Design and Validation of an Automated Dilator Prototype for the Treatment of Radiation Induced Vaginal Injury

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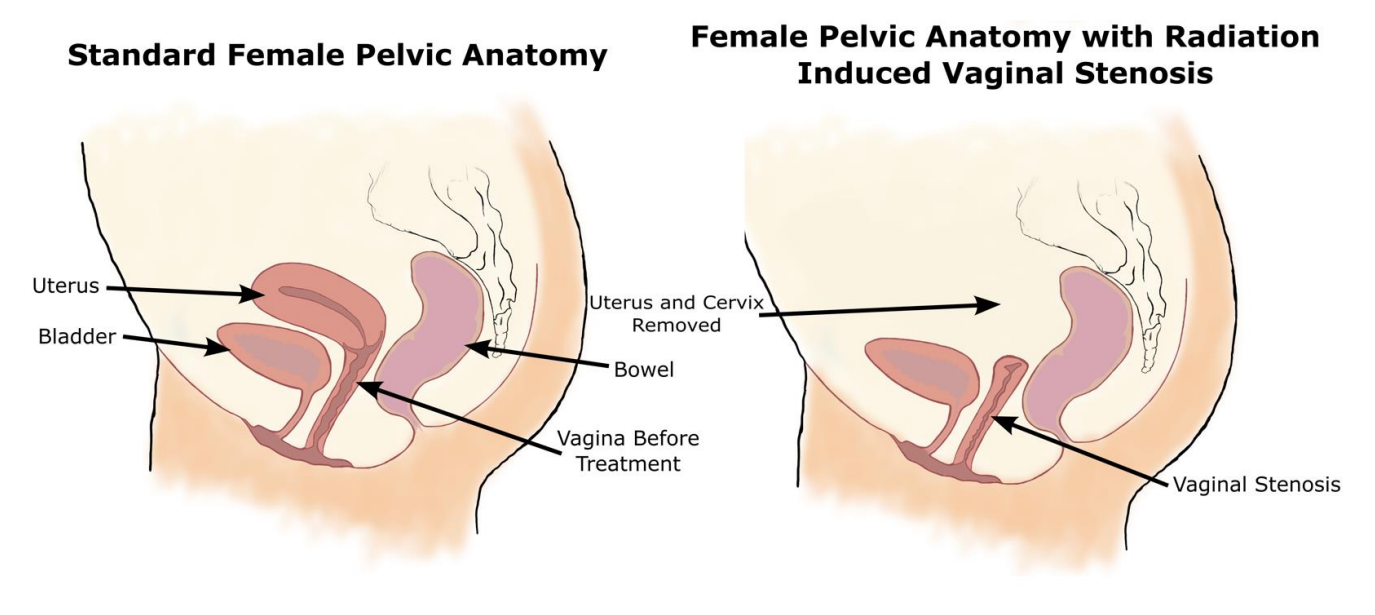
Overview:

- Clinical Problem: Vaginal Stenosis as a Complication of Cervical Cancer Treatment
- Proposed and Manufactured Solution to Vaginal Stenosis Prevention: Inflatable Vaginal Dilator System
- Initial Characterization of Dilator Prototype
- Design of a Model to Simulate Vaginal Stenosis
- Evaluation of Dilator Pressure on Tissue and Synthetic Model
- Current Progress
- Future Work

Clinical Problem: Vaginal Stenosis



- Cervical cancer affects the lives of many women every year
- Vaginal stenosis is a late complication of radiotherapy/brachytherapy used to treat cervical cancer
- Current treatment involves the use of a standard vaginal dilator that poses patient adherence issues

Diagnosis of Vaginal Stenosis: CTCAE

CTCAE Terminology	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Vaginal Stricture. Definition: a disorder characterized by a narrowing of the vaginal canal	Asymptomatic; mild vaginal shortening or narrowing	Vaginal narrowing and/or shortening not interfering with the physical examination	Vaginal narrowing and/or shortening interfering with the use of tampons, sexual activity or physical examination	-	Death

Common Terminology Criteria for Adverse Events (CTCAE) for Vaginal Stricture v5.0 (US Department of Health and Human Services)

