Washington University in St. Louis
James McKelvey School of Engineering

Final Presentation : Diagnosing Cervical Insufficiency

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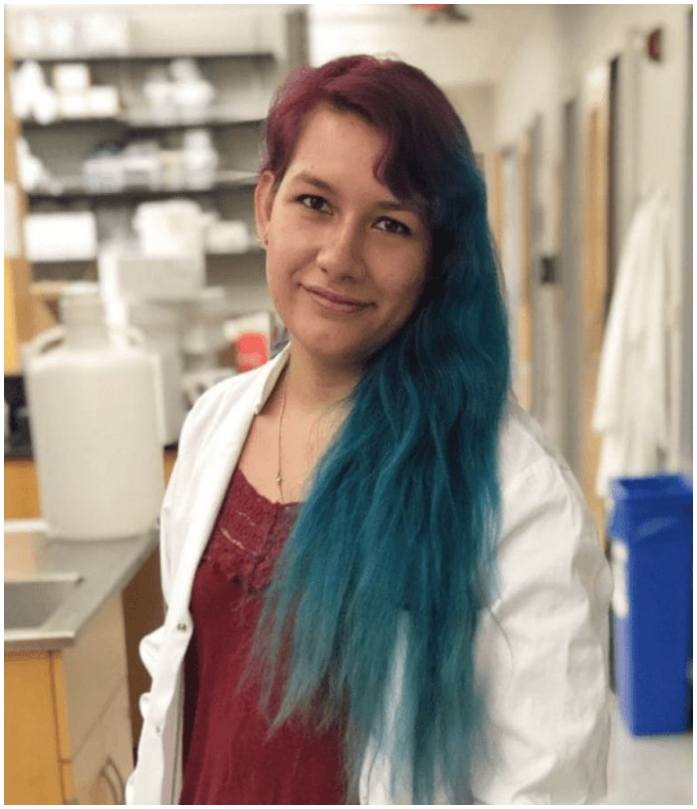
Our Clients:



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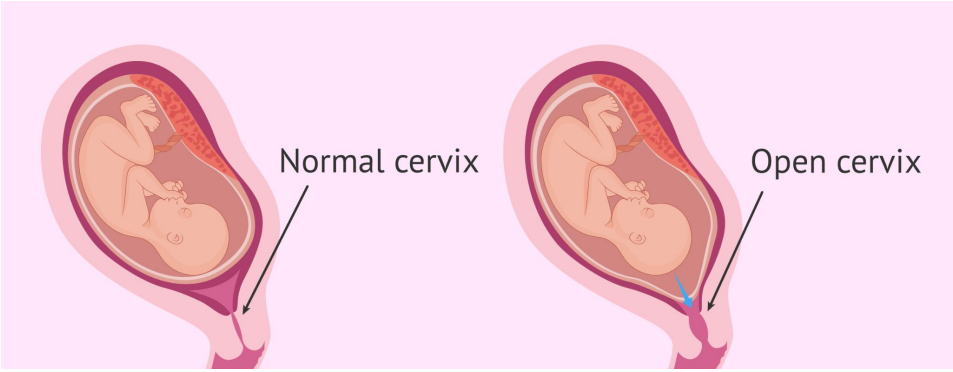
Problem: Cervical Insufficiency (CI) Diagnosis

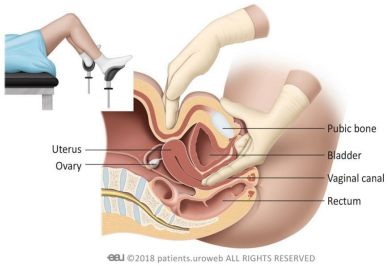
Cervical Insufficiency (CI): Mechanical softening of cervix during 1st/2nd trimester

