samples is to move to *in vivo* testing in pigs to evaluate device usability in a more realistic surgical context. In order to prepare the device for such testing, several improvements need to be made. Primarily, the device geometry needs improved to better conform to the endoscope, the deployment scheme merits refinement to work with commercially available overtubes, and the plumbing lines for compressed air and vacuum pressure need to interface with the endoscope working channel and existing lines.

Additionally, the fabrication of bellows actuators at smaller scales represents a novel addition to the suite of available pop-up MEMS actuation methods.

5.2.1 Geometry Refinement

The pop-up structural elements encasing the bellows actuators need to be adjusted to better conform to the shape of the endoscope. The gaps in the bottom layer of the pop-up structure for the flexure joints were slightly too small, causing the FR4 to pinch in the flexure joints when bent tightly around the endoscope. This could be alleviated by adding larger flexure gap distances, or by splitting the rigid FR4 segment into multiple discrete rigid panels, allowing it to achieve a tighter bend radius.

5.2.2 Overtube Deployment

The overtube and deployment scheme conceptually described in Fig. 3.1 of Ch. 3 was realized in Fig. 4-6 in Ch. 4 as a proof-of-concept check on the described method. However, the tubing used as an overtube of the endoscope was rigid, and therefore, although sufficient for benchtop *ex vivo* testing, insufficient for *in vivo* testing because of the maneuverability and tight bend radius required of the endoscope. Therefore, a flexible overtube must be selected for use. Due to the length of the tube required, evaluation of samples of commercially available over-tubes, as well as consultation with professional endoscopists, represent next steps in overtube selection. During manual benchtop deployment of the device, difficulty was encountered in sliding the overtube over the device, which tended to be pulled along with the retracted overtube. Friction between both the FR4 structure and with the tee-fittings used for connecting air pressure lines with the tubing material contributed to this effect. As such, a means of fixing the device to the endoscope until reaching the deployment site is desirable. One promising method of accomplishing this is to use the vacuum gripper of the device to keep it firmly affixed to the endoscope diameter. This will require further testing and potential vacuum gripper design modifications to accomplish.

5.2.3 Pressure/Vacuum Plumbing Interface

As mentioned above, interactions between the overtube and plumbing fittings during retraction proved problematic. It is desirable to connect the dual bellows actuators to one line of input pressure as close to the actuators as possible, to prevent potential pressure drops over long lengths of small diameter tubing, as well as to minimize potentially asymmetric inflation between the two actuators. However, the fitting used is made of rigid plastic, and not firmly affixed to the device except by several inches of flexible inlet tubing. Potential solutions to this problem include sourcing smaller and/or more flexible tee- or wye-fittings, affixing the fitting to the structure to keep it in a fixed location (perhaps adjacent to the vac-

uum gripper, on the underside of the top structural layers), or creating a custom version of this fitting with cast silicon elastomer (potentially integrating this cast fitting into the body or an adjacent portion of the vacuum gripper, allowing for fabrication of the vacuum gripper and plumbing connections in one concurrent step). After streamlining the fittings used on the device, a means of interfacing them with the pressure and vacuum lines already extant on the endoscope must be determined, or how to link them to additional external pressure sources. This will require discussion and coordination with professional endoscopists as well as the facility at which the *in vivo* tests would be performed. In order to prevent logistical challenges to the use of the device, planning to use external, independent pressure sources (likely the same dual-syringe pump set-up used in benchtop *ex vivo* testing), and developing a tabletop vacuum-pump solution capable of exerting sufficient negative pressure for the duration of a procedure would be ideal.

Currently, there are plans to perform *in vivo* testing of other endoscopic devices developed by the Harvard Microrobotics Lab in live pigs in the fall of 2017, and this device could potentially be included in those trials. The modifications and explorations mentioned above will be executed in the coming months to prepare the device for these potential *in vivo* tests.

5.2.4 Further Bellows Development

Additionally, further development work on the bellows actuators is pending and offers the potential for a fabrication methodology for bellows actuators at a novel scale. Work in the coming months will explore the possibility of fabricating bellows actuators at the scale of several millimeters diameter. This will also require machining of new custom pin-alignment plates to eliminate the need for manual alignment adjustments, which becomes increasingly difficult as the scale decreases. This new set of alignment plates will be designed with the same external footprint and features of the existing alignment plates, so it will be compatible with other processes used by the Harvard Microrobotics Lab. However, the pin layout

will be customized for this specific application, with the inclusion of additional smaller central alignment holes to align internal PTFE disks at this small scale .

5.2.5 Documentation

The design and fabrication methodology presented will also be documented in the form of an internal white-paper for the Harvard Microrobotics Lab to document the tacit knowledge, or hands-on experience and feel for the materials and processes, developed over the course of this thesis project to support continued work in similar areas without substantial duplicated work. Additionally, interested members of the Harvard Microrobotics Lab will have the opportunity to shadow the fabrication process and ensure familiarity with the necessary steps for creating functional bellows actuators.

