Design of a Robotic Implant for in-vivo Esophageal Tissue Growth

D. D. Damian, S. Arabagi, P. E. Dupont

Boston Children's Hospital, Harvard Medical School, USA dana.damian @childrens.harvard.edu

INTRODUCTION

Robotic devices in medicine have yielded numerous benefits from advanced diagnostic tools to instruments that augment surgeons' physical capabilities [1,2]. With smaller and safer technologies, medical technology is advancing from interventional robotic medicine to personalized robotic medicine with the aim of reducing clinical assistance, hospitalization, or the repetitive need for surgeries. Robotic implants, as a new category of medical robots, are implanted in the body to autonomously regulate biological processes for long periods of time. An example of their clear benefit is long-gap Esophageal Atresia (LGEA) in which a section of the esophagus longer than 3cm is missing [3,4]. Long-gap EA afflicts over 100 babies per year in the USA and Europe. One effective procedure to repair this congenital defect is Foker's technique [5,6], in which growth-inducing traction forces are applied to the esophageal segments using suture that is tied off outside the child's back. The traction is manually maintained for an average of 14 days to induce sufficient elongation to close the gap. While producing superior outcomes to alternative procedures, the child is sedated and kept on a ventilator for the duration of the treatment. It would be extremely beneficial to these patients if (1) multi-week sedation could be avoided so as to eliminate any effect on long-term neurocognitive development, (2) the need for re-operation due to suture tear-out could be reduced, and (3) the duration and cost of hospitalization could be reduced.

We present a robotic implant that has the potential to resolve these shortcomings. The implant operates in the thoracic cavity attached to the two esophageal segments using attachment rings, thus localizing the elongation procedure. In contrast to the standard Foker technique, the implant's configuration is not affected by infant motion and, consequently, the child does not need to remain paralyzed and sedated in the ICU during traction. Equipped with force and position sensors, the motorized implant allows controlled and precise tissue traction, eliminates the risks of suture tear-out due to the ring attachment that distributes forces around the esophagus, and enables traction monitoring. The design concept of the robot was introduced in [7].

In this paper, we present the robotic implant, which has been designed and tested for in vivo animal experiments. The following are the paper's contributions: (1) a robotic implant design featuring a biocompatible encapsulation, (2) an integrated system

for remote implant monitoring and control, and (3) position and force control of esophageal tissue.

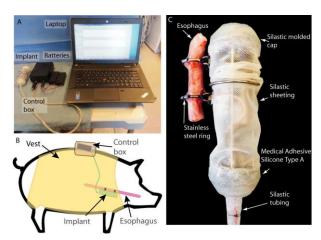


Fig. 1 Robotic implant. A. Implant and monitoring system. B. Schematic for testing in swine. C. Implant shown attached to length of porcine esophagus. Note: initial tests induce growth of esophageal segment between rings.

IMPLANT DESIGN FOR SURVIVAL TESTS

The entire system, shown in Fig. 1A, consists of the robotic implant, a control box, battery pack, and a laptop. An animal protocol, approved by IACUC (Institutional Animal Care and Use Committee), provides for two types of experiments. In this first, the robotic implant is mounted on an intact esophagus and growth is induced in the segment between the rings over a 7-day period (Fig. 1 BC). In subsequent experiments, a section of esophagus is removed to mimic actual atresia and the rings move to close the gap.

The robotic implant applies traction on the esophageal segments using a motor, which displaces the rings relative to each other. The implant is also equipped with force and position sensors to measure and control tissue forces and displacements [7]. The implant is sealed with a biocompatible encapsulation. We designed the implant encapsulation with the following properties: (1) biocompatible; (2) anti-fouling; (3) impermeable to air and water; and (4) abrasion resistant. It is fabricated from silastic (Fig. 1C), which satisfies the first three properties. The silastic (Bentec Medical) embeds a polyester mesh to satisfy the forth requirement. Silastic caps were fabricated using a molding process (Dow Corning Corp.). Thorough sealing was ensured using medical adhesive silicone Type A (Dow Corning Corp.). The tubing protecting the electric wires was also made of silastic (Bentec Medical).