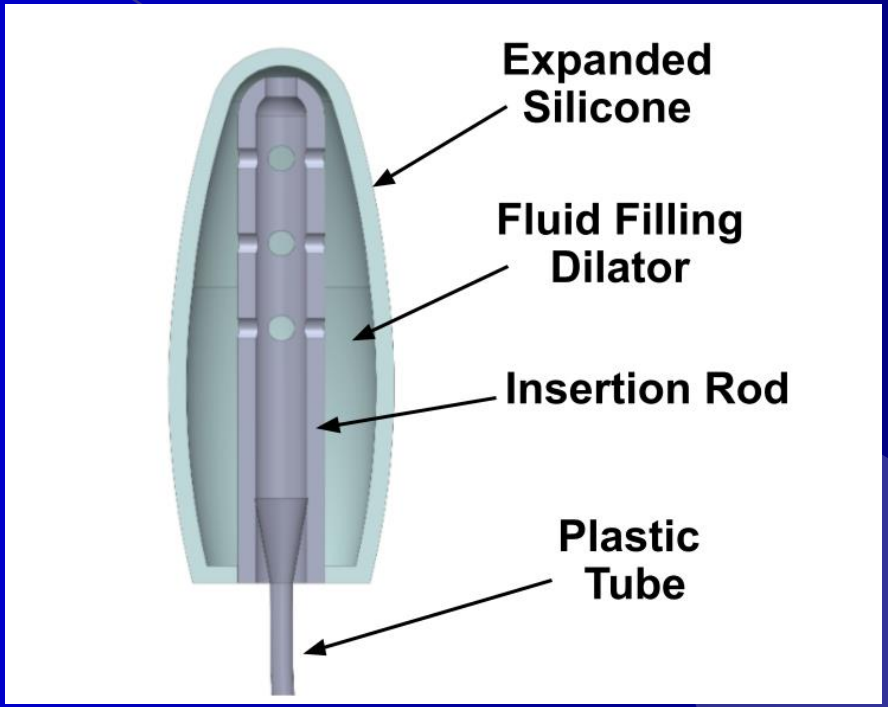
Diagnosis of Vaginal Stenosis: LENT-SOMA

	Grade 1	Grade 2	Grade 3	Grade 4
Objective:				
Stenosis/ length	>2/3 normal length	1/3-2/3 normal length	<1/3 normal length	Obliteration

Radiation Therapy Oncology Group (ETOG)/ European Organization for the Research and Treatment of Cancer (EORTC) Late Effects of Normal Tissues, Subjective, Objective, Management (LENT-SOMA)

Proposed Solution

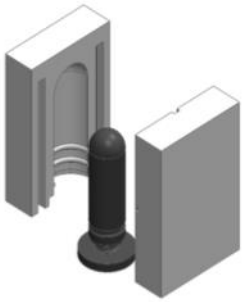
- Improved design of a vaginal dilator
  - Can be expanded through air or fluid channels
  - Can be coupled with other elements
- Used to expand vaginal canal gradually over time



