Levator Ani Device

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INTRODUCTION

Pelvic floor disorders (PFDs) are health conditions that affect 1 in 3 women resulting from a loss in strength of the levator ani muscles (Figure 1). This can cause both urinary and fecal incontinence or pelvic organ prolapse [1]. The current method of diagnosis is a very subjective test that requires specialized training for doctors.

The goal of this project is to create a more objective and consistent test that both doctors and patients feel comfortable with.

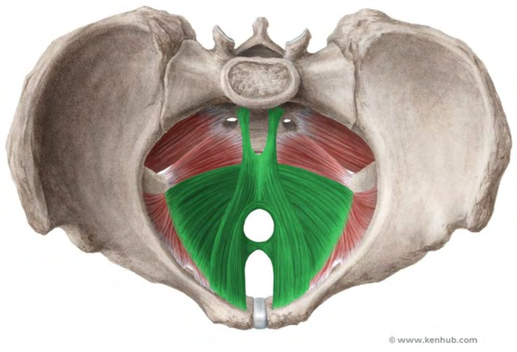

Figure 1: Pelvic floor as seen from above.
Levator ani muscles are highlighted in green [2].

PROJECT OBJECTIVE

Design a handheld device that accurately and consistently measures the maximum force applied by the levator ani muscles and displays the force to help diagnose PFDs.

The device should be:

- User-friendly
- Biocompatible
- Self-contained
- Widely accessible
- Comfortable
- Reliable
- Free of electronics

METHODS

- 3D printed prototypes as it is inexpensive, accessible, fully mechanical, requires no electronics, and allows for a print-in-place design with no assembly needed.
- Rapid prototyped and tested of 4 unique designs to choose the most promising to iterate.
- Made design changes in order to meet design specifications (Figure 2) (Table 1).
- Created a linkage mechanism that measures and displays the force via a dial (Figure 3).
- Printed prototype in polylactic acid (PLA) and polypropylene (PP)
  - PLA was chosen for its ease to 3D print
  - PP was chosen for its ability to be sterilized in an autoclave
- Tested prototype to show that it meets design specifications.
- Tested specimens before and after autoclave to validate if sterilization technique can be used.

Figure 2: Evolution of prototype design iteration, from left to right.

Table 1: Design specifications of the device.

Design Criterion	Requirement	Specification
Maximum Height of Bills (h)	3 cm	3 cm
Maximum Width of Bills (w)	2 cm	1.4 cm
Maximum Depth of Bills (d)	8 cm	6.5 cm
Applied Force to Measure	0 - 7 N	0 - 7 N
Measure Force Accurate To	0.5 N	0.5 N
Device Displacement	0 - 1 cm	0 - 0.9 cm

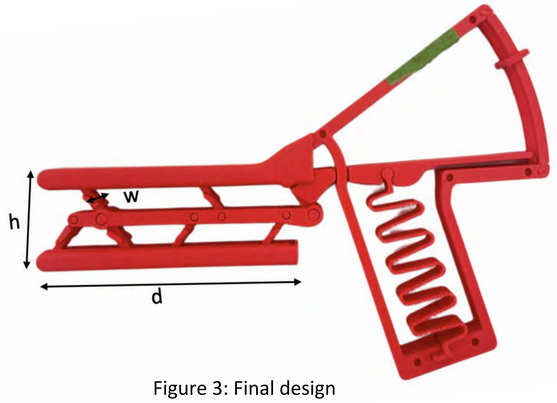

Figure 3: Final design

TESTING

Conducted tension tests on PP and PLA dogbone specimens before and after autoclaving to compare material property changes (Figures 4 and 5). After autoclaving, PLA exhibited significant changes in mechanical properties, while PP remained largely unaffected. Conducted compression tests on PLA prototype to confirm operation within performance specifications (Figure 6).

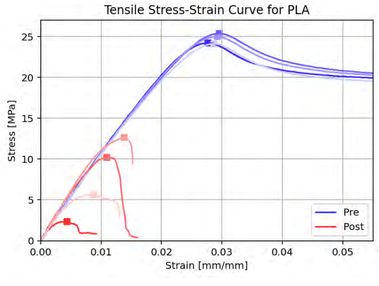

Figure 4: Stress-strain curve of PP before and after autoclaving

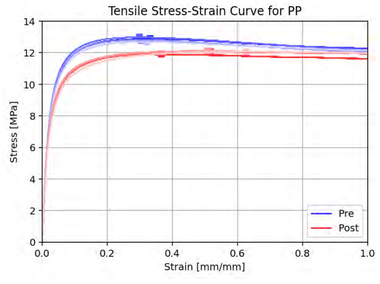

Figure 5: Stress-strain curve of PLA before and after autoclaving

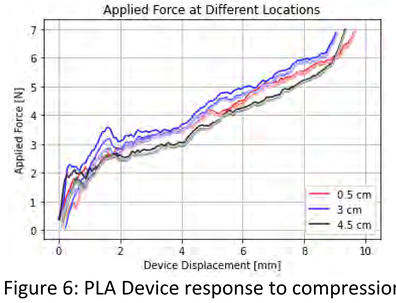

Figure 6: PLA Device response to compression test. Distances are measured from the front of the device

CONCLUSION

Although PP is capable of withstanding autoclave sterilization, inconsistencies in the printing process impacted prototype quality, suggesting the need for further refinement in manufacturing processes.

The PLA prototype meets all design specifications, has proven its functionality through testing, and meets all project objectives. The device is also consistent throughout repeated cycles and use.

NEXT STEPS

Outside the scope of this class, these are some goals we will be pursuing:

- Printing - research and test alternative printing techniques for PP device (Figure 7)
- Sterilization - test alternative sterilization techniques on the PLA device
- Clinical Trials - continue conversation with the Institutional Review Board (IRB) to gain approval for patient trials
- Bench to Bedside - patent the device

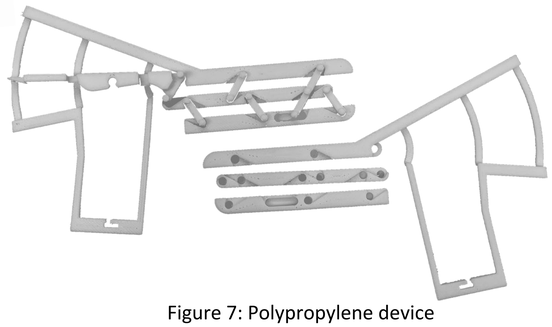

Figure 7: Polypropylene device

REFERENCES

[1] "Pelvic Floor Disorders - UChicago Medicine," *uchicagomedicine.org*, 2024 https://www.uchicagomedicine.org/conditions-services/obgyn/urogynecology/pelvic-floor-disorders#

[2] "Levator ani muscle," *Kenhub*. https://www.kenhub.com/en/library/anatomy/levator-ani