

The Orion Medical Device:

Treating Internal Hemorrhoids through Rubber Band Ligation



ENDSolutions

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Project Motivation

- Hemorrhoids afflict 50% of people at some point in their lives¹
- 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

¹Lorenzo-Rivero, S. (2009). Hemorrhoids: diagnosis and current management. *Am Surg*, 75(8), 635-42.

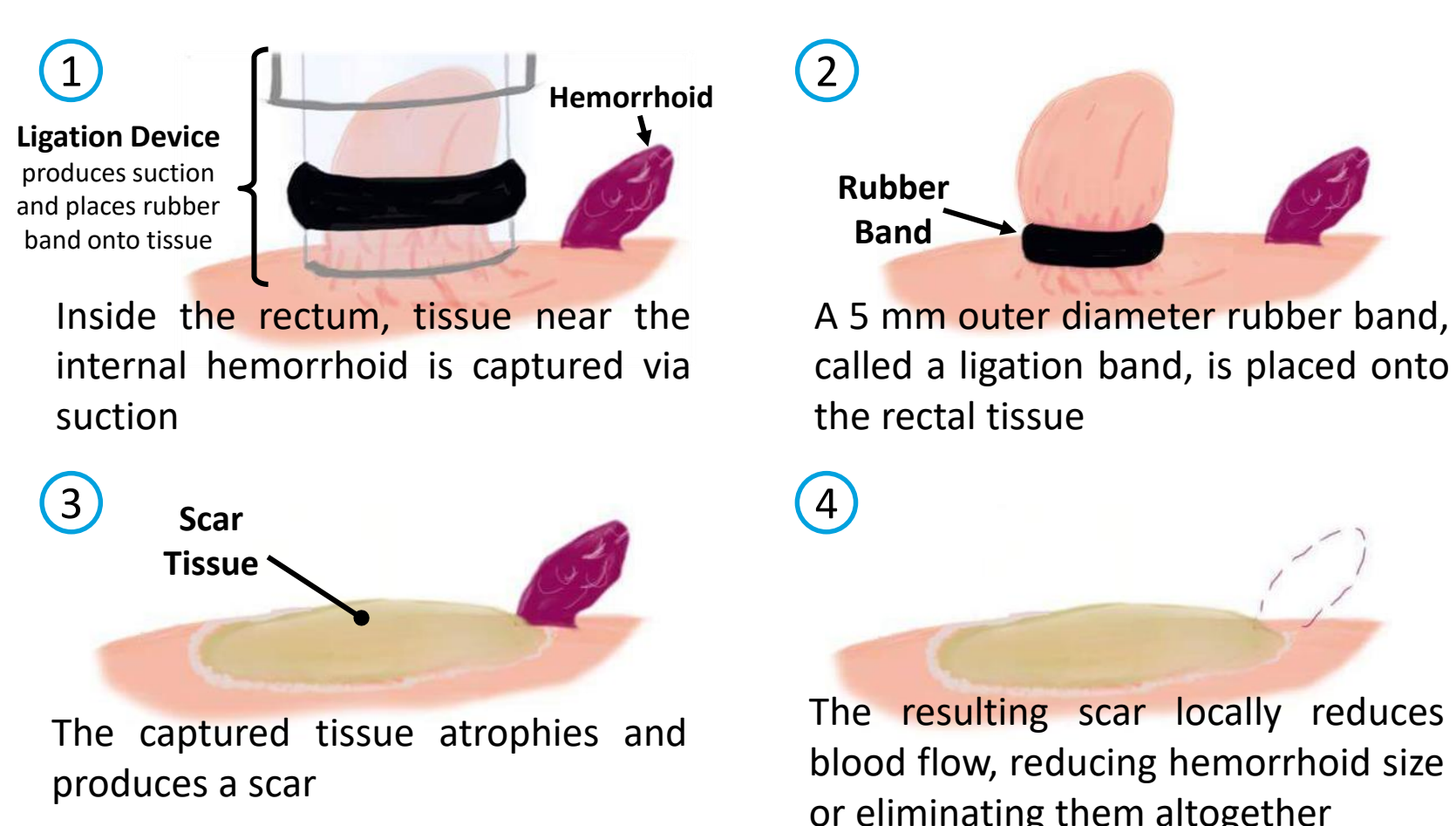
²Johanson, J. (1990). The prevalence of hemorrhoids and chronic constipation: An epidemiologic study. *Gastroenterol Clin North Am*, 98(2), 380-386.