Schematic of inflatable vaginal dilator

Manufacturing Steps

3D Modeling of 3-Part Mold

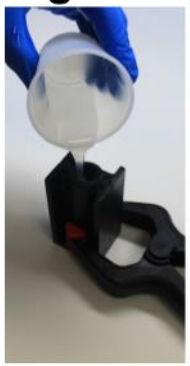


Prototype Mold

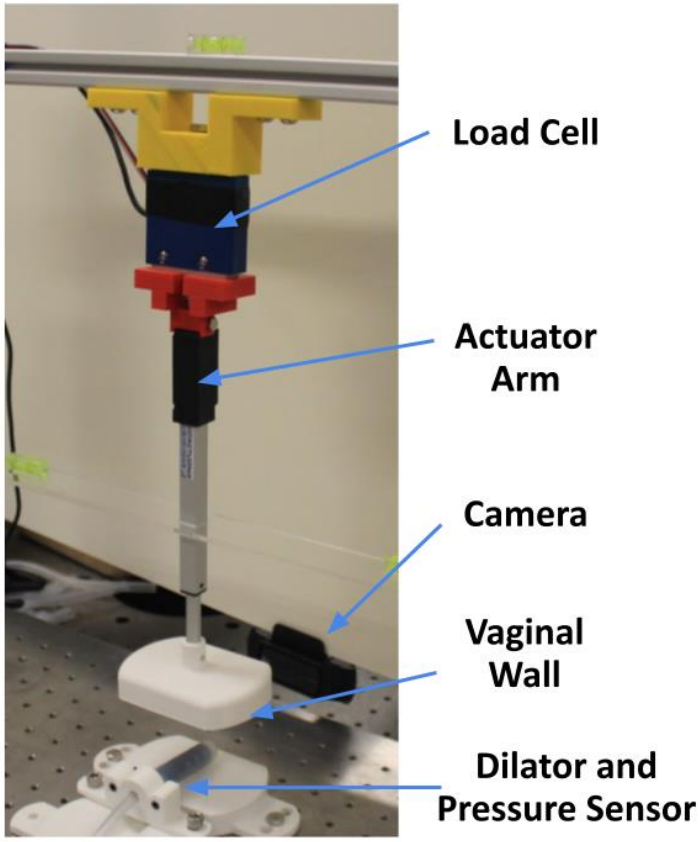
Expandable Dilator with Silicone Sheath

Additive Manufacturing