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Appendix A

Bill of Materials

The purchases presented here represent the full costs of prototyping the project, with some materials and parts used already being present in the Harvard Micro-robotics Lab or SEAS Active Learning Labs and not used in sufficient quantities to merit separate purchasing. However, the amortized cost of one final device would be substantially less than this total, with the material input costs being quite low, in the range of several dollars. The bulk of the fabrication costs if this or a similar device were to enter commercial production would be the capital and labor costs to produce the device, as industrial precision laser micro-machining was required as well as manual manipulation and alignment of individual layers and components.

Table A.1: Total Prototyping Costs

Vendor	Cost
Amazon	\$63.51
Braintree Scientific	\$75.00
McMaster-Carr	\$369.06
Total Cost	\$507.57

Table A.2: Assorted Vendor Orders

Vendor	Item Name	#	Total Cost
Amazon	Aven 18480EZ E-Z Pik 6-Piece Tweezers Set, Stainless Steel	1	\$34.51
Amazon	SE - Pick Set - Double Ended, Stainless Steel Heavy Duty, 4 Pc	1	\$10.34
Amazon	Iris Surgical Scissors 4 1/2" Curved	1	\$6.09
Amazon	Scotch Precision Ultra Edge Scissors, 8 Inch, 3-Pack (1458-3AMZ)	1	\$12.57
BrainTree Scientific	Micro-Renathane Tubing Per Ft., .040" x .025" Continuous Length, 50 ft.	1	\$75.00
Smooth - On [®]	DragonSkin [®] 20		
Smooth - On [®]	Sil-Poxy [®] Silicone Adhesive		
3M [®]	9877 Adhesive Sheet		
	25 μ m thick Polyimide Film		
Fiber Glast	38 μ m Thermoplastic Elastomer (TPE)		
	Assorted Hardware		
	Assorted Acrylic		

Table A.3: McMaster-Carr Orders

Item Name	Part #	#	Total Cost
Sheets Made with Teflon® PTFE, White Sheet, .039" Thick, 6" x 6"	8545K12	1	\$8.11
Sheets Made with Teflon® PTFE, White Sheet, 1/32" Thick, 6" x 6"	8545K11	1	\$7.31
PTFE Shim Stock, Sheet, 0.015" Thick, 8" x 12"	1192N16	1	\$16.25
Sheets Made with Teflon® PTFE, White Sheet, 1/32" Thick, 12" x 12"	8545K21	1	\$20.89
White Delrin® Acetal Resin Strip, .010" Thick, 6" Width, 5ft	8738K41	1	\$6.45
18-8 Stainless Steel Dowel Pin, 1/16" Diameter, 7/8" Length	90145A424	1	\$12.14
White Delrin® Acetal Resin Strip, .020" Thick, 6" Width, 5ft	8738K43	1	\$9.40
PTFE Shim Stock, Sheet, 0.015" Thick, 8" x 12"	1192N16	1	\$16.25
Film Made with Teflon® PTFE, 0.003" Thick, 6" Width, 3 ft. Length	8569K14	1	\$6.66
18-8 Stainless Steel Dowel Pin, 1/16" Diameter, 7/8" Length, packs of 100	90145A424	2	\$12.14
18-8 Stainless Steel Dowel Pin, 1/16" Diameter, 1-1/4" Length, packs of 50	90145A425	1	\$8.23
Flame-Retardant Garolite (G-10/FR4), .005" Thick, 24" x 36", Precision Film	1331T57	1	\$41.69
Flame-Retardant Garolite (G-10/FR4), .010" Thick, 24" x 36", Precision Film	1331T59	1	\$44.62
Flame-Retardant Garolite (G-10/FR4), .015" Thick, 24" x 36", Precision Film	1331T61	1	\$46.64
Film Made with Teflon® PTFE, 0.010" Thick, 12" Width, 2 ft. Length	8569K41	1	\$23.38
Film Made with Teflon® PTFE, 0.015" Thick, 12" Width, 2 ft. Length	8569K43	1	\$30.82
Film Made with Teflon® PTFE, 0.005" Thick, 12" Width, 2 ft. Length	8569K38	1	\$14.14
Moisture-Seal Heat-Shrink Tubing, 2:1 Shrink Ratio, 0.13" ID Before Shrinking, 4 Feet Long	74965K61	1	\$4.50
Moisture-Seal Heat-Shrink Tubing, 2.5:1 Shrink Ratio, 0.13" ID Before Shrink, 4 Feet Long	73115K71	1	\$7.52
High-Temperature Moisture-Seal Heat-Shrink Tubing, 0.19" ID Before Shrinking, 1/2 Feet Long	7960K22	1	\$6.90
Moisture-Seal Heat-Shrink Tubing, 2:1 Shrink Ratio, 0.19" ID Before Shrinking, 4 Feet Long	74965K62	1	\$5.33
Moisture-Seal Heat-Shrink Tubing, 2.5:1 Shrink Ratio, 0.19" ID Before Shrink, 4 Feet Long	73115K72	1	\$8.00
Film Made with Teflon® PTFE, 0.010" Thick, 12" Width, 1 ft. Length	8569K41	1	\$11.69