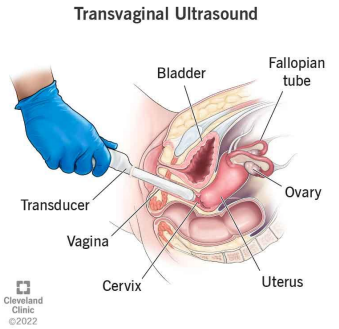
- Causes early reduction in stiffness
  - ~1% of all births
- Results in preterm birth or miscarriage
  - Birth prior to 37 weeks gestation



Garcia et. al 2022

Current care



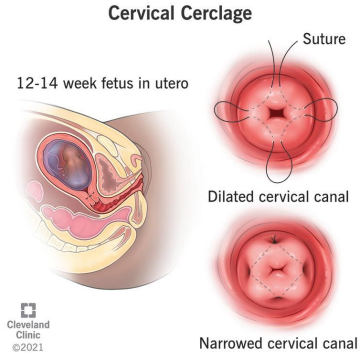


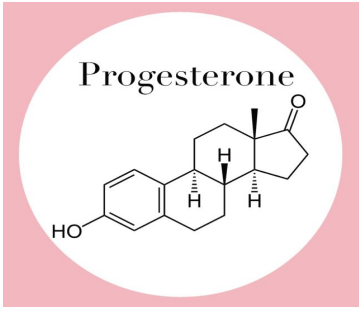
Diagnosis:

- Digital palpation
  - Qualitative, subjective, inaccurate
- Transvaginal ultrasound
  - Requires the visual effacement of the cervix and is thus reactive
- Both rely on **macroscale** changes to the cervical tissue

Treatment:

- Cerclage
  - Sewing shut of the cervix
- Progesterone
  - Hormonal treatment





Need Statement

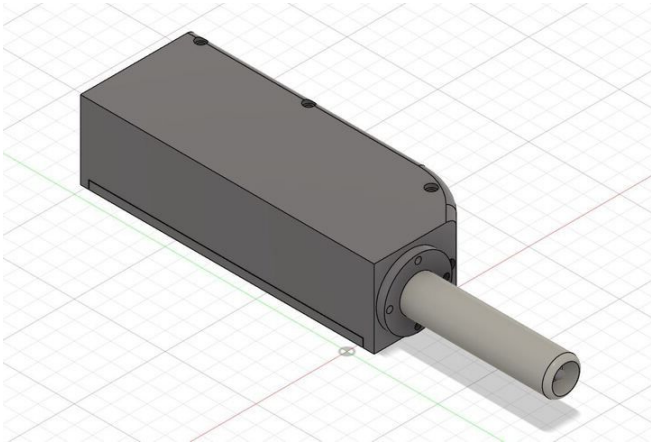
There is a need for the development of a device that clinicians can use to detect indicators of cervical stiffness changes to diagnose cervical insufficiency, in order to prevent preterm birth and miscarriage in pregnant patients.

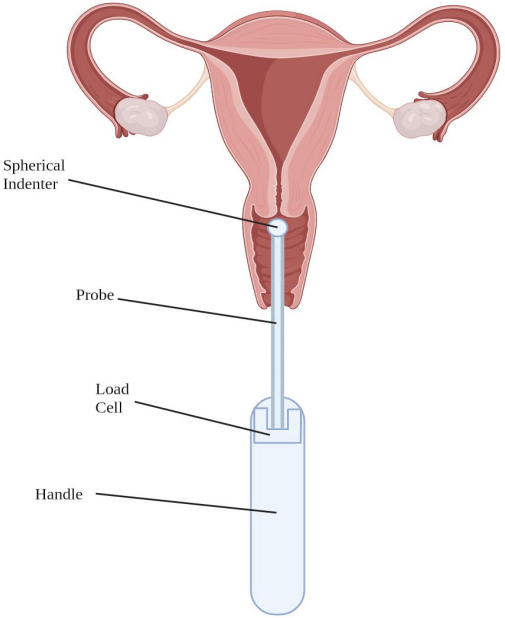
Our solution

A force-sensing probe that measures changes in cervical tissue via spherical indentation at any point in gestation