Silicone Molding Processing

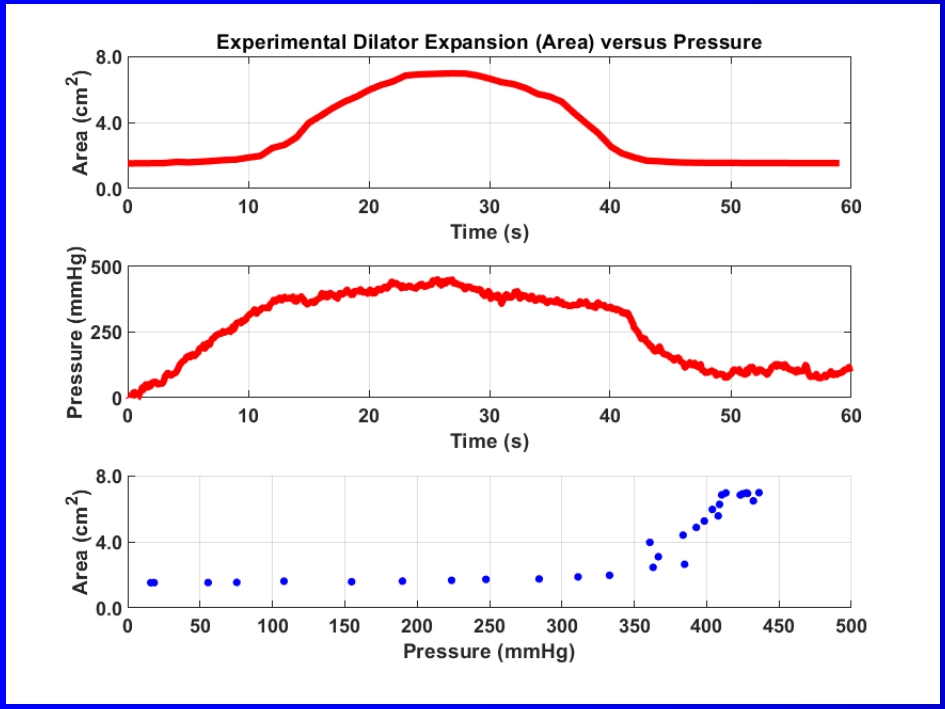


Initial Experimental Tests

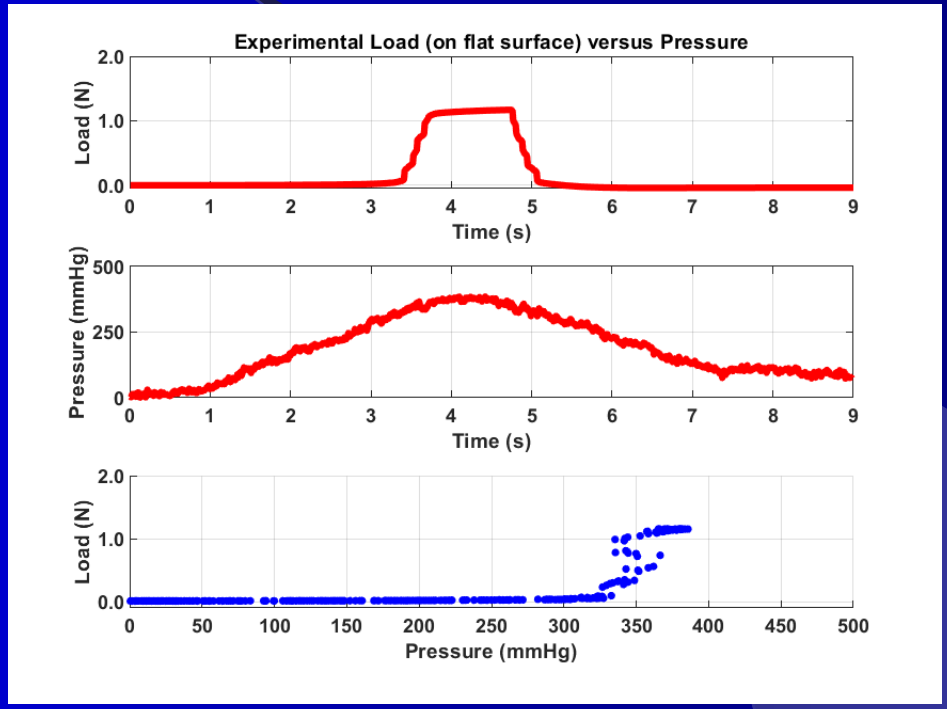


Experimental setup to measure dilator expansion versus pressure and force on the adjacent vaginal walls versus pressure