Appendix B

Engineering Drawings

Table B.1: Bellows Actuators Engineering Drawings Details

Drawing Name	Material	Fabrication Method	Page #
TPE_full	38 μm TPE	Laser-Cutting	71
TPE_innerbond	38 μm TPE	Laser-Cutting	72
Teflon_innerbond_step1	38 μm TPE	Laser-Cutting	73
FR4_spacerdisk_outerbond	254 μm PTFE	Laser-Cutting	74
narrow_tonge_recreation	254 μm PTFE	Laser-Cutting	75
teflon_top_press1	254 μm PTFE	Laser-Cutting	76

Table B.2: Pop-Up Structure Engineering Drawings Details

Drawing Name	Material	Fabrication Method	Page #
2-20-topFR4_1	254 μm FR4, 3M [®] 9877 Adhesive	Laser-Cutting	77
2-20-GlueCenter	3M [®] 9877 Adhesive	Laser-Cutting	78
2-20-outlinethrucut	25 μm Polyimide Film	Laser-Cutting	79
2-20-RELEASE	N/A, Release Cut	Laser-Cutting	80

Table B.3: Vacuum Gripper Engineering Drawing Details

Drawing Name	Material	Fabrication Method	Page #
v5_sucker_molds_high_res	Formlabs Clear Resin	3D-Printing	81

Appendix C

IROS Submission

The following paper was submitted on March 1, 2017 to the IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS) Conference to be held September 24 - 28, 2017 in Vancouver, Canada and is currently under peer review. The paper presents the highlight and overview of the work presented in this thesis.

The paper that follows reflects several minor typographical corrections but is otherwise the same as was submitted for peer review.

Pop-Up Tissue Retraction Mechanism for Endoscopic Surgery*

S. Becker¹, T. Ranzani², S. Russo², R. J. Wood²

Abstract—Numerous therapeutic transendoscopic procedures exist to treat lesions in the GI tract. However, these procedures are limited by their difficulty and the amount of training required to successfully perform them. The surgeon is tasked with simultaneously steering the distal tip of the endoscope, applying tension to tissue to retract it, and manipulating electro-cautery tools with limited dexterity. In this paper, we propose a device designed to assist with anchoring and tissue retraction during endoscopic surgical procedures. The designed solution decouples the tissue-grasping function from the movement of the endoscope tip, leaving the surgeon free to use the endoscope tip solely for positioning of electro-cautery or biopsy tools deployed through the endoscope working channel. The anchoring and retraction device uses pop-up book MEMS techniques, allowing for a flat structure to expand into a 3-dimensional structure many times its initial height. The proposed device has three main integrated components: a rigid expandable geometric structure, inflatable pneumatic actuators, and a vacuum gripper. These inflatable actuators include internal rigid discs, allowing for resistance to buckling while maintaining the benefits of the established lightweight, low profile actuator design scheme. Proof-of-concept *ex vivo* testing demonstrates that the integrated device can be used to retract tissue to a height of 13.5 mm, providing access for endoscopy tools to contact a sample of porcine stomach tissue.

I. INTRODUCTION

Current trends in surgical procedures have focused on minimally invasive surgery (MIS) with the end goal of shortening recovery time and improving patient outcomes. Since their development in the 1960s, flexible and steerable endoscopes have become the standard approach for diagnostic and therapeutic procedures in the gastrointestinal (GI) tract [1]. Although endoscopic diagnostic procedures performed are well-established and routine, many challenges exist when using endoscopes for therapeutic procedures, such as excising or ablating cancerous sites or other lesions. These challenges include distal tip instability, a lack of control for fine distal positioning, and the low amount of force that can be exerted by the endoscope tip without causing deflection of the endoscope itself [2]. Techniques such as endoscopic submucosal dissection (ESD) have been

Fig. 1. Illustration of usage case of the proposed device and the workflow for deployment and tissue retraction: (a) collapsed device affixed to endoscope within hollow overtube, (b) deployment by retracting the overtube to expose the device, (c) positioning of the device with forceps over the targeted lesion, and (d) mechanism retracting tissue, allowing conventional tools to be used to excise the lesion with electro-cautery.

developed [3] to help address these shortcomings, but they require extensive training to successfully perform. Endoscopic mucosal resection (EMR) is another procedure aimed at removing small lesions (< 25 mm) in the GI tract, but is challenged by the lack of endoscope distal tip dexterity [3]. Additional research has included the development of endoscopic add-ons to supplement the existing capabilities of conventional endoscopes [4]–[8], but these are similarly hampered by the inherent flexibility of the endoscope. Although this flexibility is crucial for navigating the curving GI tract to reach the surgical site, the flexibility of the distal tip of the endoscope limits the capabilities of endoscopic therapeutic procedures [2], [9]. Proposed solutions of anchoring the endoscope are numerous in the literature, with examples including inflatable balloons, pop-up structures, and adhesives [10]–[13]. Work has also been done to enhance distal tip dexterity with a highly-controllable means of steering the endoscope tools, minimizing the need to move the endoscope itself [4].