Prototype Qualities:

- 10N load cell (reads 0.5 kPa to 3000 kPa)
- Customizable insertion probe
- Self-contained microprocessor
- Linear actuator (accuracy to 0.1 mm)
- Temporal resolution 80 Hz





Our solution

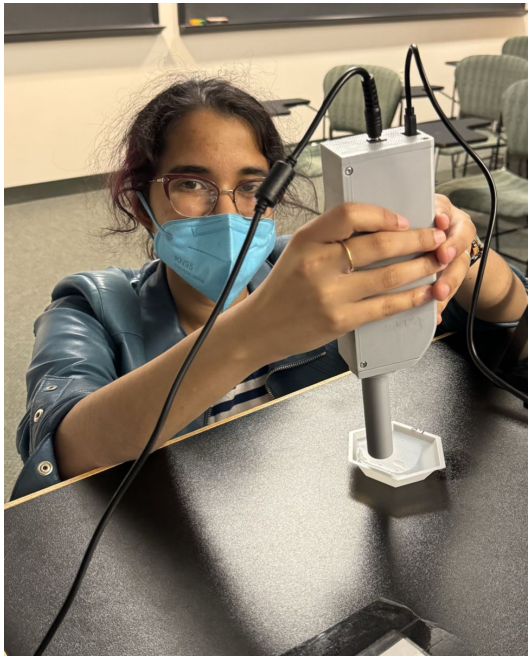
A force-sensing probe that measures changes in cervical tissue via spherical indentation at any point in gestation

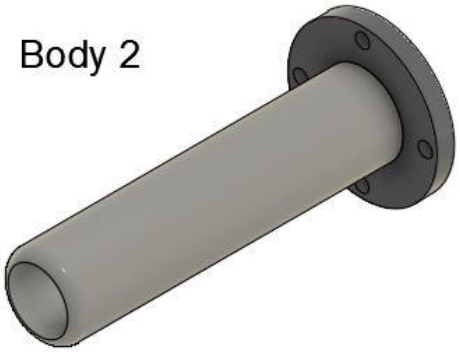
Verification and Results

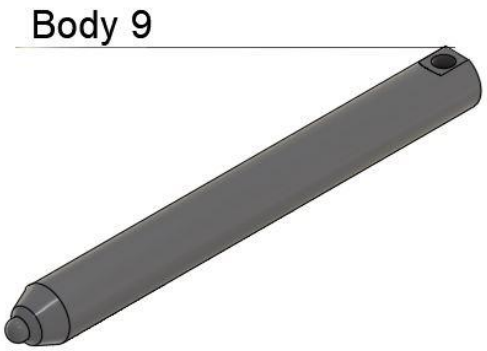
Dimensions and weight

The device meets the metrics:

