VAGINAL SELF-SWAB DEVICE TO LIMIT CONTACT CONTAMINATION

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BME Design

Abstract

Sexually transmitted infections (STIs) are estimated to afflict 1 in 5 people in the U.S., with 70% of those affected being women [1]. Vaginal self-swab tests can encourage routine testing and prevent proliferation of STIs by providing privacy in STI screening and increasing ease of testing [2]. Current testing methods can contaminate the testing environment, with one study finding that 4 out of 6 patients that tested positive for Chlamydia had actually received false-positive results due to environmental contamination [3]. As a result, the goal of this project was to design a vaginal self-swab to limit contamination and promote testing.

Motivation & Background

Motivation:

- Current self-swab designs have issues with contamination.
  - The patient has to transport the swab to a test tube while ensuring no contact with the environment.
- Our team's goal is to design a self-swab for STI testing that minimizes potential environment contamination within a clinical setting.

Fig. 1: Aptima Multitest Swab

Background:

- STIs are under-tested especially in young women
  - Some barriers include cost, transportation, stigma [4]
  - Many STIs are asymptomatic (Chlamydia)
- Long term complications if untreated [2]
  - Infertility and pelvic floor disease
- Current tests use Nucleic Acid Amplification (PCR) testing [2]
- Current designs pose a greater risk of false positives [3]

Design Criteria

- Deployment, retraction, sealing mechanisms (slider or plunger), similar to tampon or IUD insertion device
- Head of swab must insert 5 cm into the vagina [5]
- Transport media [2]
- User-friendly
- Overall device length under ~17 cm
- Able to manufacture with 3D-printing
- Biocompatible and non-toxic materials
  - Non-cotton fiber (Dacron) [6]
  - Universal transport media
  - Autoclavable body of device (i.e. polypropylene)
- Budget: $500

Main design criteria: limiting contamination, ease of use and fabrication, patient comfort, safety

Final Design

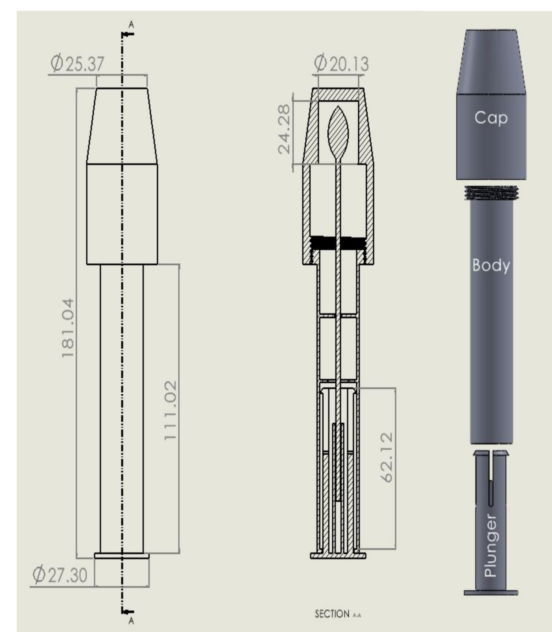

Fig. 2:. Dimensioned drawing of Final Design

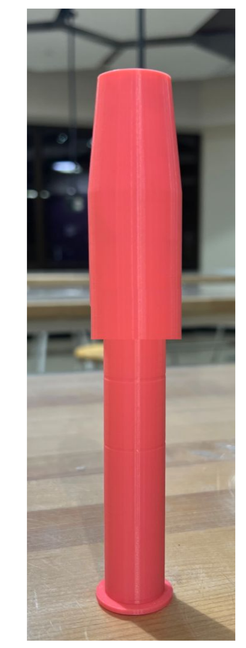

Fig. 3:. Final prototype 3D-printed out of pink PLA

- Plunger
  - Contains swab holder
  - Allows for 6.2 cm of motion
- Body
  - Contains threading for cap attachment
  - Prevents removal of plunger from device
- Cap
  - Can contain up to 7.7 ml of media
  - Has a rim for thin film attachment site

Final Material: Polylactic Acid (PLA)
Cost: ~ $4.50
Weight: 44.84 g
Note: PLA was used due to lack of availability of PP at the MakerSpace and for aesthetic purposes.