In this paper, we address the limitations of current resection or ablation-based surgical procedures targeting early colorectal cancer (ECC) lesions in the lower GI tract performed with conventional flexible endoscopes. In order to fit within the current workflow of therapeutic endoscopic procedures, the proposed tissue retraction device can be introduced into the body along the outside of the distal end of an endoscope

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and encased in a retractable overtube (Fig. 1). By automating the act of placing tissue under tension and decoupling this action from the motion of the endoscope tip, the integrated device presented here has the potential to expand surgeons' capabilities and increase the number of surgeons capable of performing these types of procedures.

In Section II, we introduce a fabrication scheme for embedding rigid disks in TPE bellows actuators based upon prior work [14], with planar manufacturing techniques. We also introduce the fabrication of an integrated device consisting of an expandable structure, inflatable bellows actuators, and a vacuum gripper to enable tissue retraction. The expandable structure is based upon the pop-up book MEMS fabrication methodology [15]. Pop-up book MEMS has been used successfully for the development of medical devices in the literature [16]. The concept of integrating soft, inflatable devices with expandable rigid structures to constrain the inflation of the actuator has also been previously proposed [8] [17]. The integrated device and its components are tested with protocols presented in Section III, and the results of these experiments are presented in Section IV.

II. DESIGN & FABRICATION

A. Concept Design

The proposed device can be affixed to the outside surface of the distal end of an endoscope and constrained within an overtube to shield the device from contacting tissue until at the surgical site in the GI tract, as shown in Fig. 1 (a). The overtube is then retracted to expose the device (Fig. 1 (b)). Forceps deployed through the endoscope working channel are used by the surgeon to position the device atop a lesion, with visual guidance and confirmation from the illuminated distal camera (Fig. 1 (c)). Although shown placing the device on a horizontal section of tissue, because it is grasped by forceps during positioning, the distal endoscope position and orientation can be adjusted by the surgeon to place the device in the GI tract regardless of orientation to horizontal. Once properly positioned, negative pressure is applied to the vacuum gripper at the center of the device, adhering the device to the lesion site while negative pressure is sustained. The dual bellows actuators are then inflated, expanding the pop-up structure and retracting the grasped tissue. The surgeon can now use conventional endoscopy tools such as electro-cautery probes inserted through the endoscope working channel to cut through the mucosa and muscularis layers beneath the lesion site, as shown in Fig. 1 (d). The dissected tissue is still held by the device's vacuum gripper and can be grasped with forceps for removal from the body for pathology analysis. The device is rapidly collapsed by venting pressure from the bellows actuators. To excise larger lesions, the device is repeatedly expanded, collapsed,

and repositioned with forceps delivered through the endoscope working channel to adjust vacuum gripper location between rounds of electro-cautery. To remove the device from the body upon completion of a procedure, negative pressure is applied to the bellows actuators to keep them in a deflated state, the overtube is advanced, and forceps are used to maneuver the device back into the overtube while the endoscope is retracted. The thickness of the device before inflation should add less than 10 mm to the endoscope diameter to maintain overtube compatibility, and the device requires an expanded height of 13 mm or greater to retract tissue to a height of 10 mm, which offers sufficient access to the retracted tissue by endoscope end-effectors. However, the fabrication workflow presented here could be customized for different actuator use cases.

B. Bellows Actuator Design and Improvements

Heat- and pressure-bonded Thermoplastic Elastomer, TPE (Fiber Glast, USA) bellows actuators with Polytetrafluoroethylene (PTFE) mask layers have been developed that demonstrate a linear relationship between blocked force and input pressure at low displacement heights, but exert limited retractive forces due to the tendency of bellows chambers to buckle inwards when vacuum is applied, rather than move axially [14].

Here we propose the introduction of rigid PTFE disks within the enclosed chambers of the soft bellows actuators at the same scale. The planar fabrication method of combining subunits to form complete bellows chambers enables the inclusion of additional bellows chambers and thus customizable inflation height. This paper will focus on bellows actuators with a diameter of 9 mm and four bellows chambers. These dimensions were selected for suitability for integration into the tissue retraction device and limits on overtube size.

The first sub-unit of the a soft bellows actuator is fabricated with two adjacent layers of 38 μm thick TPE following the process shown in Fig. 2. This double layer of TPE enhances robustness of the material when undergoing deformation during heating, as this deformation is required to accommodate internal disks of sufficient thickness to resist buckling under applied negative pressure. Different layers of TPE are cut with a CO_2 laser cutter and alternated with laser-cut 254 μm and 76.2 μm PTFE layers to act as masks and forms. Layers of TPE and PTFE are aligned using precision dowel pins and stacked manually. The layers of TPE in the first two steps of the process are bonded at 180°C for one hour under 0.07 MPa pressure, as shown in Fig. 2. The 76.2 μm PTFE layers serve in the first step to mask the TPE and allow only desired areas to bond (Fig. 2 (a)). This first step produces the layer that interfaces between two bellows chambers. The 254 μm PTFE also serves as a mask to the TPE but also as a form to create sufficient vertical space while the TPE is

Fig. 2. Fabrication workflow for the proposed bellows actuators with internal rigid disks: (a) Interface layer between adjacent bellows chambers (b) Additional mold layers with the result of the previous step, creating pocket for enclosed disk (c) Final bonding of top TPE layer and input tubing (d) Enclosed disk dimensions.

heated to encase rigid PTFE disks within the bellows chambers.

