MiaFit: Mechanotherapeutic Intravaginal Dilator for Treatment of Vaginal Stenosis

UC San Diego
JACOBS SCHOOL OF ENGINEERING
Shu Chien-Gene Lay Department of Bioengineering

Ritika Singh[1], German Gonzalez[1], Melina Tsotras[1], Stella Kotzabasakis[1], Frank E. Talke[2], Melissa Ledgerwood-Lee[3]

1. UC San Diego, Department of Bioengineering
2. UC San Diego, Department of Mechanical and Aerospace Engineering
3. UC San Diego, Department of Infectious Diseases

MiaFit

Background

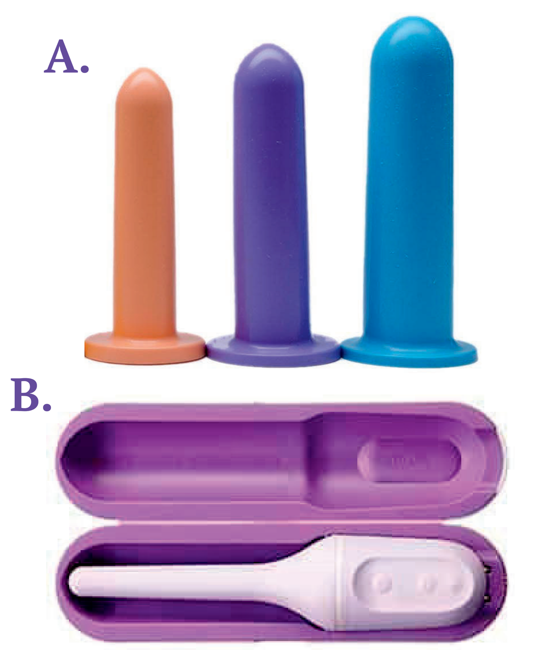

Figure 1: **A.** Discrete-sized vaginal trainers **B.** Milli Dilator

- **Vaginal stenosis** (VS) → narrowing and shortening of the vaginal canal caused by scarring of vaginal tissue
  - results in physical + emotional pain
- About **half a million** people develop gynecological cancers each year, and of those patients, around **88%** are diagnosed with vaginal stenosis[1]
- Current treatment options have low patient adherence due to excessive pain or cost (*Fig 1*)[2]

Study Aim

With this project, we have sought to develop and test a prototype of an intravaginal dilator that is *expandable, easy to use, portable* and *affordable* to *diminish painful symptoms* of vaginal stenosis and revolutionize vaginal dilation therapy.

Objectives

An expandable, affordable, easy-to-use dilator design aims to...

- **Resolve pain,** discomfort, and embarrassment from VDT
- **Simplify** the process of dilation, improve accessibility and usability
- Improve **adherence** to vaginal stenosis treatment options
  - consistent dilation → remodel vaginal canal over time
- Give physicians the ability to perform **pelvic examinations** to monitor gynecological health and cancer
- Collect more **data** of gynecological conditions and efficacy of VDT

