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CONNECTING THE "MICRO" AND "MESO" SCALES THROUGH POP-UP BOOK MICROELECTROMECHANICAL SYSTEMS (MEMS)

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Final Report

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14. ABSTRACT *(Maximum 200 words)*

Our work in the A2P program has been focused on the development of new tools for minimally-invasive and microsurgery, along with advances in core technologies to enable those devices. Specifically, we have targeted endoscopic procedures such as endoscopic submucosal direction (ESD) and new methods for micro-and mesh-scale fabrication to support the development of these tools and associated components such as small-scale actuators. This work has resulted in: (1) the creation of a new paradigm for multi-scale, multi-material fabrication that is based on laser micromachining and lamination of both soft and rigid lamina; (2) the demonstration of several novel microsurgical devices, along with *ex vivo* and *in vivo* validation trials; and (3) the creation of several novel types of high performance and/or small-scale actuation, further enabling advances in small-scale or soft biomedical devices. Our efforts to merge popup devices with soft materials borrows the best aspects from both: popup devices that rely on flexure hinges for articulation have high precision for repeatable motions while soft materials allow delicate interactions with biological tissue. Work in this program has resulted in 14 papers, including seven journal papers (including one recently accepted) and seven papers in top conferences.

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1. Summary

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2. Introduction

Our goal in the A2P program has been to fill a technology gap in meso- and micro-scale fabrication, motivated by needs of advanced surgical tools for minimally invasive procedures. These types of procedures (e.g., endoscopy or laparoscopy) have severe size constraints that have historically limited the function and dexterity of these devices and/or required tremendous skill from the physician. Robotic solutions could dramatically improve outcomes and reduce the skill required by the surgeon. Our approach is enabled by advances in fabrication techniques aimed at millimeter-scale devices with embedded sensing and actuation, and including both rigid materials (that are conducive to tasks requiring precision, e.g., kinematic linkages involved in a manipulator arm) and soft materials (that are appropriate for delicate tasks such as interaction with soft tissue).

3. Methods, Assumptions, and Procedures

Underlying all of our device development has been the merging of pop-up book MEMS and soft lithography. Pup-up book MEMS is a set of techniques that has evolved from the challenges associated with creating insect-like robots. This has historically involved the use of non-contact bulk micromachining, such as laser micromachining, to pattern features in thin lamina that are subsequently combined into a quasi-2D multi-material laminate. This laminate is then folded into 3D via the use of compliant flexures built into the laminate. This has proven successful for several classes or bioinspired microrobots. However, adoption for microsurgery requires the inclusion of softer materials that are impedance matched to the tissues they encounter. To address this challenge, work in this program has leveraged Harvard's historical strength in soft lithography and microfluidics to incorporate soft materials as layers in the softrigid hybrid laminate. Furthermore, due to the biomedical applications of the devices we are creating, we have focused on biocompatible materials. The results, highlighted below, are processes that can create devices with arbitrary geometric and material complexity with feature sizes ranging from micrometer to centimeter.

4. Results and Discussion

Endoscopic robots:

• At the start of the project, we consulted with several physicians regarding needs for assistive devices for complex surgical procedures. We identified endoscopic submucosal dissection (ESD) — removal of early-stage tumors from the gastrointestinal tract — as the target procedure due to the complex motions and tissue manipulation required as well as due to the anticipated positive outcomes of successful procedures. At that time, it was made clear to us that this type of procedure, often involving full inversion of the endoscope tip, was only attempted by top endoscopists. In addition to developing a device to enhance the outcomes of ESD, we also aimed to reduce the skill required and thereby decreasing the barrier to entry for surgeons attempting ESD.

• We have created a modular endoscope cap (called EndoMODRA) that consists of one or two actuated "arms". The first is a tool-steering mechanism that attaches to tools passed through the working channel of the endoscope and deflects the tool independently of the motion of the endoscope. This allows the tool (e.g., an electrocautery device) to be moved while keeping the endoscope (and thus the vision system) stationary. Work on this system includes: successful integration of a tool force sensor; integration with an ergonomic snapon controller; and implementation of a fuzzy-based controller to close the loop on position commands. We have also made prototypes of a version with a second arm — consisting of three degrees of freedom for deployment and articulation — with the aim of providing dexterous tissue resection (e.g., to assist with cutting).

• We completed several rounds of *ex vivo* tests with collaborators at the Bringham & Women's Hospital, Boston. This has provided tremendous experience and validation of our devices. No failures were encountered and our tool-steering mechanisms successfully performed simulated procedures. This was not only successful in terms of performance, but also in the lessons we learned in terms of device fit (i.e., with the endoscope) and ergonomics of the interface. This has been translated into further design changes in anticipation for *in vivo* tests.