During the second step of the process (Fig. 2 (b)), multiple subunits resulting from the first step may be added, serving to customize expanded height of the finished actuator. Additional 254 μm PTFE mold layers are added to transmit the vertically applied force of 0.07 MPa to the areas of TPE being bonded. In this step, the bonds around the outer diameter of all bellows chambers except that with the inlet tubing are formed. Following heat- and pressure-bonding, the top layers of this laminate are manually removed, and additional 254 μm PTFE layers are added as forms to create bonds that will enclose the last bellows chamber with its inlet tubing. A tube with internal diameter of 0.64 mm (Micro Renathane Catheter Tubing, Braintree Scientific, USA) is inserted and a drop of Loctite Vinyl, Fabric & Plastic Flexible Adhesive is added before the top sheet of TPE and an upper PTFE mold layer are added. The resulting laminate is heated at 145°C for one hour under 0.06 MPa pressure, as shown in Fig. 2 (c). The external PTFE layers are manually cut away before the laminate has cooled, and the inlet tubing is trimmed, producing bellows actuators like those shown in Fig. 3 (a).

The output force of an actuator produced from this process can be modeled by the simple $F = P \times A$ relationship, where F is the force produced, P is the input pressure, and A is the area of the circular bellows chamber when flat, as determined by the 254 μm PTFE layers that transmit the applied force during heating in Fig. 2 (b) and (c). This relationship holds true when expanding from flat, with decreased force output as the overall height increases and the TPE begins to strain. However, as this outputted force magnitude diminishes, $\Delta F = \Delta P \times A$ is a better description. The rate at which force output increases with an increase

in pressure will be relatively constant and dependent upon the area of a bellows chamber, and is detailed in Section IV.

Previous iterations of soft bellows actuators fabricated with a 76.2 μm PTFE film disk encased in each bellows chamber (solely to mask the TPE layers from bonding in the chamber) were susceptible to bending and buckling when under applied negative pressure, limiting the pulling force output to 0.50N [14]. Bellows actuators under retraction also undergo a time-dependent decay in applied force as they approach a steady-state constant output when the TPE and 76.2 μm PTFE have buckled to their minimum internal volume. As such, it was hypothesized that the incorporation of a thicker, more rigid PTFE disk would minimize these effects and improve the retraction performance of the actuator. Modeling the system as a disk under uniform radial compression, which the TPE would apply to the disk under applied negative pressure, as discussed in Eqn. 1, supports this hypothesis.

We model the enclosed disk as a circular plate with a concentric hole under uniform radial compression on its outer edge, with a being outside diameter of the disk, b being the inner diameter of the disk as shown in Fig. 2 (d), t being thickness of the disk, E being Young's modulus, ν being Poisson's ratio, and σ' being critical unit compressive stress. Because the ratio of diameter to thickness $\frac{a}{t}$ is greater than 10, this model holds and we can say that:

$$\sigma' = K \left(\frac{E}{1-\nu^2} \right)^2 \left(\frac{t}{a} \right)^2 \quad (1)$$

where K is a tabulated value dependent upon $\frac{b}{a}$ and equal to a linearly interpolated value of 0.285 from [18], thus $\sigma' \propto t^2$.

Therefore, increasing the thickness of the internal PTFE disks from 76.2 μm (solely to mask the TPE) to a thicker sheet (to provide rigidity as well as to act as a mask) suggests that the bending stiffness of a chamber of the bellows actuator would increase by $(t_{thick}/t_{thin})^2$. Thus, when increasing disk thickness from 76.2 μm to 254 μm , this results in increased resistance to buckling by a factor of 3.3², or 10.89.

This assumes both versions are subjected to the same radial compression, as both are tested under equal vacuum line pressure applied to actuators that are identical other than thickness of their enclosed disks. A thicker internal disk, then, will allow individual bellows actuator chambers to resist subsequent buckling under vacuum and therefore allows higher retractive forces to be achieved.

C. Vacuum Grippers

In order to readily integrate the vacuum gripper into the laminar fabrication methodology of the pop-up structure, the mold is designed to yield a flat sheet of cast elastomer at the top of the vacuum

gripper which could be mechanically constrained between two structural sheets with a pass-through for the tubing through which negative pressure is applied. Molds are 3D-printed on an SLA Formlabs 2 (Formlabs, Somerville, MA, USA). A silicone elastomer, DragonSkin 20 (Smooth-On, Macungie, PA, USA), is cast into the molds and placed into a vacuum chamber until all trapped air escapes after about ten minutes, before being cured at 60°C for 60 minutes. Individual vacuum grippers are cut apart from the larger array in which they are cast, and a small hole is poked through the top of the cured vacuum gripper. Tubing with internal diameter of 0.64 mm (Micro Renathane Cather Tubing, Braintree Scientific, USA) is inserted and the connection is sealed with additional uncured DragonSkin 20 applied on the interior side of the seal with the vacuum gripper, as shown in Fig. 3 (b).