Initial Experimental Results

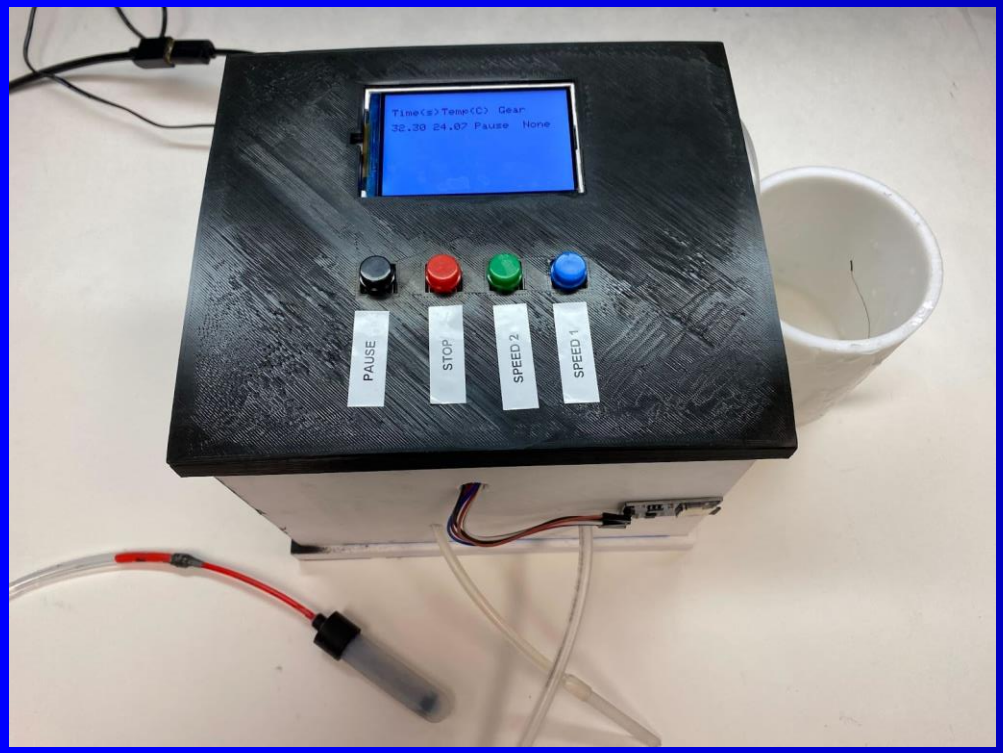


Dilator expansion (area) versus pressure



Load (on a flat surface) versus pressure

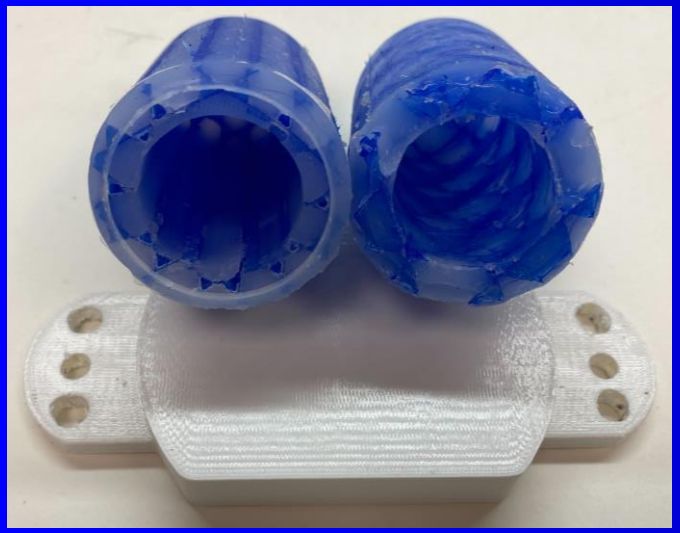
Current Prototypes



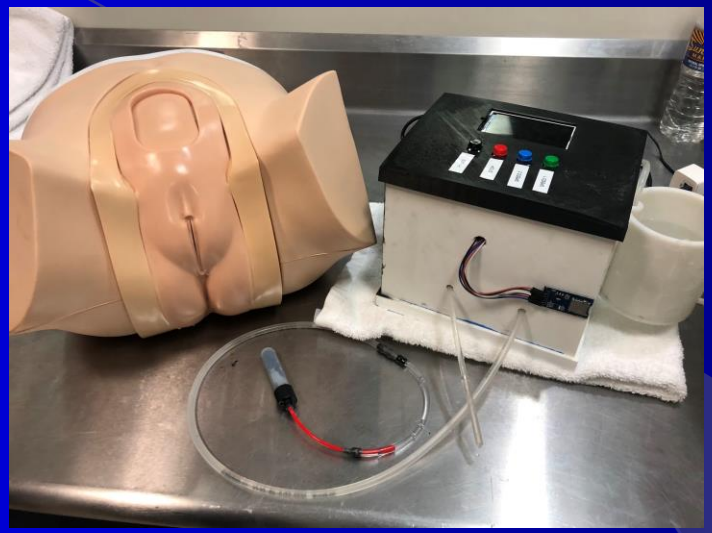
VS Dilation System Including Pressure Measurement and Automated Expansion

