Design of a Robotic Balloon-catheter Endoscope for Sinus Procedures

Yingtian Li[1], Reza Rahbar[2], Pierre E. Dupont[1, a]
[1]Cardiovascular Surgery, Boston Children's Hospital, Harvard Medical School,
[2]Department of Otolaryngology, Boston Children's Hospital, Harvard Medical School
[a]Pierre.Dupont@childrens.harvard.edu (DOI10.31256/HSMR2019.5)

INTRODUCTION

Over 30 million cases of Chronic RhinoSinusitis (CRS) occur annually in the U.S. [1, 2]. This condition involves blockage of the sinuses resulting in accumulation of mucus, pain and susceptibility to infection. Diagnosis often involves transnasal endoscopic examination of the sinuses. Subsequent treatment can also involve endoscopically-guided balloon dilation of the sinus ostia. This procedure, balloon catheter sinuplasty (BCS), has proven to be feasible, safe and effective [3], and the trend to perform this technique in treating CRS has largely increased in recent years [4].

The procedure can be challenging to perform, however, since endoscopic inspection of the airways (seeing around corners) as well as endoscopically-guided balloon positioning remain awkward (Fig. 1a). To address these challenges, transcutaneous illumination is often used to confirm the balloon catheter is properly placed before inflating the balloon [5]. And although there are flexible endoscopes on the market, poor imaging quality has limited their adoption.

Toward addressing this need, this paper introduces a concept for a multi-segment endoscopic balloon catheter that is able to crawl through the sinuses. The scalable robot design is described along with experiments that demonstrate that it can crawl through flexible lubricated tubes and navigate through a simplified model of the nasal passages while providing an endoscopic view of its path.

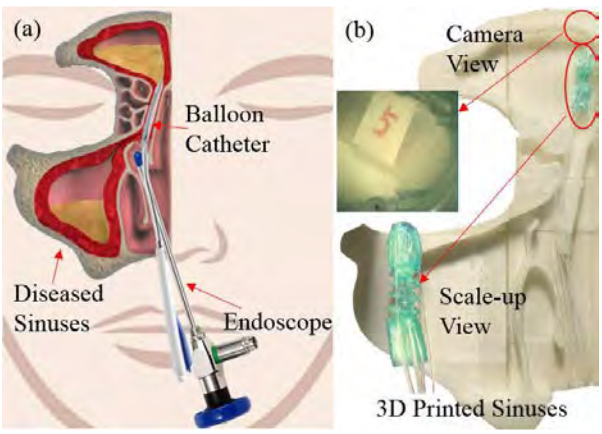

Fig. 1. Balloon catheter Sinuplasty (BCS) used to open blocked sinus ostia. (a) Current procedure – rigid endoscope is used to guide balloon catheter into ostia. (b) Robotic endoscope navigating through model of sinuses to reach frontal sinus. Chip camera mounted on balloon-catheter robot provides tip view during navigation.

MATERIALS AND METHODS

The proposed design, different from the other crawling medical robots [6 - 8], is comprised of two buckling balloons as anchor units connected by a linearly-expanding balloon as the actuator unit to control the movement. The distal buckling balloon can also be used for dilation of the sinus ostia. The prototype and the design parameters are shown in Fig. 2. This prototype was built at 2X scale to facilitate fabrication and testing.

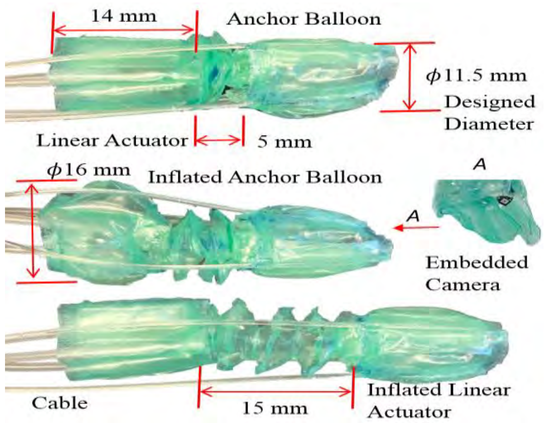

Fig. 2. Robotic balloon-catheter endoscope. Locomotion is achieved by first expanding the linear-actuator balloon when the proximal anchor balloon is inflated and the distal anchor balloon is deflated. Next, the distal balloon is inflated, the proximal balloon is deflated and then the linear actuator is deflated.

The three balloon units, fabricated as shown in Fig. 3, are made of a soft polyethylene membrane (Pregis Corp.) with a camera embedded in the distal anchor balloon. The robot has a tether comprised of three 2mm OD silicone tubes for inflating and deflating the balloons and wiring for the camera. In the current prototype, the tether also includes nylon tendons for steering the distal anchor balloon. Future versions will employ differential inflation of balloon chambers to produce steering.

One full cycle of forward locomotion is comprised of the six steps. The steps consist of sequentially inflating the proximal anchor, linear actuator and the distal anchor and then sequentially deflating the proximal anchor, the linear actuator and the distal anchor. To execute turning of the distal section for visualization of the workspace or for navigating around a corner, the proximal anchor is inflated and the distal anchor is deflated. Differential tension is applied to the tendons to achieve the desired bending. To lock in the tip direction, the distal anchor is then inflated.