Testing & Results

Leak Testing - Liquid added to the device to assess potential leaking.

- Liquid did not leak through the cap, but all came out at the bottom of the device.

Clinical Use Testing - A tube was used to model a vagina and a swab was taken to assess feasibility of clinical use.

- Swab picked up dye that was on the interior of the test tube, indicating a successful swab was achieved.

Ease of Using Testing - A survey was sent to potential female users to assess if the device is intuitive to use (n=12).

- ⅔ of respondents described device as visually appealing
- All respondents felt able to perform a self-swab after reading instructions or after a demonstration
- Over 80% felt the new device would prevent contamination
- Feedback included modifying the threading design

Mechanical Strength Testing - Compressive (10, 100, 1000 N) and tensile (25, 50, 75 N) tests conducted on the body and plunger of the device using SolidWorks.

- Withstood compressive loads greater than 1000 N and tensile loads greater than 75 N.
- Both experienced significant deformation.
- Greatest Stresses
  - Body
    - Compressive average of 6.6 MPa
    - Tensile average 0.56 MPa
  - Plunger
    - Compressive average of 72.4 MPa
    - Tensile average of 4.85 MPa

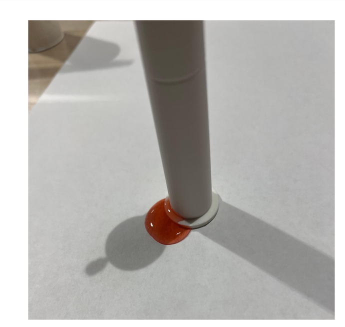

Fig. 4: Leaking from end of device during leak testing

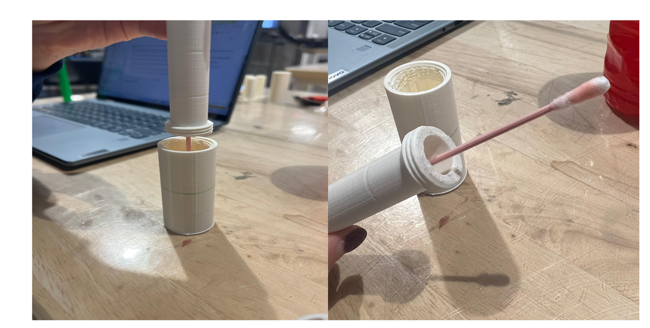

Fig. 5: Clinical use testing and swab after test was completed.

On a scale of 1-5, how comfortable would you being using this device?