- Mass of 1.4 Kg
- Portable and easy to handle



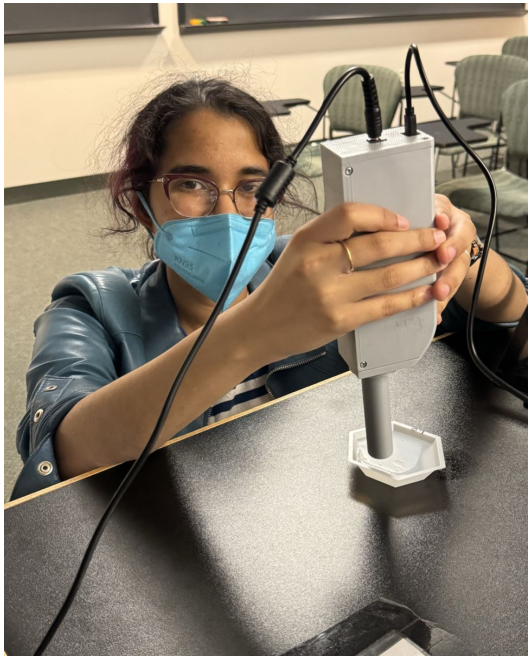


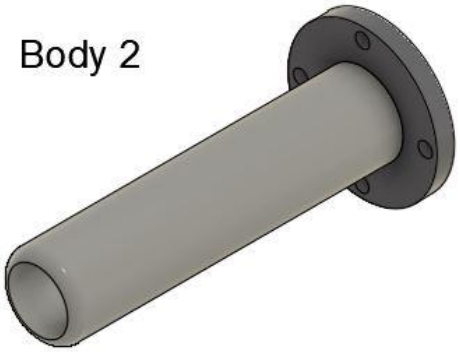


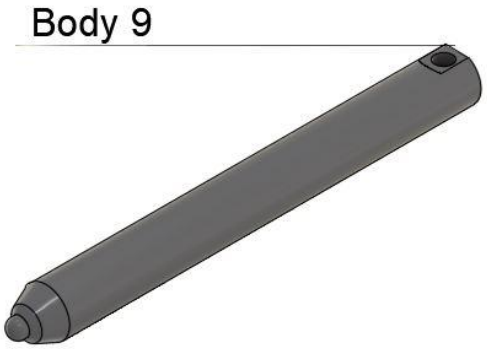
Dimensions and weight

The device meets the metrics:

- Mass of 1.4 Kg
- Portable and easy to handle
- Length retracts to 8.0 cm and extends to 8.5 cm : Fits the vaginal canal
- Diameter of 1.991 cm







Biocompatibility & Sterilizability

- The external housing of the device, handle, and probe are made from **M58 Gray Tough ABS Like 3D Printer Resin** : Robust and rigid, was recommended by client but **NOT FDA approved** for gynecologist devices.
- No current list ways to sterilize the M58 Gray Tough ABS like 3D Printer Resin.

Future iterations : Using materials like stainless steel with polypropylene external housing or having plastic disposable probe and external housing

Stiffness Accuracy

- The device takes low stiffness measurements within the cervical stiffness ranges as indicated in the specifications (between 5 kPa to 235 kPa).
- The device accuracy does **NOT meet the ±0.1 mN range** due to the sensitivity of the load cell due to external forces

Gel	Average Device Stiffness (kPa)	Instron Stiffness Measurement (kPa)
0.8%	39.431979	11.33287
1%	59.399	34.66836
1.5%	85.725454	61.12199

