CERVOS: A Novel Inflatable Pessary for Cervical Insufficiency

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Introduction

Problem: Cervical insufficiency accounts for about 25% of losses beyond 14 weeks of gestation [1].

- Cervical insufficiency: shortening of the cervix below the typical healthy length of 4-5 cm, compromising structural support and leading to miscarriage or premature birth [2].
- Cervical cerclage is an invasive suturing procedure to close the cervix and prevent early dilation [3].
  - Risk of infection, bleeding, and injury to surrounding organs [4].
- Vaginal pessaries provide mechanical support to the cervix during pregnancy [5].
  - Does not accommodate different cervix sizes and shapes [6, 7].
  - Requires frequent, costly doctor visits for adjustments

Solution: Develop an adaptable novel inflatable pessary to accommodate all cervix sizes and shapes throughout pregnancy

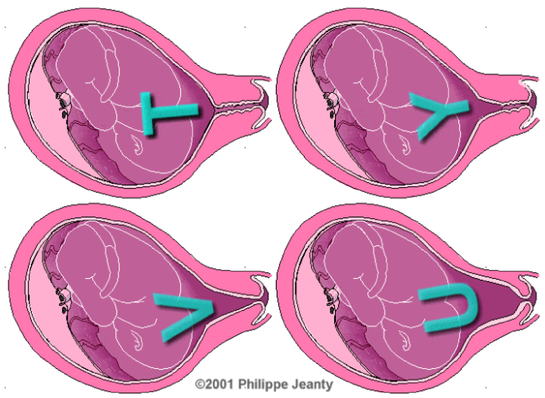

Figure 1. Stages of cervical insufficiency during pregnancy: A closed cervix (T), progressive funneling (Y), weakened cervix (V), end-stage funneling (U) [8].

Materials and Methods

1. Design and Fabrication
   - Pessary fabricated with two-part and injection molded Smooth-Sil™ 960 (SmoothOn, Macungie, PA)
   - Valve, pressure sensors, and micro-pump valve secured with silicone adhesive [Fig. 2].
2. Verification Testing
   - Pressure testing: confirm pressure delivered by micropump stays in 6-20 kPa range, the average pressure the vaginal wall exerts [8].
   - Weight testing: Device holds up to 10 lbs, the maximum weight of newborns [7].

Device Design

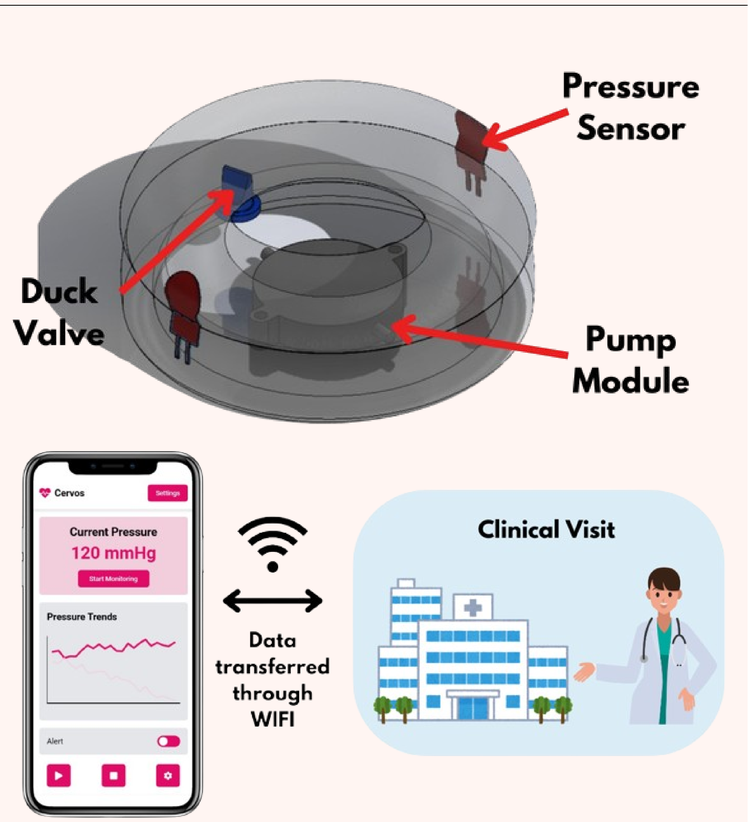

Figure 2. CAD model of the CERVOS pessary (top) with assembled pressure sensors (red), duck valve (blue), and pump module (gray). Data acquisition and transfer flowchart (bottom).

Pessary

- Modeled after the Arabin pessary to surround and close the cervix
- Inflatable core used to accommodate cervix changes during pregnancy
- Comes in two sizes to reduce number of doctor visits

Micropump-Sensor System

- Pressure sensors measure vaginal wall pressures and signal the micropump to inflate
- Pessary electronics and haptic feedback controlled by WiFi via microcontroller
- Data presented on app for live health monitoring

Test Results

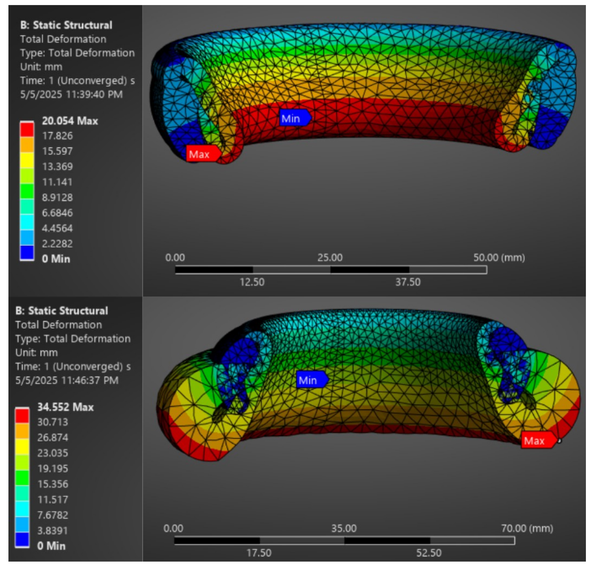

Figure 3. Total deformation of pessary after simulating a downward force of 10 lbs and inner pressure of 12 kPa. Ecoflex™00-50 (top), Ecoflex™00-30 (bottom)

- Failure of convergence due to complexity of material properties and simulation indicates need for mechanical material testing

Future Direction

- Finalize fabrication methods using FDA GMP regulations with medical-grade silicone
- Further in-vitro mechanical and material testing of the device to assess durability and biocompatibility
- Create a more compact and streamlined electrical system using piezoelectric micro pumps
- Conduct clinical Phase 0 trial of the micro pump system to ensure safety and performance in-vivo

References

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