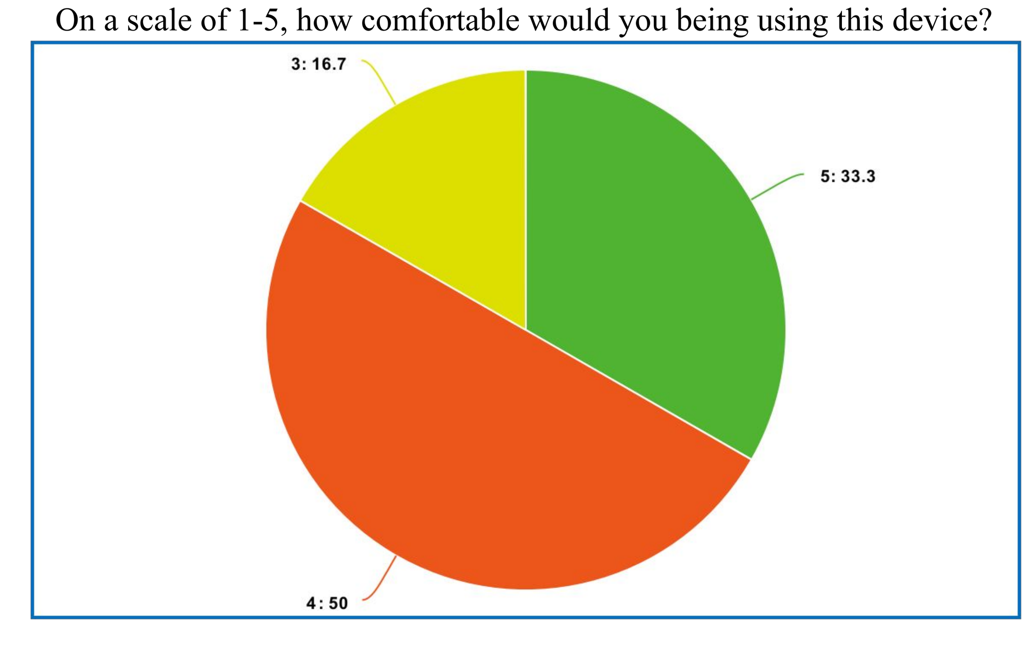

Fig. 6: Pie chart demonstrating the portions of survey respondents rating their comfortability using the team's device.

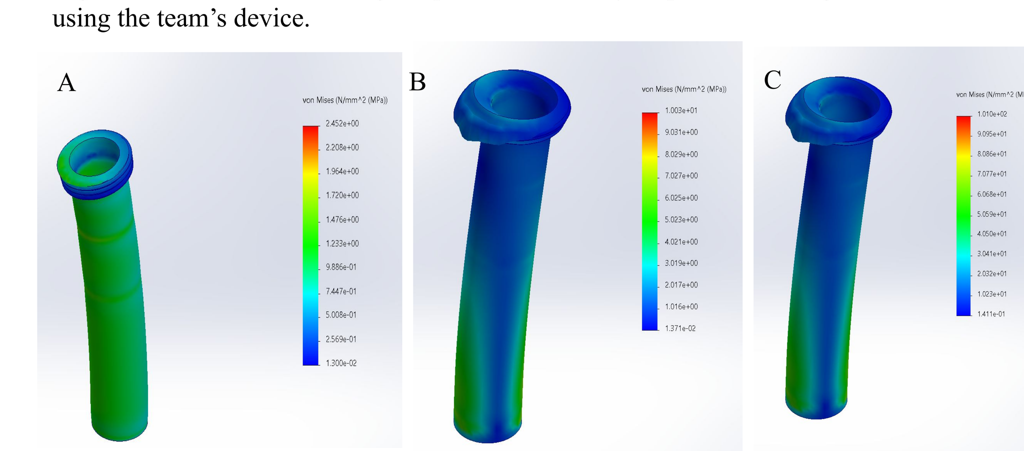

Fig. 7: Stress distribution of body at (A) 10 N compressive load (B) 100 N compressive load (C) 1000 N compressive load.

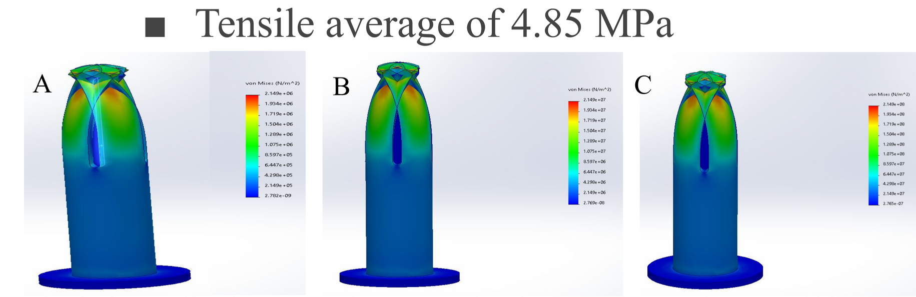

Fig. 9: Stress distribution of plunger at (A) 10 N compressive load (B) 100 N compressive load (C) 1000 N compressive load.