³OECD (2013). OECD Health Data: Health care utilization. *OECD Health Statistics* (database).

⁴U.S. Census Bureau, Population Division. (2016) Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2015. *United States Census Bureau: American Fact Finder* (database).

Rubber Band Ligation Background

Rubber Band Ligation (RBL) is a treatment option for internal hemorrhoids:



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

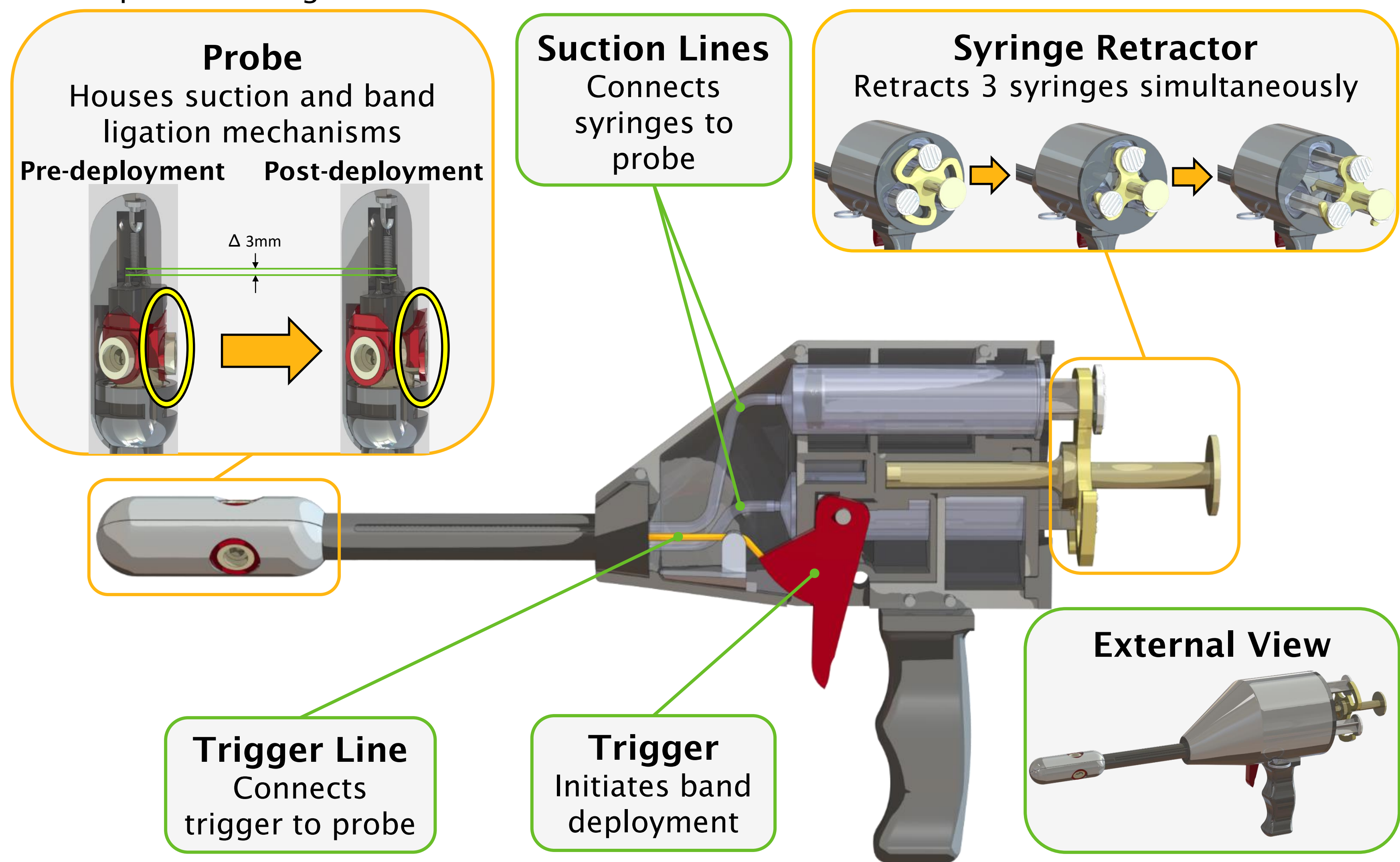
Final Design: The Orion

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

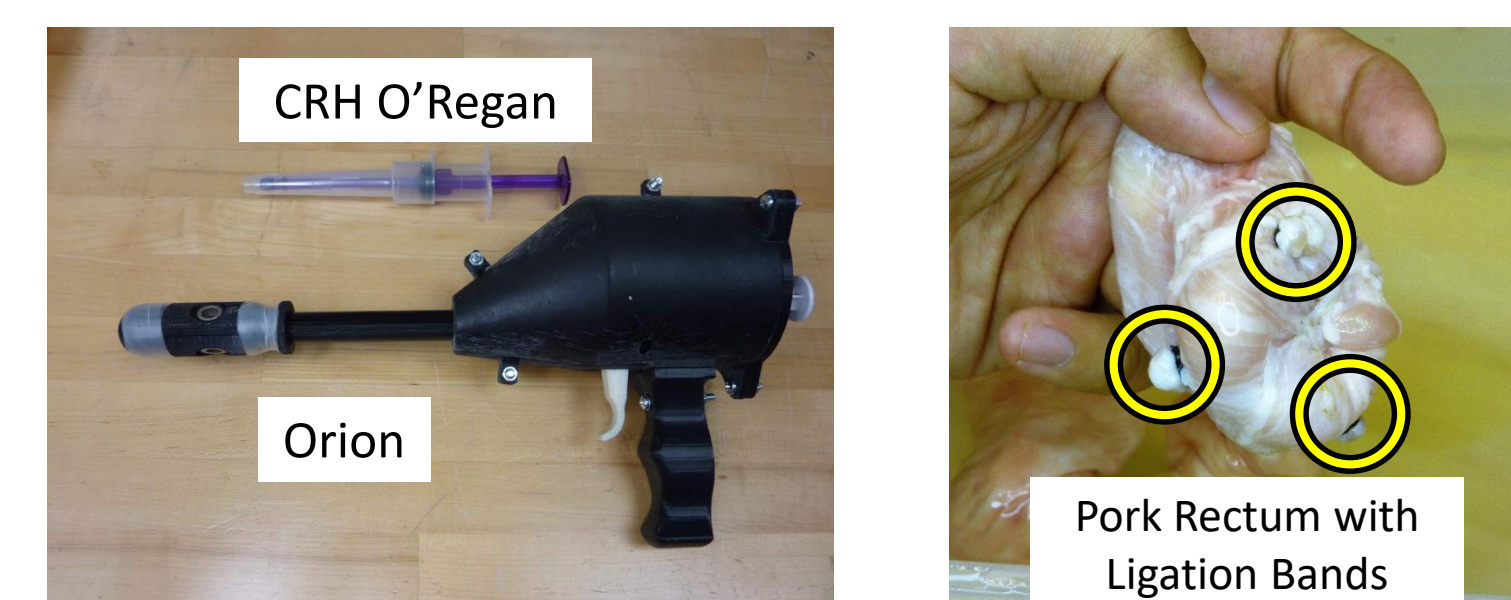
Operation:

- Retract syringes to apply suction
- Wait 30 seconds
- Pull trigger to displace bands onto tissue
- Release suction