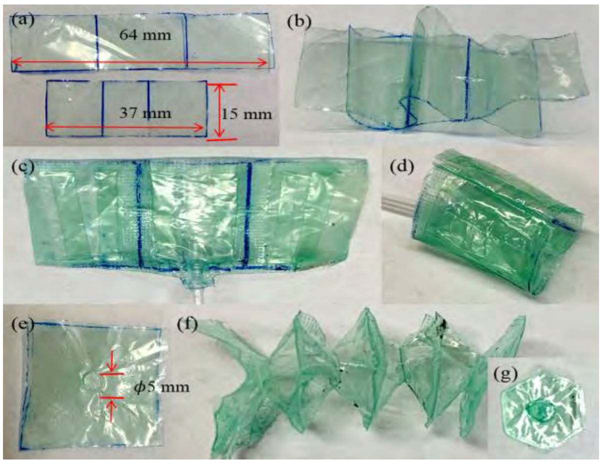

Fig. 3. Balloon fabrication. (a) Anchor balloon is made from two pieces of membrane. (b) Heat sealing on marker lines creates three chambers. (c) Chambers are sealed on proximal and distal edges. (d) Chambers are sealed longitudinally to create cylindrical balloon. (e) Linear actuator is fabricated from 8 chambers sealed to each other around circular 5mm diameter port. (f) Connected chambers. (g) Final chamber shape is hexagonal.

To evaluate the prototype, we tested its ability to locomote through three environments. The first experiment consisted of crawling through a rigid tube. Since tissues are soft, we next tested the system inside a thin flexible silicone tube. In both cases, we lubricated the interior of the tubes to mimic the slipperiness of mucus-lined passages. Finally, we tested the ability of the system to navigate inside the curved passages of a phantom model of the sinuses.

RESULTS

Robot control was performed via sequential inflation and deflation of the balloons via control tubes attached to syringes. Inflation / deflation times for all balloons is less than one second and there was no observable delay time between syringe motion and balloon response.

Fig. 4 presents the three experiments conducted for evaluating the robot. Syringe operation was performed manually and was the limiting factor with respect to robot speed, which averaged 1.5mm/sec. We are currently implementing microprocessor control of motorized syringe actuation. We demonstrated navigation to the frontal sinus in our phantom model, which required the robot to make turns. The current prototype can produce follow curves with a 35mm radius of curvature.

DISCUSSION

This paper provides proof of concept results for the design of an endoscopic balloon catheter for navigating in the sinuses. We demonstrated the ability to crawl inside lubricated soft tubes and in a model of the sinus passages.

The use of a soft robotic balloon with integrated sensing can provide a number of advantages over the current approach in which a rigid endoscope is inserted in parallel with a standard balloon catheter. The robotic balloon endoscope can traverse the sinuses with minimal trauma while providing the ability to both visualize and navigate around corners. Furthermore, the robot can also be used to perform balloon dilation inside the sinuses with the embedded camera providing accurate localization of the dilation.

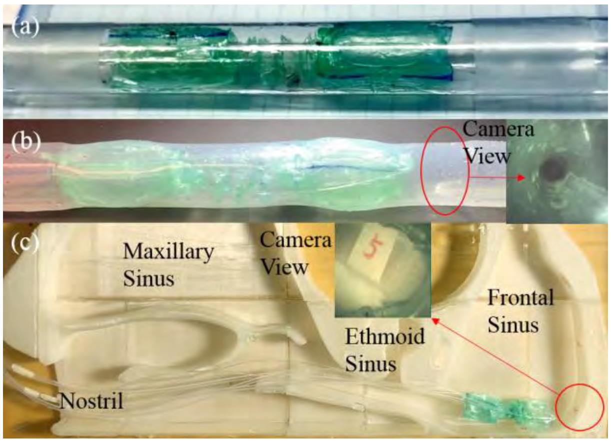

Fig. 4. Experimental results. (a) Crawling through a lubricated, but rigid tube. (b) Crawling through a lubricated soft silicone tube. (c) Balloon catheter navigating to the frontal sinus in a 3D-printed planar model of the sinuses.

ACKNOWLEDGEMENTS

This work was supported by the National Institutes of Health under grant R21HD089136.

REFERENCES

[1] Makary CA, Ramadan HH. Sinus and Upper Airway Surgery in Children. Current allergy and asthma reports. 2018 18:1-5.

[2] https://www.energiasmarketresearch.com/global-sinusitis-treatment-market-outlook

[3] Ramadan HH. Safety and feasibility of balloon sinuplasty for treatment of chronic rhinosinusitis in children. Annals of Otology, Rhinology & Laryngology. 2009 118(3):161-165.

[4] Svider PF. Evolving trends in sinus surgery: what is the impact of balloon sinus dilation? The Laryngoscope. 2018 128(6):1299-1303.

[5] Makary CA, Ramadan HH. Balloon catheter sinuplasty in pediatric chronic rhinosinusitis. Operative Techniques in Otolaryngology-Head and Neck Surgery. 2018 29(2):94-98.

[6] Dario P et al. A microrobotic system for colonoscopy. Proc Int Conf Robot Auto. 1997 2:1567-1572.

[7] Patronik NA et al. Crawling on the heart: A mobile robotic device for minimally invasive cardiac interventions. Int Conf Med Image Comput Comput Assist Interv. 2004: 9-16.

[8] Gilbertson MD et al. Soft passive valves for serial actuation in a soft hydraulic robotic catheter. J. Med Devices. 2016 10(3):030931.