Dilator Prototypes Sizes Small, Medium and Large

Design of Graded Vaginal Phantoms



VS Phantom Top View

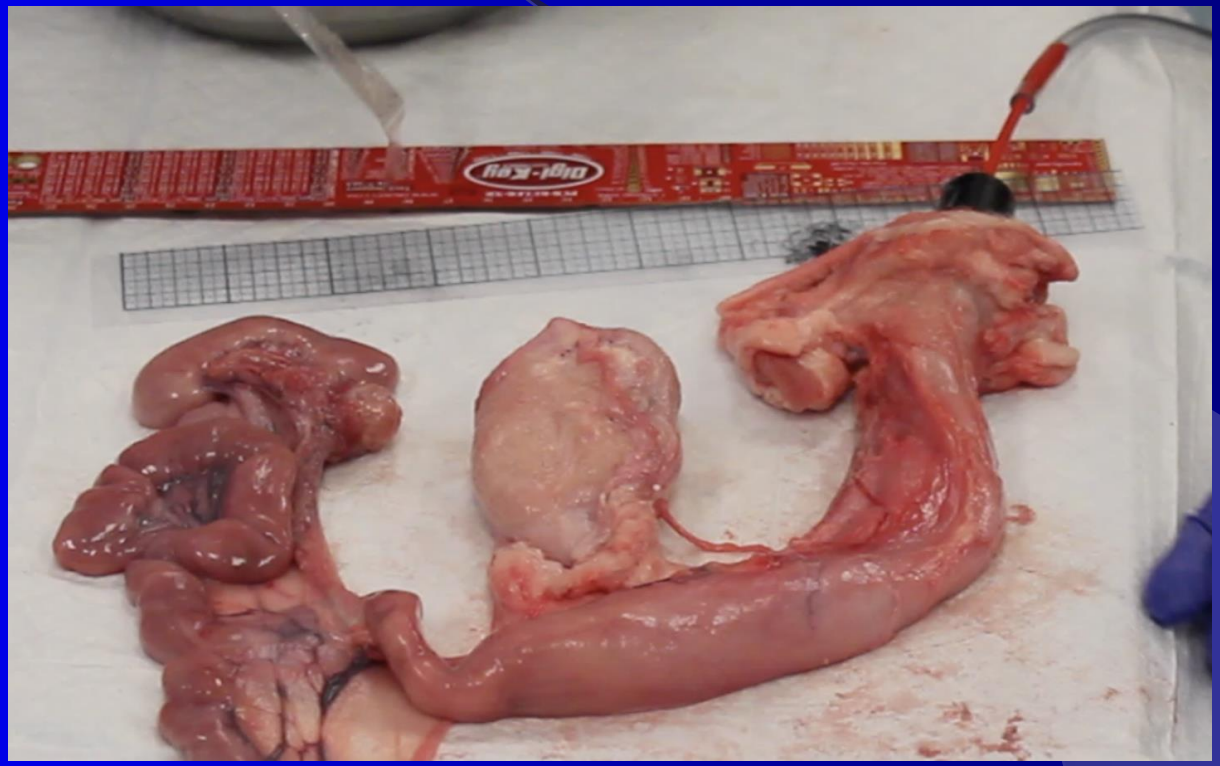


Commercially Available Pelvic Simulator

VS Phantom Front View

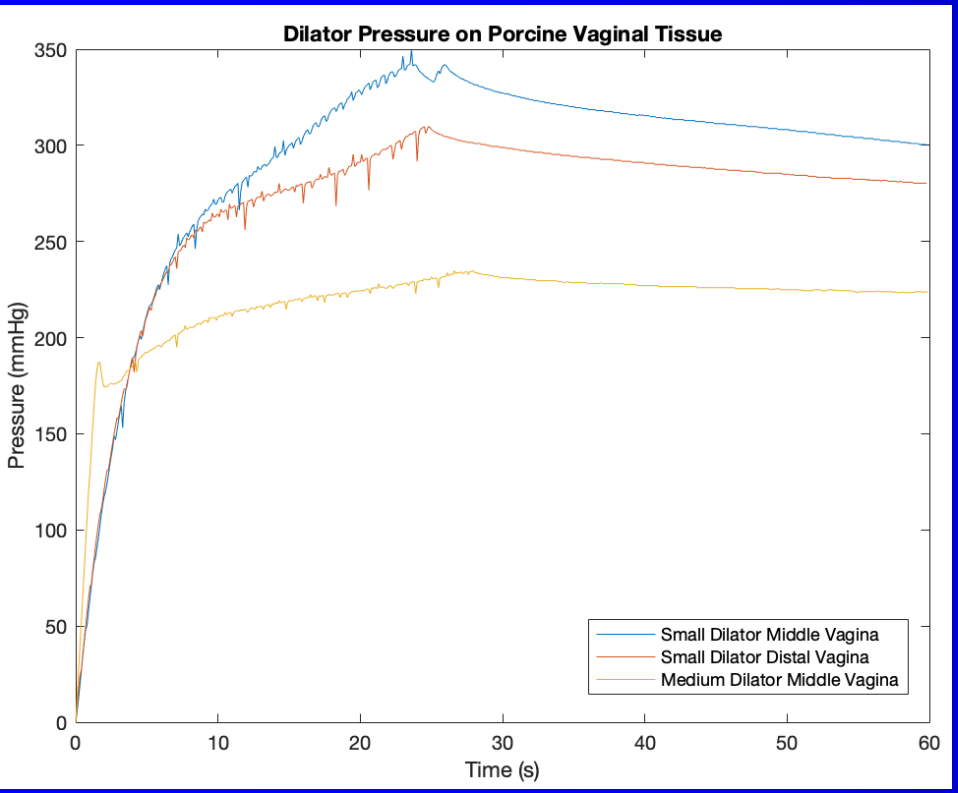
Methods: Pressure Tests on Porcine Vaginal Tissue