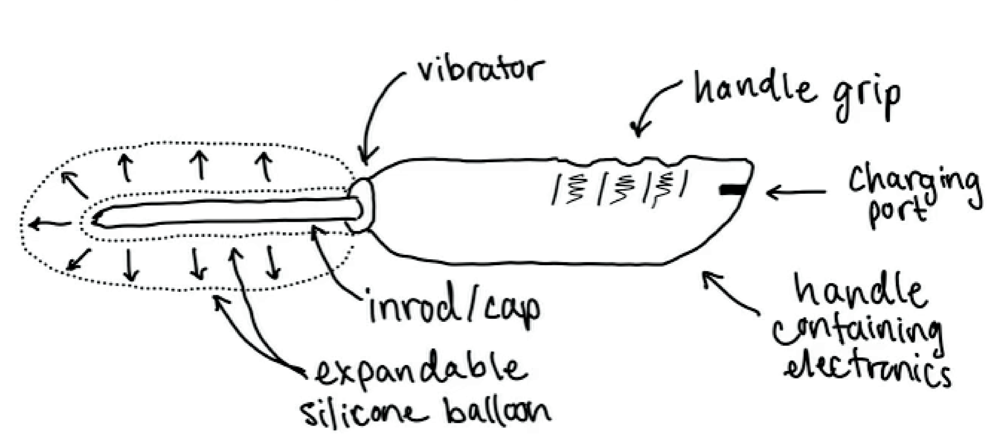

Figure 2: Labeled sketch of MiaFit dilator design

Experimental Design

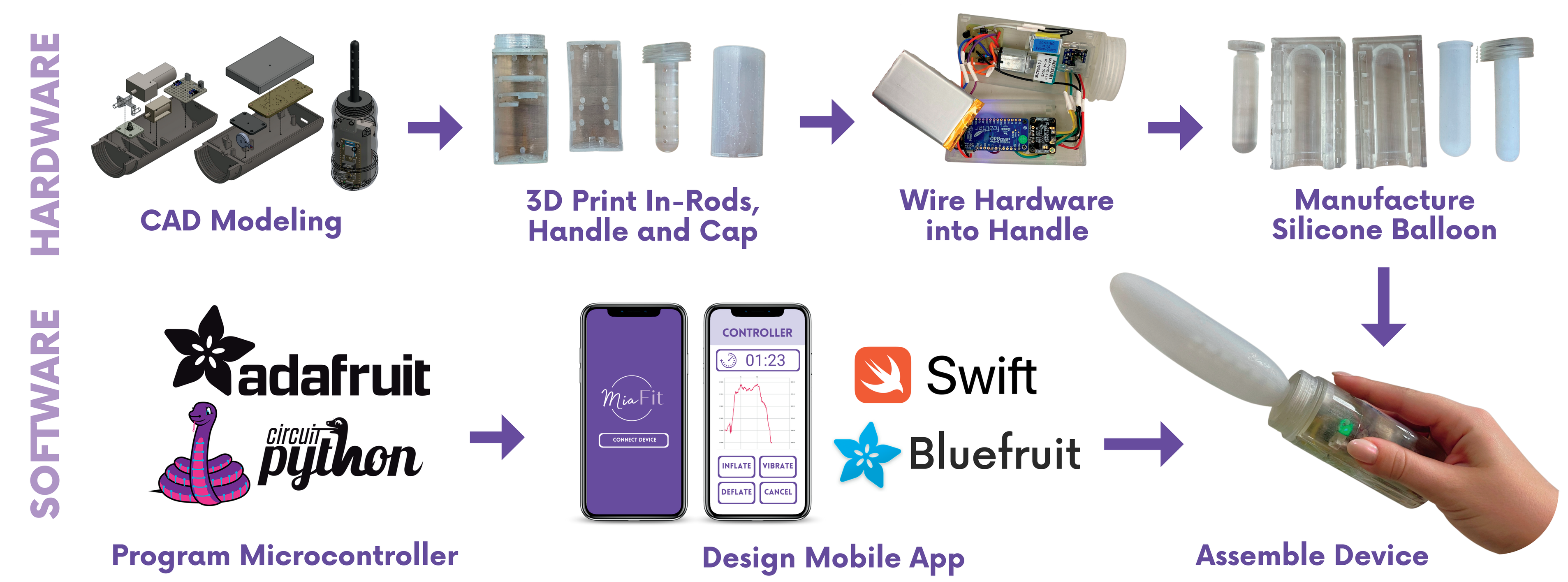

Figure 3: Schematic of hardware (top) and software (bottom) methods to develop expandable dilator prototype

Preliminary Testing Results

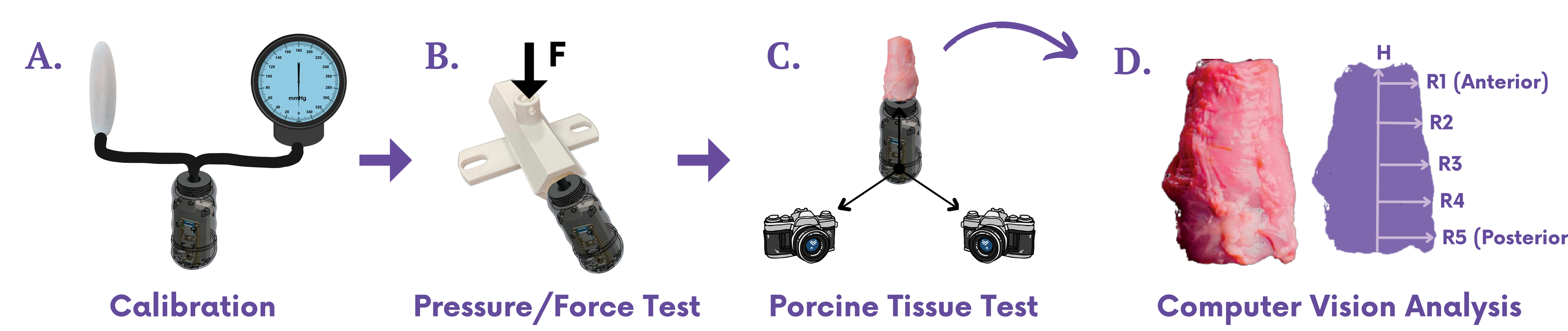

Figure 4: Schematic of testing methods: **A.** Calibration of pressure measurement, **B.** P vs. F testing using hexagonal chamber simulating Lent/Soma grade 1 model for vaginal stenosis, **C.** Porcine tissue testing with orthogonal camera setup, **D.** Transverse cross-section of porcine tissue before and after computer vision analysis labeled with radii and height