D. Pop-up Structure

Pop-up book MEMS is a design and fabrication methodology in which thin layers of material are machined individually and selectively laminated together with adhesive and flexible layers, allowing a flat structure to expand into a 3-dimensional device based on flexure joints [15]. The pop-up structure presented here is designed to accommodate the incorporation of a vacuum gripper and strain-relieving expandable housing for two bellows actuators, without substantial deformation during use. Materials for the fabrication of the pop-up structure include 381 μm thick fiberglass-epoxy laminate sheets as structural material (Garolite G-10/FR4), 25 μm thick polyimide film as flexure layers, and pressure-sensitive 3M[®] sheet adhesive (9877). Each layer is individually machined using a diode-pumped solid state (DPSS) laser, and aligned using precision dowel pins. The resulting laminate is laser machined to release the final device structure, shown in Fig. 3 (c) from the bulk substrate before integration of the vacuum gripper. The design of the pop-up structure depends upon the deployment method of the device, in which it is affixed to the outer diameter of the endoscope within a flexible overtube. As such, the pop-up structure is designed to minimize the marginal increase in endoscope diameter before the device is deployed.

E. Integrated System

The bellows actuators with internal rigid PTFE disks and vacuum gripper are incorporated into the pop-up structure to complete the device, as shown in Fig. 3 (d) and (e). The vacuum gripper is mechanically constrained between two layers of fiberglass-epoxy laminate sheets. The bellows actuators are affixed on the top and bottom TPE layers with the same adhesive sheet. Input tubing lines for the bellows actuators are linked together by a tee-fitting to operate from a single input pressure line.

III. EXPERIMENTS

All subsystems of the integrated device were tested and characterized individually before incorporation into the integrated device. The soft bellows actuators with rigid internal disks were characterized both in expansion and retraction, a working range of output forces by vacuum suckers was experimentally determined, and the pop-up structure was measured to ensure suitable geometry. *Ex vivo* tests using porcine stomach were performed to simulate the use of the integrated device in the GI tract. The device was also affixed to an endoscope and a proof-of-concept deployment method was demonstrated. The burst pressure of the actuators was measured by pressuring actuators to failure and was found to be 299 kPa.

A. Bellows Actuator Force Characterization

A four-stage bellows actuator was tested on a materials testing machine (Instron[®]) by placing it between two flat rigid plates displaced from one another at various discrete heights. Dual syringe pumps provide controllable input pressure measured by a pressure gauge (BSP B010-EV002-A00A0B-S4, Balluff, USA), and force readings from the load cells (Instron[®] $\pm$ 10N Static Load Cell, Cat. No: 2530-428) were taken at regular pressure intervals. These values were compared to the theoretical model. The top and bottom layers of TPE were adhered to 254 μm fiberglass-epoxy laminate sheets with sheets of 3M[®] 9877 adhesive. This was done to cause a constant area of the TPE pressing against the fiberglass-epoxy laminate, and therefore also the Instron[®] plate and load cell, regardless of expansion. Without this flat sheet, the contact area decreases as total expansion height increases, as the top bellows chamber does not deform sufficiently to press fully flat against the top plate.

Bellows actuators were also tested under applied negative pressure to determine the efficacy of the rigid PTFE disks contained within each chamber in resisting buckling and exerting forces under applied negative pressure. The top and bottom layers of TPE were adhered to 254 μm fiberglass-epoxy laminate sheets with sheets of 3M[®] 9877 adhesive, with attached acrylic fixtures to hold these plates in the Instron[®] jaws. The top and bottom plates were spaced 10 mm apart before negative pressure was applied. Negative pressure was measured using a pressure sensor manifold (MPX4115V, Motorola Freescale Semiconductor, Inc., USA) and the retractive force was measured by the load cell of the Instron[®]. This test was performed for bellows actuators with internal PTFE disks of 254 μm thickness and otherwise identical actuators with 76.2 μm internal PTFE disks.

B. Vacuum Gripper Testing

Vacuum grippers cast from silicone elastomers in 3D-printed molds were fixtured in a fiberglass-epoxy and

acrylic jig to firmly retain the gripper and affix it to the movable vertical axis of the Instron[®]. Vacuum was applied (92 kPa) once the base of the vacuum gripper was in contact with a sample of porcine stomach tissue. Once the gripper had retracted a portion of the porcine stomach tissue, the movable plate of the Instron[®] was raised vertically at a rate of 20 mm/min. Incrementally larger masses of tissue were lifted until the vacuum gripper could no longer fully raise the tissue from its enclosing container.

C. Pop-up Structure Testing

Pop-up structures and their component material selections described in Section II. and shown in Fig. 3 (d) and (e) were evaluated by comparing performance relative to desired expanded height, and desired stiffness of the overall structure. The flexure joints of the mechanism were also evaluated and manually flexed through their full range of motion to ensure sufficient gap distance to prevent the fiberglass-epoxy laminate layers from pinching the joint or contacting one another. The pop-up structures were manually opened with precision tweezers and the deployed height of the structure was measured using calipers.