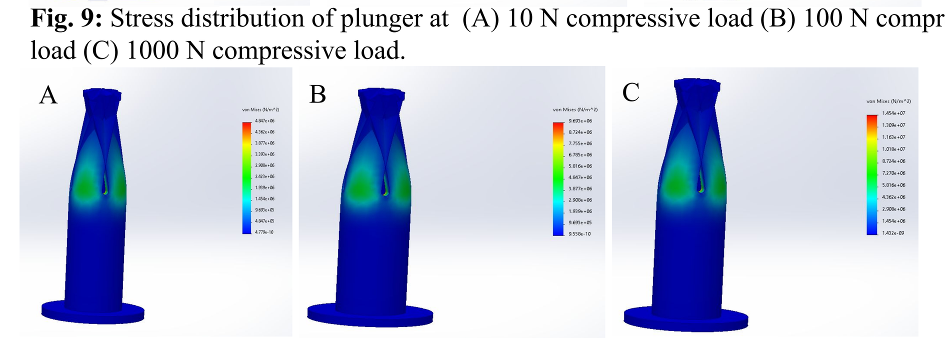

Fig. 10: (A) Stress distribution of plunger at (A) 25 N tensile load (B) 50 N tensile load (C) 75 N tensile load.

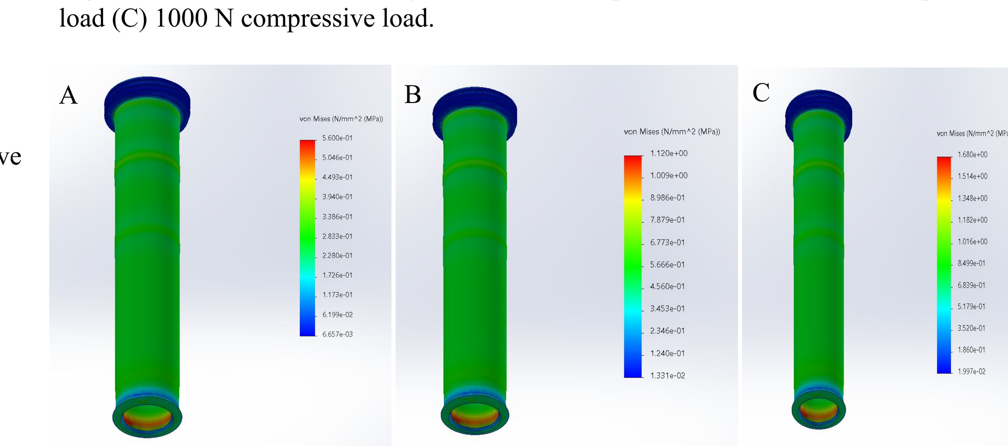

Fig. 8: (A) Stress distribution of body at (A) 25 N tensile load (B) 50 N tensile load (C) 75 N tensile load.

Discussion

Mechanical Considerations

- Polypropylene (PP)
  - Young's Modulus: 1.3 GPa [7]
  - Tensile Strength: 30 MPa [7]
  - Compressive Strength: ~40 MPa [8]
- Polylactic Acid (PLA)
  - Young's Modulus: 3.5 GPa [9]
  - Tensile Strength: 59 MPa [9]
  - Compressive Strength: ~98 MPa [10]
- Both plastics are biocompatible. PP is autoclavable while PLA is not [11]
- Both materials can withstand loads greater than anticipated and PP will ultimately be used due to its more favorable thermal properties

Testing

- Leaking indicates a need for an improved sealing mechanism
  - O-ring
  - Twist lock
- Incorporate feedback from survey in future prototype
- Device does not impede the ability to collect specimens (Fig 5)
- Device limits contamination as dye was not picked up by the body itself (Fig 5)
- Mechanical testing indicates need for redesign of one-time snap mechanism of the plunger as it is most likely to fail