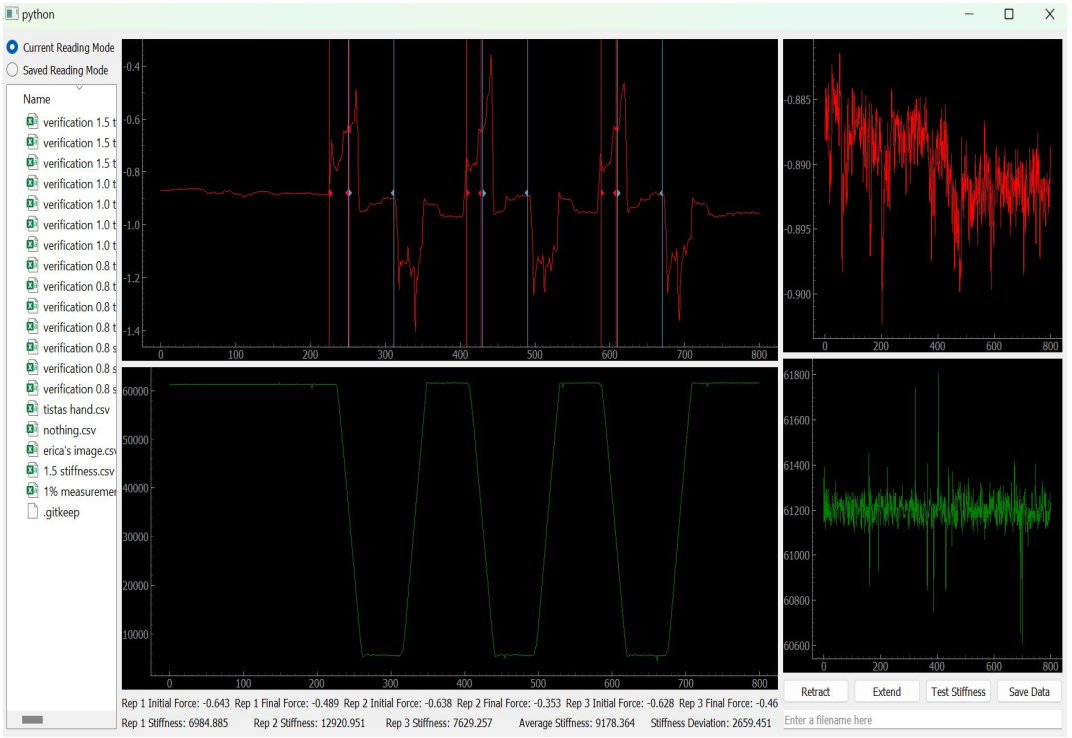
Future iterations : Creating a robot arm to decrease noises and decreasing the velocity of the linear actuator.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3946334/

Time efficiency

The device meets the metric of reporting a stiffness within 60 seconds:

- User can get a stiffness reading approximately 5 seconds



Cost

The device meets the metric :

- Device cost was less than 500 $

Part	Price
3D Printer Resin	$55.00
Force Detecting Load Cell	$142.38
Linear Actuator Motor	$80.
Load Cell Amplifier	$9.21
Raspberry Pi Pico Computer	$11.99
Linear Rail	$12.39
Power Cord	$11.99
Power Adaptor	$5.49
Control Board	$20.00
Linear Ball Bearing	$27.54
100 Ohm Resistors	$5.51
Screws of various sizes	$39.45
Jumper wires	$11.99
Total	**$440.20**

Validation and Results

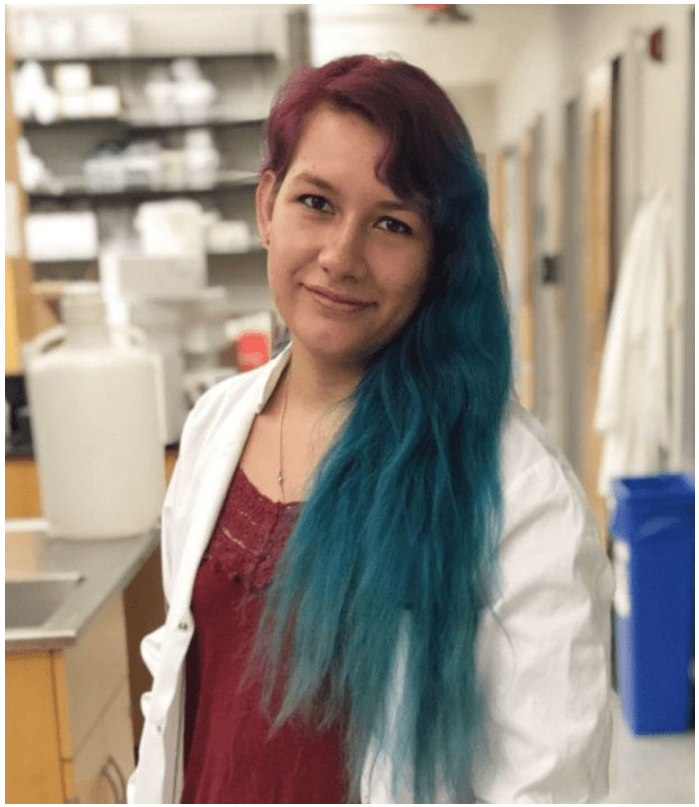
Medical Expert Test and Feedback

- Assistant OB/GYN Professor at Washington University School of Medicine
- Clinical Researcher in Center for Reproductive Health Sciences

