Vaginal Self-Swab Device to Limit Contact Contamination

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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 thus increasing ease of testing [2]. Current self-swab testing methods can contaminate the testing environment, with one study finding 4 out of 6 patients to receive false-positive results for chlamydia due to surface contamination [3]. As a result, the goal of this project was to design a modified vaginal self-swab device that limits contamination of the testing environment and promotes universal STI testing.

MOTIVATION & BACKGROUND

Motivation:

- Contamination issues with current self-swab
- Minimize potential testing environment contamination within clinical setting
- 67% of women received false positive result due to contamination [3]

Background:

- STIs are under-tested especially in young women
- Barriers: cost, transportation, stigma [4]
- Long term complications if untreated [2]
- Current tests use Nucleic Acid Amplification (NAAT) [2]
- Current designs pose greater risk of false positives [3]

Previous Design:

- Utilized body, plunger, cap
- Contained 2.9 mL of media in cap
- Issues with leaking, threading
- Did not utilize Aptima media tube

Fig. 1: Aptima Multitest Swab [5].

Fig. 2: Previous semester design with cap, body, and plunger.

DESIGN CRITERIA

- Head of swab must insert 5 cm into the vagina [6]
- Mechanism for swab breakage
- Overall device length under ~17 cm
- User-friendly
- Able to manufacture with 3D-printing
- Biocompatible and non-toxic materials
- Compatible with the Hologic Panther testing system
- Budget: $500

Main design criteria:
Limiting contamination, Ease of use, Fabrication, Patient comfort, Safety

FINAL DESIGN

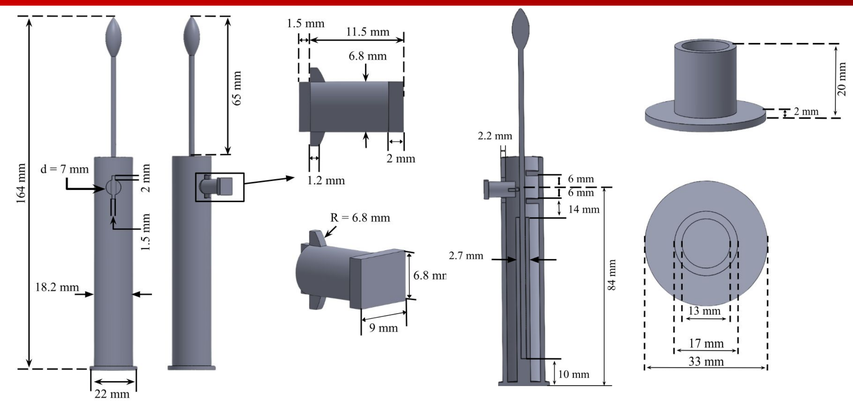

Fig. 3:. Dimensioned drawing of final design including the 3-point bend mechanism and the media tube stand.

Components:

- External casing
  - Swab holder
  - Friction fit
- 3-point bend
  - Internal supports
  - External push-button
- Media stand

Material: Polylactic Acid (PLA)
Weight: 19 grams
Cost: $0.93

TESTING & RESULTS

Contamination Testing:

- Measure of contaminated area, other instances of contamination (i.e. gloves, media tube) during collection process
- Aptima Multitest Swab Specimen Collection Kit vs prototype

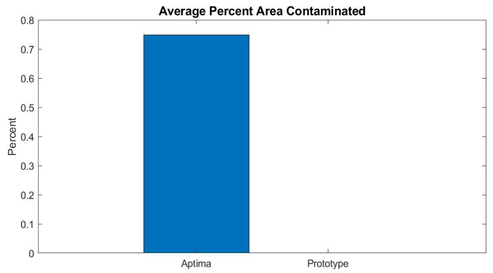

Fig. 4:. Average percentage of testing area contaminated by Aptima Collection Kit vs Prototype (n=4 for each group, n.s., p>0.05, Wilcoxon Rank-Sum).

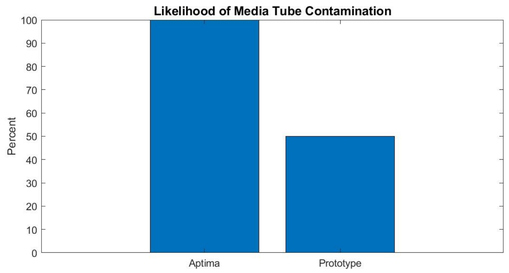

Fig. 5:. Likelihood of media tube contamination for Aptima Collection Kit vs Prototype (n=4 for each group).

Force Testing:

- Two of most common types of swabs were tested
- Used MTS machine to measure force required to break swabs within three point bend configuration

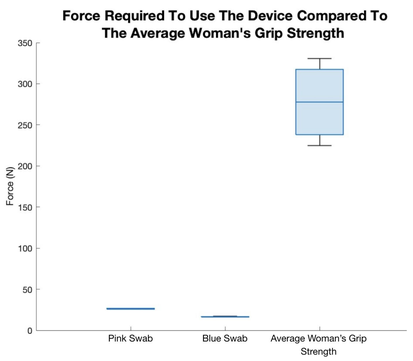

Fig. 6: The force required to break the pink and blue swabs compared to the average women's grip strength [7].

Design Survey:

- Long vs. Short prototype
- Ease of Use
  - Instructions
  - Design aspects
- n = 24

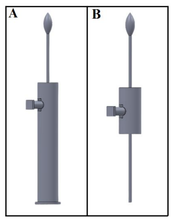

Fig. 7: Prototype A and B as presented on the survey.

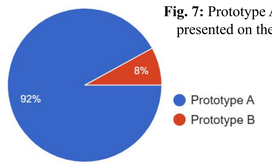

Fig. 8: 92% of respondents would feel more comfortable using prototype A to conduct a vaginal self-swab.

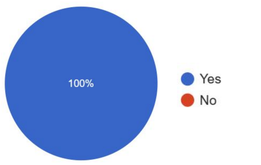

Fig. 9: 100% of respondents felt that the instructions effectively taught them how to use either prototype.

Tip Testing:

- Tilt angle with base:
  - ~30° from cap
- Tilt angle without base:
  - ~3° from cap
- Base lowers center of gravity, increases base of support

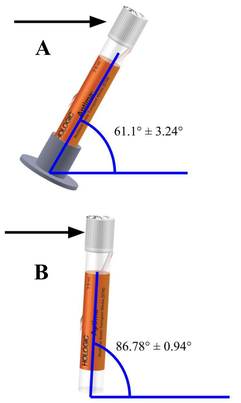

Fig. 10: Tipping angle of transport media tube with applied force at the cap with the stand (A) and without the stand (B).

DISCUSSION

Device meets design specifications:

- Contamination:
  - Reduced contamination of testing environment compared to Aptima Multitest Swab
  - Lowered rate of media tube contamination which helps to reduce false positives
- Mechanical:
  - Swab breakage mechanism successful
  - Force required within grip strength
- Survey & Aesthetics:
  - User-friendly, ergonomic design
  - Successful integration with Hologic Panther machine

FUTURE WORK

Device:

- Stop the rotation of the button
- Ensure the swab and the tip of the button are always aligned for the three point bend
- Make the device more manufacturable at a large scale
- Possibly utilize threading rather than the friction fit

Testing:

- Conduct additional contamination testing with more diverse participants
- Run a test to evaluate the effectiveness of the instructions

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