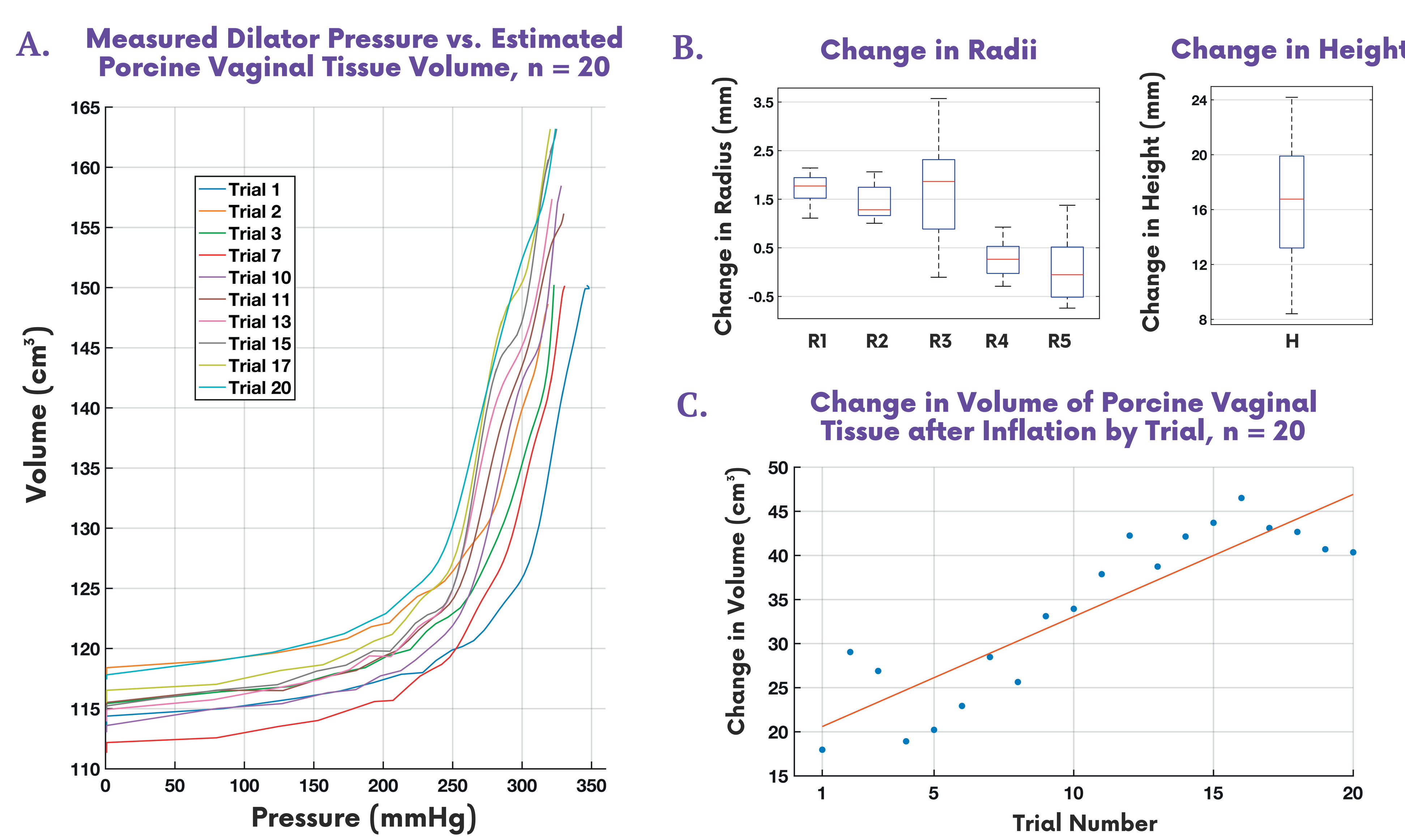

Figure 5: **A.** Measured Pressure vs Estimated Volume for 10 of 20 trials, **B.** Box and whisker plot of change in radii, n = 20, **C.** Box and whisker plot of change in height, n = 20, **D.** Change in volume after inflation of 0 to 325 mmHg, n = 20

Conclusions

- Dilator pressure **600 mmHg** = **55 N** of applied force
- Dilator pressure **331 mmHg** = **169 cm³** of Vaginal Tissue Volume = **139%** of its original size after 20 trials. (*Fig 5A*)
- During dilation, vaginal tissue experiences a greater change in radius at the **anterior** end as compared to the posterior end of the vaginal canal (*Fig 5B*)
- Vaginal tissue experiences **2.2 times** more change in volume at 325 mmHg after 20 dilation trials (*Fig 5C*) → **deformation**

Future Development

- *In vivo* **animal testing** to evaluate mechanical properties of irradiated vaginal tissue and assess efficacy of VDT
- Inflation via **saline** instead of air
  - Impedance sensor to measure the radius of expansion
  - Calculate hoop stress to implement PID control system
- Improvements in **UI/UX design** of mobile application
- Adaptations to the current silicone and in-rod **manufacturing** method for more homogenous, air-tight design and more uniform inflation
- Apply device to **other gynecological conditions** (vaginismus, post-vaginoplasty care, etc.)

Acknowledgements and References

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[1] Varytė, G. et al. (2021). Pelvic Radiation Therapy Induced Vaginal Stenosis: A Review of Current Modalities and Recent Treatment Advances.

[2] Friedman, L. et al. (2011). Adherence to Vaginal Dilation Following High Dose Rate Brachytherapy for Endometrial Cancer.

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