Specification	Rating (0-10)
Easy to control the probe	7
Heaviness of the device	6
Time efficiency when taking measurements	10
Ability to produce accurate stiffness values	2
Ability to angle the device within the vaginal canal	6

Dr. Peinan Zhao

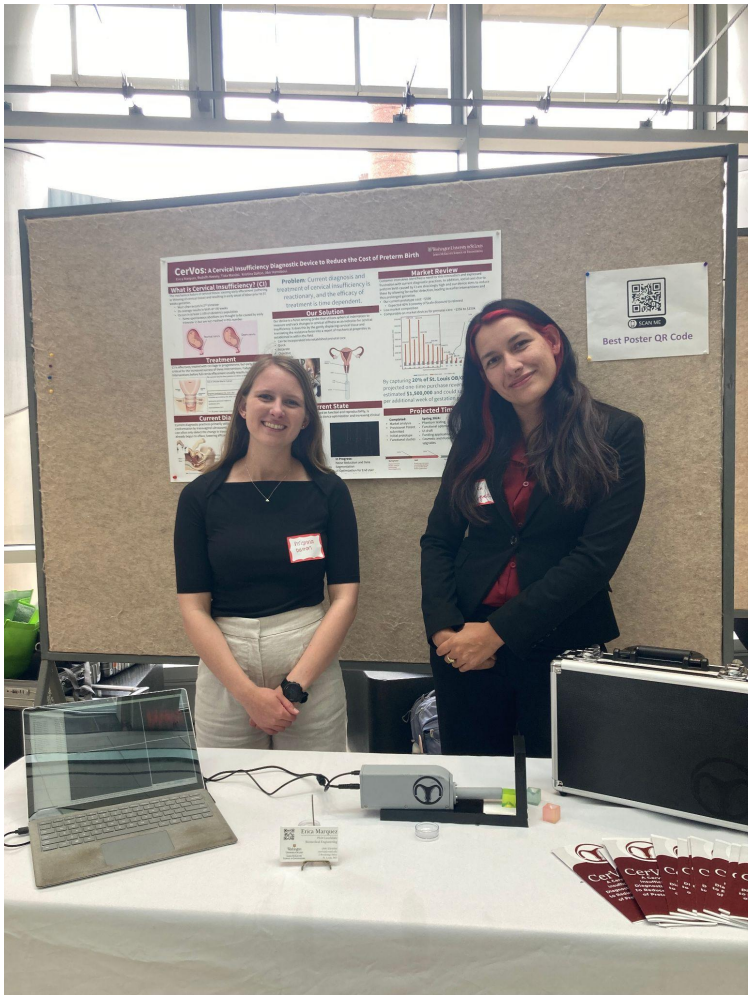
Client Satisfaction and Feedback



- BME PhD Candidate at Washington University and Sling Health Project Lead

- Satisfied with current prototype as proof-of-concept for cervical stiffness detector
  - **made aware of accuracy concerns**
  - **intends to continue reiterating device and software to improve stiffness detection ability**

Sling Health National Demo Day



Conclusion

- We believe our device is a promising start on an innovative solution for diagnosing cervical insufficiency in a quantitative manner
  - All device specifications were NOT met, but can be improved upon in future iterations
- Ethical Considerations:
  - Potential pain to patient or risks to pregnancy must be considered at every stage of design and reiteration
- What we learned:
  - 3D printing and CAD modeling
  - Communication and teamwork
  - Networking and collaboration with clients
- Intellectual Property:
  - Spherical cervical indenter is novel idea
  - Provisional Patent filed on 12/4/23

Device Demonstration

Thank You!

References

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