• We performed *in vivo* tests with collaborators from the Bringham & Women's Hospital, Boston. This was completed under the Institutional Animal Care and Use Committee (IACUC) approved protocol number 17-04, entitled 'Robotic Module for Endoscopic Submucosal Dissection', at Pine Acres Rabbitry Farm in Norton, MA. The trials were successful — the clinicians were able to use our modular endoscope cap to remove a superficial lesion from an anesthetized porcine intestine. The procedure took approximately 70 minutes and there was no evidence of burning or charring as is sometimes the case for electrosurgical overuse.

Micro- and mesh-scale fabrication methods:

• We have developed a combined soft/pop-up process for micro- and miso-scale fabrication. As part of this, we have characterized geometry, tolerances, and actuation modes we can achieve. This process involves the creation of soft laminates by a combination of soft lithography and laser micromachining. This new process also integrates multi-layer microfluidic systems in which each layer has nearly arbitrary geometry and the fluidic channels can pass through to adjacent layers. This has enabled us to create millimeterscale discs that incorporate soft actuators to form cup-shapes for suction and also contain channels for pulling vacuum. In addition to the above described surgical devices, we have created a demonstration devices — for example a 14 layer soft spider with multiple structural and actuation degrees of freedom.

Soft and small actuation:

• Motivated by the need for scalable soft actuation (e.g., for delicate tissue manipulation), we developed a new artificial muscle concept called "Fluidic Origami-inspired Artificial Muscles (FOAM)". This concept was described in a paper in the Proc. of the National Academy of Sciences. This involves a folded origami-like "skeleton" encapsulated by a soft "skin". When vacuum is applied, the skin causes deformation that is mediated by the underlying skeleton. This has been thoroughly characterized as a function of material, scale, and underlying geometry (i.e., the internal "skeleton" geometry that defines how the actuator moves). We believe this will be a very impactful result, both for this project and beyond (e.g., in the soft robotics community). With respect to the specific goals of this A2P project, we also brought this actuator class back to its initial purpose: actuating appendages in capsule endoscopy.

• We have developed a new concept for low-profile out-of-plane actuation based on a spirallike architecture. This leverages a basic unimorph actuator configuration, but for compactness while maximizing out-of-plane displacement, the actuator spirals around itself in the plane. We leverage laminated anisotropic composite materials to both form the unimorph and to locally control off-axis curvature to ensure that the output plane is parallel to the ground plane during actuation. Initial results show a remarkably large out-of-plane displacement of 1-2mm and point to potential applications in surgical imaging.

• Our group also demonstrated wireless, near-field RF power transmission and application to soft and folding based devices. We leveraged this technology to create wireless soft actuators for gastrointestinal applications such as modular actuators for capsule endoscopy (e.g., for station keeping). This involves RF power transmission to a tuned resonant receiver circuit that converts the energy to heat. This heat then is used to trigger a phase transition — either in a shape memory actuator or in a low boiling point fluid to generate gas that produces a dramatic expansion of a soft actuator. We have also demonstrated their potential utility in surgical applications where we have wirelessly and gently actuated portions of a GI phantom to separate tissue and open a clogged pathway.

5. Conclusion

We have had several technology breakthroughs in the A2P program. These can be summarized as:

1. the creation of a new paradigm for multi-scale, multi-material fabrication that is based on laser micromachining and lamination of both soft and rigid lamina;
2. the demonstration of several novel microsurgical devices, along with ex vivo and in vivo validation trials; and
3. The creation of several novel types of high performance and/or small-scale actuation, further enabling advances in small-scale or soft biomedical devices.

Our efforts to merge popup devices with soft materials borrows the best aspects from both: popup devices that rely on flexure hinges for articulation have high precision for repeatable motions while soft materials allow delicate interactions with biological tissue.

Work in this program has resulted in 14 papers, including seven journal papers (including one recently accepted) and seven papers in top conferences. These papers can be found as separate entries within the final report documentation.

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LIST OF SYMBOLS, ABBREVIATIONS, AND ACRONYMS

AFRL	Air Force Research Laboratory
EDS	endoscopic submucosal direction
AndoMODRA	Endoscopic Module for On-Demand Robotic Assistance
FOAM	Fluidic Origami-inspired Artificial Muscles
IACUC	Institutional Animal Care and Use Committee
RX	Material and Manufacturing Directorate
RXAS	Soft Matter Materials Branch, Functional Materials Division, Materials and Manufacturing Directorate
WPAFB	Wright-Patterson Air Force Base