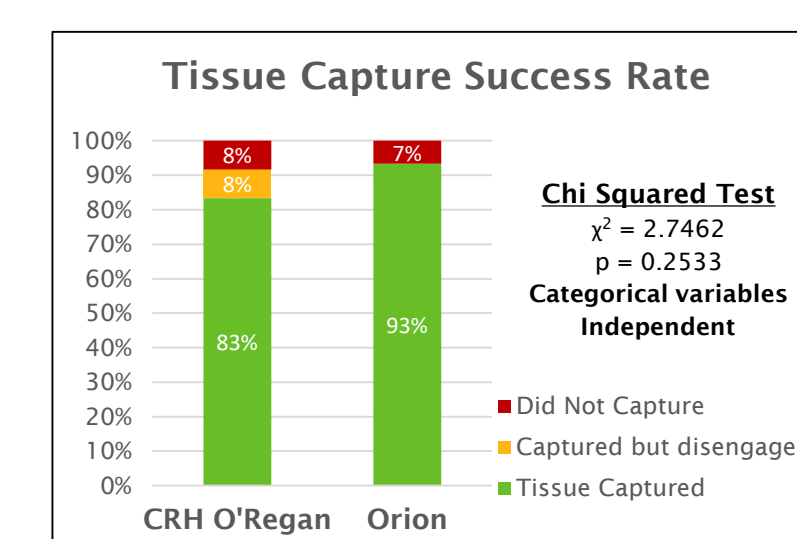
Prototype Validation

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

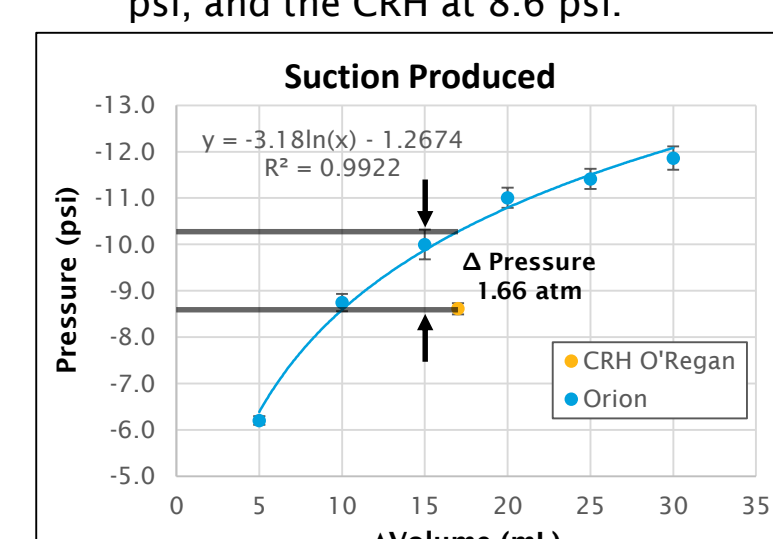


Performance was compared using objective metrics:

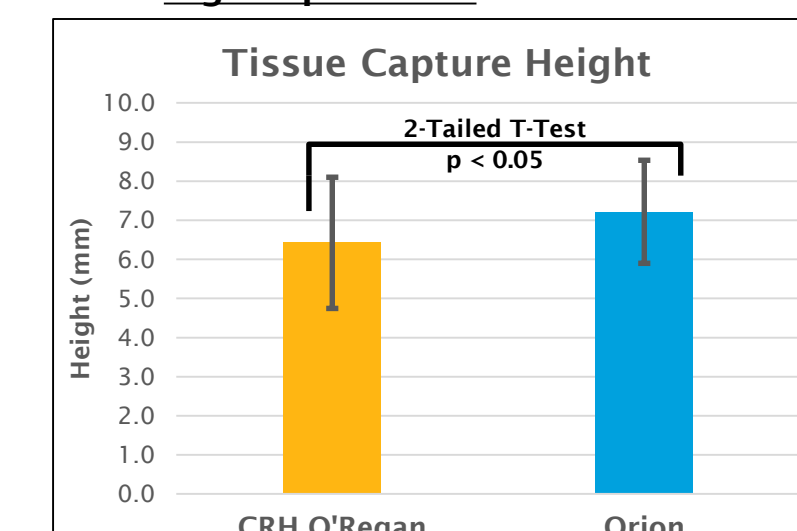
1) Tissue Capture Success Rate:
Chi Squared analysis demonstrates that the Orion's performance is **as effective** as the CRH in **applying ligation bands** onto tissue.



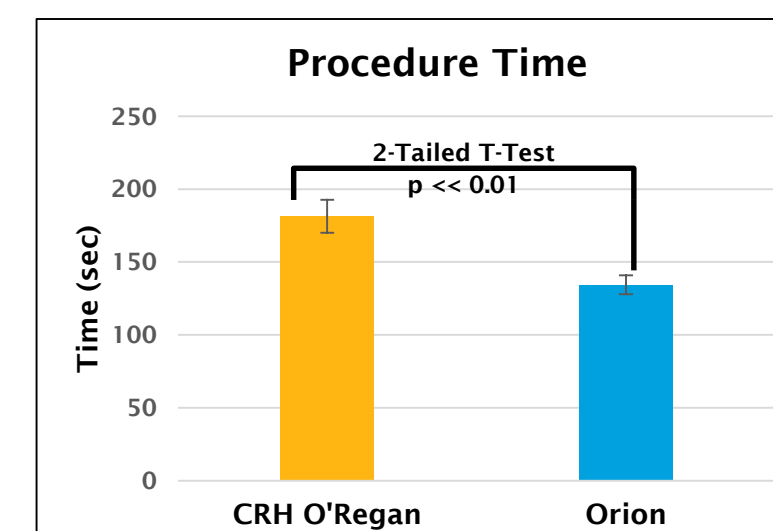
2) Suction Produced:
Orion can generate **19% more suction** than the CRH at a 17 mL volume change in each syringe, with the Orion projected at 10.3 psi, and the CRH at 8.6 psi.



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 **25% faster** with a total set up and treatment time of 131.4 seconds compared to the CRH at 181.4 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

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Ethics Statement

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

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