D. Integrated Device Testing

The integrated device was deployed from an Olympus CF-100L endoscope onto porcine stomach tissue samples using an FEP (Fluorinated Ethylene Propylene) tube to serve as an overtube to contain the integrated device, as described in Fig. 1 (a) and (b). This added diameter is comparable to commercially available endoscopes in common use, which have outside diameters ranging from 12.2 - 21 mm [19]. Placing the device with thickness of 4.70 mm and width of 10 mm tangential to the outer surface of the endoscope increases the effective endoscope diameter to 20 mm, but future work on geometric design changes could decrease this diameter to operate with a smaller overtube. Negative pressure (92 kPa) was applied through the vacuum gripper to anchor the device to the tissue before the two bellows actuators were concurrently inflated.

The structure of porcine stomach is comprised of mucosa and muscularis layers which together measure 2500 μm thick. This is thicker than reported thicknesses of human GI tract mucosa and muscularis layers of the intestinal wall, which vary from 495-1090 μm , thus making porcine stomach an acceptable substitute for benchtop *ex vivo* testing [20]. Using conventional endoscopy tools, the retracted porcine stomach tissue was successfully contacted by tools inserted through the endoscope working channel.

IV. RESULTS & DISCUSSION

Prototypes of the bellows actuators with internal rigid PTFE disks are shown in Fig. 3 (a). The deflated height of the four-stage bellows without rigid internal

Fig. 3. Several subsystems are integrated together in the final device: (a) A four-stage TPE bellows actuators with rigid internal disks (shown in various stages of expansion), to expand the device (b) A silicone elastomer vacuum gripper, to grip the tissue to be retracted (c) The pop-up book MEMS structure comprised of structural, flexural, and adhesive layers. These are laminated together to create the final device (d) Integrated device in undeployed state (e) Integrated device fully expanded by inflated bellows actuators.

Fig. 4. Plot of pressure vs. force for four-stage bellows actuators in extension at various displacement heights.

disks is 0.85 mm with an expanded height of 18 mm; the deflated height of the comparable actuator with internal disks is 1.8 mm with a comparable expanded height.

Fig. 5. Plot of displacement (mm) vs. pressure (kPa) during inflation of a four-stage bellows actuator with top and bottom TPE faces attached to 381 μm FR4 with 3M[®] 9877 sheet adhesive.

Fig. 6. Plot of pressure vs. force for four-stage bellows actuators in retraction, with and without rigid internal disks. Top and bottom TPE faces are bonded to FR4 sheets and fixed at 10 mm displacement.

A. Bellows Actuator Force Characterization (Extension)

In extension, four-stage bellows actuators could produce 10 N of force when expanding from fully flat. The relationship between pressure and area as $F = P \times A$ holds at low displacement heights, and can be better described as $\Delta F = \Delta P \times A$, with the rate of force increasing with a marginal increase in pressure remaining constant across various displacement heights. Regardless of total height, forces on the order of Newtons were produced. Based upon the $\Delta F = \Delta P \times A$ relationship, given the average slope of the plot in Fig. 4, the effective area is found to be $41.7 \pm 8.46 \text{ mm}^2$. This yields an experimental result for diameter of 7.29 mm, which is 8.88% less than the diameter of the rigid PTFE disk (8 mm) and 19% less than that of the bellows chamber (9 mm).

The above slope data for calculating marginal force exerted with a change in pressure can be combined with displacement results shown in Fig. 5 to generate an expression for the observed behavior of the bellows actuator. To determine the force to be exerted at a particular height of an actuator with a 9 mm outer diameter and an 8 mm outer diameter embedded rigid disk, the required pressure value can be interpolated from Fig. 5, or approximated by a linear fit, with the

linear change added to this fixed offset. This means that

$$F = (4.17 \times 10^{-5})(\Delta P) \quad (2)$$

where $\Delta P = P_{\text{input}} - P_{\text{Disp}}$, the difference between final input pressure and the displacement pressure required for the bellows actuator to reach a particular height. The slope here results from Fig. 4 and P_{Disp} is the interpolated pressure required for the bellows actuator to reach a particular height. P_{Disp} can be found with a linear model fitted to the displacement vs. pressure data, which holds with an R-square value of 0.990 at displacements greater than 6 mm. The linear model

$$H_{\text{Disp}} = (4.78 \times 10^{-2})(P_{\text{Disp}}) + 5.41 \quad (3)$$

can be used in conjunction with Eqn. 2 to get an estimate of the forces these actuators can produce at large displacements, above 6 mm. Below this displacement, the simple $F = P \times A$ model described previously could be used to estimate the forces produced. The linear fit above 6 mm of displacement is sufficient for a device such as this, because we assume that the forces applied at large displacements (to sustain tissue retraction) are more important than those applied at small displacements. 2 mm of bellows actuator displacement is necessary for the base of the device to contact the tissue, due to the height of the vacuum gripper. This model is limited because the actuators deform when encountering resistance, but is presented as a useful way to estimate forces produced in a particular configuration.