- Small and Medium vaginal dilators tested on different portions of porcine vaginal tissue

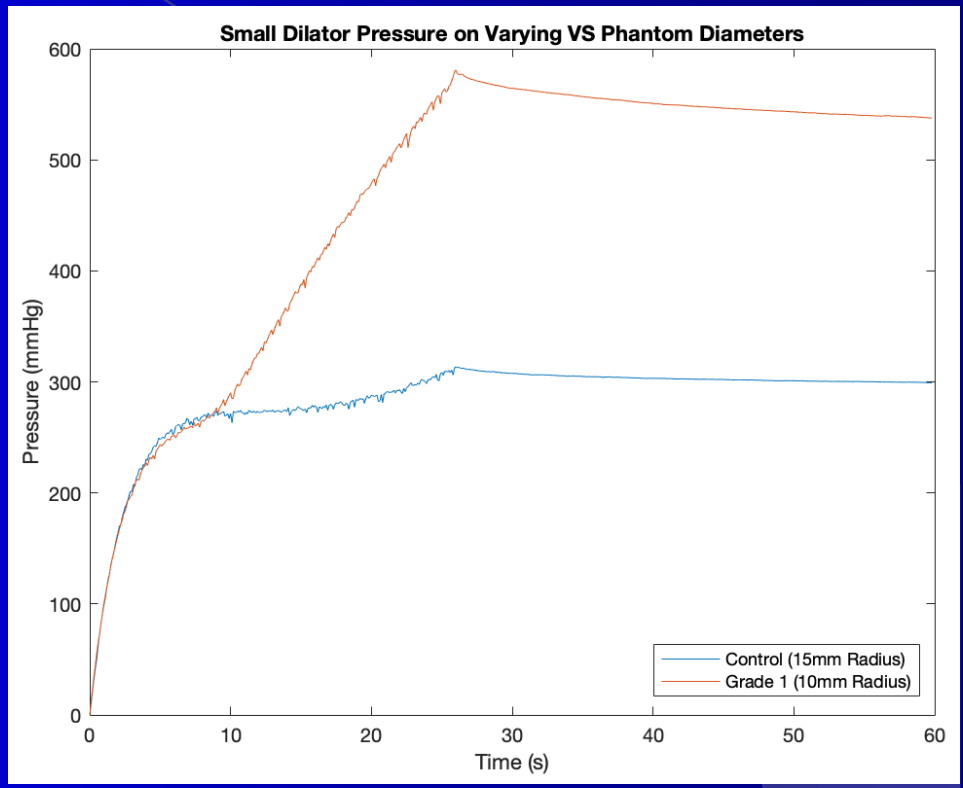


Vaginal Dilator Prototype Tested on Porcine Vaginal Tissue

Dilator Pressure on Vaginal Tissue and Graded Vaginal Phantoms



Dilator Pressure on Porcine Vaginal Tissue



Dilator Pressure on VS Phantom

Current Progress

- Uniaxial tests on porcine vaginal tissue
- Uniaxial tests on composite material used for graded vaginal phantoms
- Evaluating dilator pressure on vaginal phantoms varying in:
  - diameter
  - infill density
- Iterating on VS system and dilator prototypes

Uniaxial Tests on Vaginal Tissue

Future Considerations

- Clinical testing of dilator prototypes
- Design iterations on dilator prototype
  - Apex expansion
  - Multi-chamber prototypes
- Evaluating pressure distribution along vaginal wall
- Application of active ingredients (e.g. hormones or medication)

Biocompatible Dilator Prototype

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