The Orion Medical Device:
Treating Internal Hemorrhoids through Rubber Band Ligation

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Sponsored by: Logan Medical Devices

BMEN 4389/MECH 4382
Spring 2018

Project Motivation
- Hemorrhoids afflict 50% of people at some point in their lives.
- 15 million annual U.S. doctor visits are due to hemorrhoids.2,3,4
- At-home hemorrhoid treatments only offer symptom relief.
- Curative treatments are limited to administration by specialist medical doctors, such as gastroenterologists.

Rubber Band Ligation Background
Rubber Band Ligation (RBL) is a treatment option for internal hemorrhoids:
1. Inside the rectum, tissue near the internal hemorrhoid is captured via suction.
2. A 5 mm outer diameter rubber band, called a ligation band, is placed onto the metal tissue.
3. The captured tissue strangles and produces a scar.

Project Goals
Create a medical device prototype which:
- Nominally requires one insertion.
- Does not require visualization or medical grade suction.
- Deploys 3 ligation bands at 120 degree increments around the rectum to treat all local hemorrhoids.
- Removes complexity of the procedure through mechanical automation, reducing skill requirement.

Final Design: The Orion
Description:
- Named after the constellation because of the 3 stars in Orion’s belt.
- Ligates 3 bands simultaneously.
- No visualization of hemorrhoids needed.
- Disposable design for low cost.

Operation:
1. Retract syringes to apply suction.
2. Wait 30 seconds.
3. Pull trigger to displace bands onto tissue.

Prototype Validation
The Orion prototype was compared to the CRH O’Regan, a current market solution.

Performance was compared using objective metrics:
1) Tissue Capture Success Rate: Chi-Squared analysis demonstrates that the Orion’s performance is 4% effective as the CRH in capturing ligation bands onto tissue.
2) Suction Produced: Orion can generate 19% more suction than the CRH at a 17 psi increase in each syringe, with the Orion projected at 10.3 psi and the CRH at 8.4 psi.
3) Tissue Capture Height: The Orion captured tissue at a lower standard deviation of 1.32 mm, compared to 1.68 mm of the CRH, capturing 12% more tissue at a higher precision than the CRH.
4) Procedure Time: Orion was 22% faster with a total set up and treatment time of 131.4 seconds compared to the CRH at 184.4 seconds for three bands.

Future
- Small Business Innovation Research (SBIR) Grant Proposal.
- 510(k) FDA Clearance and Market Introduction.
- Possible licensing with larger medical device company.
- Patent coverage based on design project prototype.

Acknowledgements
The ENDsolutions team would like to thank:
- Dennis Robbins, PhD, Logan Medical.
- José Rodriguez, MD, FACP, Logan Medical.
- Steven Foland, PhD, University of Texas at Dallas.
- The invaluable UTDesign Staff.
Thank you for your unwavering support. We couldn’t have done it without you all.

Ethics Statement
Ex vivo tissue was used in place of animal testing and human testing.

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