B. Bellows Actuator Force Characterization (Retraction)

When fixtured in an extended state with top and bottom layers of the bellows constrained 10 mm apart, the maximum force outputted by a four-stage bellows actuator with rigid internal PTFE disks peaked at 3.096 N. The drop in force output after the peak value results from time-dependent behavior of the actuators as they continually buckle and compress inwards with sustained negative pressure. Internal disks of 254 μm thickness resulted in a peak force output of 3.10 N compared to 1.68 N for an otherwise identical actuator with 76.2 μm internal disks, as shown in Fig. 6. This represents a 1.8-fold increase in applied force by bellows actuators in retraction, a substantial increase in force exerted compared to prior versions of these actuators with thinner TPE and PTFE layers [14], validating the prediction made from Eqn. 1. The buckling of actuators with 76.2 μm internal disks is shown in Fig. 7 (a), and the resistance to buckling for actuators with 254 μm internal disks is visible in Fig. 7 (b).

C. Vacuum Gripper Lifting Characterization

Vacuum grippers made from a cast silicon elastomer were successful in lifting 40 g masses of porcine stomach tissue, corresponding to exerted forces in excess of 0.40 N. This is comparable to those measured in the

Fig. 7. (a) Bellows actuator with internal PTFE film undergoing buckling during retraction testing with applied vacuum. (b) Bellows actuator with rigid internal disks resisting buckling under applied vacuum.

literature for similar grippers that produced up to 1.2 N [21] [22].

D. Integrated Device Retracting Tissue

The integrated device was placed inside an FEP overtube (23.81 mm outer diameter and 22.23 mm inner diameter) with the Olympus CF-100L endoscope (Fig. 8 (a)). Following the scheme described in Fig. 1, the overtube was retracted from the endoscope to expose the device, as shown in Fig. 8 (b). This proof-of-concept demonstration of deployment validates the described workflow as a means of conducting the device to the site of a lesion. The vacuum gripper is then actuated with applied negative pressure, and inflation of the soft bellows actuators begins, retracting the porcine stomach tissue, as shown in Fig. 9. An end-effector is deployed through the working channel of the endoscope, which is capable of interacting with the retracted tissue with visual feedback provided by the endoscope distal illuminated camera, as shown in Fig. 8 (c). See attached video of synchronized distal and external camera views of the endoscope end-effector interacting with the retracted tissue.

As is visible in Fig. 8 (d), the tip of the endoscope is decoupled from the integrated tissue retraction device (linked only by flexible tubing for the vacuum gripper and soft bellows actuators). This is a major strength of the device, as once the device is deployed and retracting tissue, the surgeon is free to manipulate the endoscope to best approach the retracted tissue for electro-cautery and biopsy.

Although the integrated device successfully retracts tissue without causing damage to the surrounding area, one major limitation of pop-up MEMS devices deployed in living systems is the sharp, planar nature of the laser micro-machined layers. Future work could be done to minimize this shortcoming by changing the geometric design of the device and adding fillets to the corners or encasing the structure in a layer of soft silicone elastomer.

V. CONCLUSIONS

In this paper, we present a device fabricated with pop-up book MEMS techniques to retract tissue in the GI tract while remaining decoupled from the endoscope tip. We introduce a layer-by-layer manufacturing method for using heat and pressure to bond TPE sheets

Fig. 8. (a) Integrated device encased in 23.81 mm outer diameter overtube (b) Integrated device during deployment and overtube retraction (c) View from endoscope distal camera, end-effector in foreground (d) Deployed device retracting tissue, endoscope with tool contacting tissue retracted by integrated device, as an electro-cautery tool would be used to ablate tissue.

Fig. 9. Integrated device deployed on porcine stomach tissue. Tissue is retracted to height of 13.5 mm.

to create pockets with sufficient depth to contain a rigid PTFE disk within each chamber of a larger bellows actuator, using PTFE forms to deform the TPE while at elevated temperatures. The manufacturing method allows for batch fabrication, as well as the inclusion of additional bellows chambers to customize the final stroke of the actuator. All proposed systems are characterized thoroughly and are fabricated with materials previously used in the fabrication of medical devices.

The inclusion of internal rigid planar disks expands the capabilities of soft TPE bellows actuators, increasing the potential use cases for a mostly-soft bidirectional actuator. On the millimeter-to-centimeter scale, soft TPE bellows offer a relatively large stroke and the ability to exert sustained forces. Furthermore, the bellows actuator design offers the potential to exert proportionally larger forces at the centimeter-scale with similarly large flat-to-expanded ratios, if designed and fabricated with larger bellows chambers.

We also introduce a retraction device which can be deployed from conventionally used endoscopes to provide the necessary counteraction to ablate tissue, paving the way for applications in endoscopic removal of early stage cancers. The integrated tissue retraction device offers surgeons an additional method to simplify endoscopic procedures, potentially solving the issues of limited distal tip dexterity and the extensive train-

ing requirements to perform these procedures. Future work could adapt the device to retract larger portions of tissues using a row or array of vacuum grippers to excise larger lesions, as well as exploring the use of the inflatable bellows actuators described here for other procedures where an initially-flat device capable of substantial expansion and exertion of force as a distance is beneficial, such as collapsed lungs or airways, as well as further applications in the GI tract. Furthermore, porcine *in vivo* testing will be performed to verify device performance in a living system and to evaluate procedure outcomes resulting from the use of the presented device.

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