The attachment rings were fabricated from stainless steel by TIG welding to preserve the material properties and avoid corrosion. The rings are detachable and adjustable in order to allow easy implantation and suturing, depending on the diameter of the esophagus. The control box contains an Atmel controller (Baby Orangutan B-328, Pololu), force sensor amplifier, and Bluetooth module (BlueSMiRF, Sparkfun Electronics). The control box is worn in a vest pocket by the animal during the survival experiments. The laptop is used to launch a graphical interface for visualizing real-time sensor data, inputting controller commands and data logging via Bluetooth. A low-level controller generates traction forces using either force or position set-point control. Set points can be set manually or using a highlevel controller to produce a desired waveform, e.g., adjustment once per day or every few minutes. Automated adjustment during animal studies enables controlled comparison of traction histories and their effect on tissue growth rate and properties.

IMPLANT CONTROL

The controllers were tested in 36-hour *ex vivo* studies with swine esophagus during which the implant and esophageal segment were submerged in saline. The saline kept the tissue wet while also testing the impermeability of the encapsulation. The esophageal segments were taken from swine weighing 43 kg on average. The initial relaxed length of the esophagus segment was 20 mm (Fig. 1C). The laptop was used to command the implant and to log position and force data during testing. There were no liquid leaks inside the robotic implant during and after these experiments, as observed from the signals of the electronic components and from visual inspection of the interior of the robot.

Figure 2 shows implant signals corresponding to automatic position control. Position and force signals are reported for a 1200s duration during which the commanded displacement was a square wave of amplitude 10mm and a period of 130s.

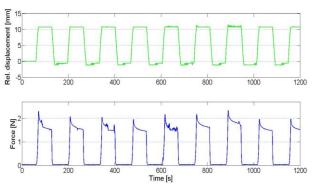


Fig. 2. Robot position set-point control. Response to commanded 10mm position square wave.

Under position control, the implant generated a peak force in the tissue of about 2N, which reduced to about 1.5N after one minute due to relaxation of the tissue.

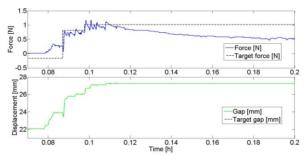


Fig. 3. Robot force set-point control. Response to force-control set points of 0.8N and 1.0N.

Figure 3 presents the response to force set-point commands of 0.8N and 1.0N obtained during long-term testing. The plots also show the response after the controller was turned off at 0.1138h. Force fluctuations occur due to relaxation of the tissue.

IN VIVO TESTING

The implant is sterilized using the Ethylene Oxide (EtO) sterilization process in order to protect the electronic components. It is implanted through a right thoracotomy, which provides access to the esophagus while keeping a safe distance from the heart. The cable from the implant is tunneled to the control box in the vest through the skin. The animal is fed a semi-solid diet for the duration of the experiment. Traction is applied every day. The tissue growth is assessed by comparing the stretched segment with a control segment, and by histological analysis.

ACKNOWLEDGEMENTS

This project is supported by Boston Children's Hospital's Translational Research Program, Manton Center for Orphan Disease Research, and the Swiss National Science Foundation.

REFERENCES

- [1] B.J. Nelson, I.K. Kaliakatsos, and J.J. Abbott. Microrobots for minimally invasive medicine, *Annual Review of Biomedical Engineering*, 12:55–85, 2010.
- [2] C. Bergeles and Y. Guang-Zhong, From Passive Tool Holders to Microsurgeons: Safer, Smaller, Smarter Surgical Robots, *IEEE Trans. Biomed. Eng.*, 61(5):1565-76, 2014.
- [3] P.F. Martins Pinheiro, A.C. Simoes e Silva, and R.M. Pereira. Current knowledge on esophageal atresia. *World Journal of Gastroenterology*, 18(28):3662–72, 2012.
- [4] R. Sfeir, L. Michaud, J. Salleron, F. Gottrand, Epidemiology of esophageal atresia, *Dis. Esophagus*, 26(4):354-5, 2013.
- [5] J.E. Foker, B.C. Linden, E.M. Boyle, and C. Marquardt. Development of a true primary repair for the full spectrum of esophageal atresia. *Annals of Surgery*, 226:4:533–543, 1997.
- [6] J.E. Foker, T.C. Kendall Krosch, K. Catton, F. Munro, and K.M. Khan. Long-gap esophageal atresia treated by growth induction: the biological potential and early follow-up results. *Seminars in Pediatric Surgery*, 18:23–29, 2009.
- [7] D.D. Damian, S. Arabagi, A. Fabozzo, P. Ngo, R. Jennings, M. Manfredi, and P.E. Dupont. Robotic Implant to Apply Tissue Traction Forces in the Treatment of Esophageal Atresia, *IEEE International Conference on Robotics and Automation* (ICRA), pp. 786-792, 2014.