Future Work

- A thin, puncturable film included inside the cap to contain the transport media
- A more aesthetically pleasing design
  - Slimmer body
  - Threading on the inside of the body
- A sealing mechanism will be incorporated into the design
  - O-ring on the plunger to prevent leaking of transport media
  - Twist-lock mechanism between plunger and body
- A prototype 3D printed out of polypropylene
- Research into mass-production methods to encourage universal STI testing
  - Injection moulding

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References

[1] "The Dangers of Undiagnosed Sexually Transmitted Infections," ASM.org, https://asm.org/articles/2022/december/the-dangers-of-undiagnosed-sexually-transmitted-in#:~:text=However%2C%20treatment%20of%20STIs%20is,not%20realize%20they%20are%20infected. (accessed Dec. 2, 2023).
[2] M. Muljadi, C.-M. Cheng, C.-Y. Yang, T.-C. Chang, and C.-J. Shen, "A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women," Frontiers, https://www.frontiersin.org/articles/10.3389/fbioe.2022.1008761/full (accessed Dec. 2, 2023).
[3] M. Toepfe, B. Hermann, M. Sansone, C. Lilja, and P. Nolskog, "Environmental contamination by Chlamydia trachomatis RNA can cause false-positive test results in clinical samples," Sexually Transmitted Diseases, vol. Publish Ahead of Print, Oct. 2020, doi: https://doi.org/10.1097/olq.0000000000001323.
[4] R. J. Steiner, S. L. Michael, J. E. Hall, L. C. Barrios, and L. Robin, "Youth Violence and Connectedness in Adolescence: What Are the Implications for Later Sexually Transmitted Infections?," Journal of Adolescent Health, vol. 54, no. 3, pp. 312-318.e1, Mar. 2014, doi: https://doi.org/10.1016/j.jadohealth.2013.09.008.
[5] "Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia." Accessed: May 05, 2020. [Online]. Available: https://epi.dph.ncdhhs.gov/cd/lhds/manuals/std/labtesting/selfcollectedswabs.pdf
[6] R. N. Kashapov and A. N. Tsibin, "Comparison of the Physical Properties and Effectiveness of Medical Swabs for Sampling Biomaterials," Biomedical Engineering, vol. 55, no. 4, pp. 289–293, Nov. 2021, doi: https://doi.org/10.1007/s10527-021-10120-z.
[7] N. Connor, "Polycarbonate | Density, Strength, Melting Point, Thermal Conductivity," *Material Properties*, May 07, 2021. https://material-properties.org/polycarbonate-density-strength-melting-point-thermal-conductivity/#google_vignette (accessed Dec. 05, 2023).
[8] MatWeb, "Compressive Strength Testing of Plastics," *www.matweb.com*. https://www.matweb.com/reference/compressivestrength.aspx
[9]"Physical and mechanical properties of PLA, and their functions in widespread applications -A comprehensive review Publisher Elsevier BV Terms of Use Creative Commons Attribution-NonCommercial-NoDerivs License Detailed Terms http://creativecommons.org/licenses/by-nc-nd/4.0." Available: https://dspace.mit.edu/bitstream/handle/1721.1/112940/Anderson_Physical%20and%20mechanical%20properties.pdf?sequence=1
[10]M. S. Barkhad, B. Abu-Jdayil, A. H. I. Mourad, and M. Z. Iqbal, "Thermal Insulation and Mechanical Properties of Polylactic Acid (PLA) at Different Processing Conditions," *Polymers*, vol. 12, no. 9, p. 2091, Sep. 2020, doi: https://doi.org/10.3390/polym12092091.
[11]"Plastics Compatibility with Sterilization Methods." Available: https://www.industrialspec.com/images/files/plastics-sterilization-compatibility-chart-from-is-med-specialties.pdf