Device for Cervical Cerclage Alternative

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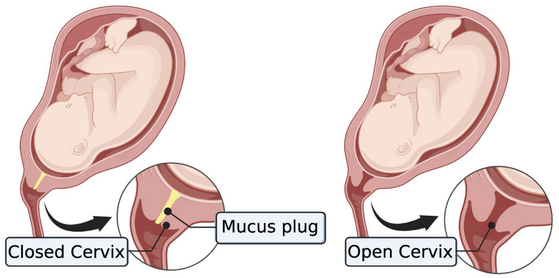
BACKGROUND

Cervical Insufficiency:

- Inability of cervix to retain fetus in the womb during gestation
- Weakness of cervix (shortened, thinned) and increased dilation
  - Presents in 4th or 5th month of the pregnancy [1]
- Affects 1-2% of all pregnancies and accounts for approximately 45% of miscarriages [2]



Normal Cervix Cervical Insufficiency

Current Treatments:

1. Shirodkar & McDonald cerclage
   - Trans-vaginal suture placed to cinch cervix
   - Requires anesthesia
   - Complications in weeks 12-14
     i. Cervical infections, lacerations, membrane rupture, dystocia (inability to dilate after cerclage removal)
2. Progesterone administration (oral, intravenous, or intravaginal)
3. Cervical pessary (silicone plate/cup)
   - Placed around tip of cervix for support

Need:

- Safer, comfortable cervical reinforcement alternative without the use of anesthesia

PROTOTYPE

Workflow:

- 3D model the prototype and mold using Autodesk Fusion 360
- 3D print the mold in PETG plastic
- Cast prototype in mold using Mold Star 30 silicone

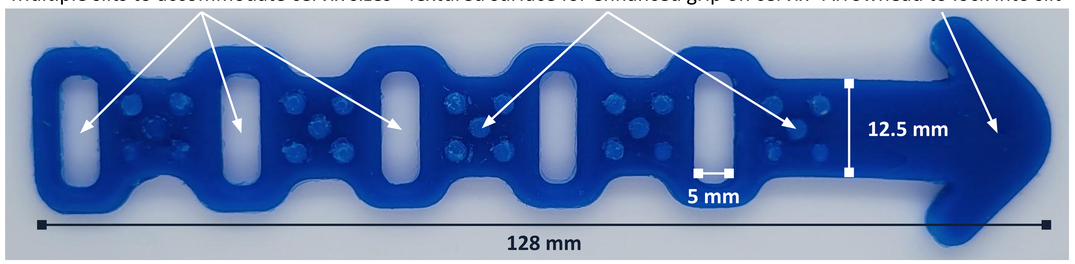


Fig. 1 *Silicone model of device prototype*

Fig. 2 *Mold for device prototype*

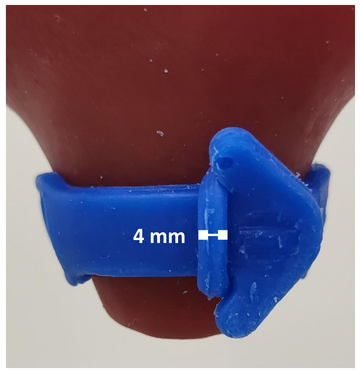


Fig. 3 *Device placed around cervix*

ENGINEERING STANDARDS

- **ISO 10993**: Biological evaluation of medical devices
- **ISO 11135**: Sterilization of health-care products - Ethylene oxide
- **ISO 11737**: Sterilization of health-care products - Microbiological methods
- **ASTM D2240-15**: Standard Test Method for Rubber Property
- **ASTM F2038-18**: Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part I
- **ASTM F2042-18**: Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II
- **JIS K 6249**: Testing Methods for Uncured and Cured Silicone Rubber

FUTURE DIRECTIONS

Material characterization:

- Medical grade silicone
  - Aim for similar shore hardness and durability
  - Possible materials:
    - NuSil, Model# MED-4920 silicone
    - Applied Silicone, Model# LSR-40 silicone
  - Material testing for biocompatibility
- Antimicrobial silver ion coating
  - Affects coefficient of friction against ectocervix
  - Incorporation of silver into silicone gel
  - Antimicrobial testing
- Synthetic progesterone to prevent uterine contractions
  - Use PLGA composite to ensure 6 month linear release

Ex vivo testing:

- Pig cervix

DESIGN CRITERIA

Sufficient strength to cinch cervix	Mechanical testing on cervical models
Biocompatible materials to prevent inflammation	Characterization of medical grade silicone
Fit general cervix sizes	5 - 10 cm circumference
Size flexibility for comfort without compromising design	Adjustable circumference range
Antimicrobial coating to prevent infection	Characterization of silver ion coatings
Ease and speed of insertion/removal	<25 minutes with normal surgical tools
Low cost	<$1000

TESTING

Mechanical properties:

- Maximum force of static friction
  - Quantification with iOLab device
- Average Shore A hardness: **29.7 ± 2.19** (n=4)
- Manipulation with surgical tools

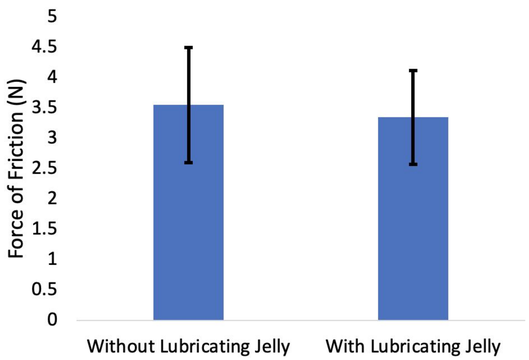


Fig. 4 *Maximum force of static friction before device slips off silicone cervical model (n=6). T-test, p: 0.7335*

Fig. 5 *Experimental setup for friction tests*

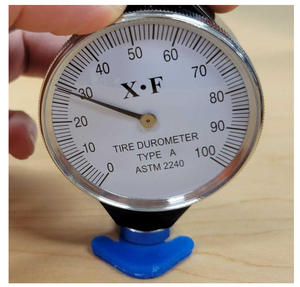


Fig. 6 *Experimental setup for shore hardness tests*

Fig. 7 *Forceps can twist device without slipping*

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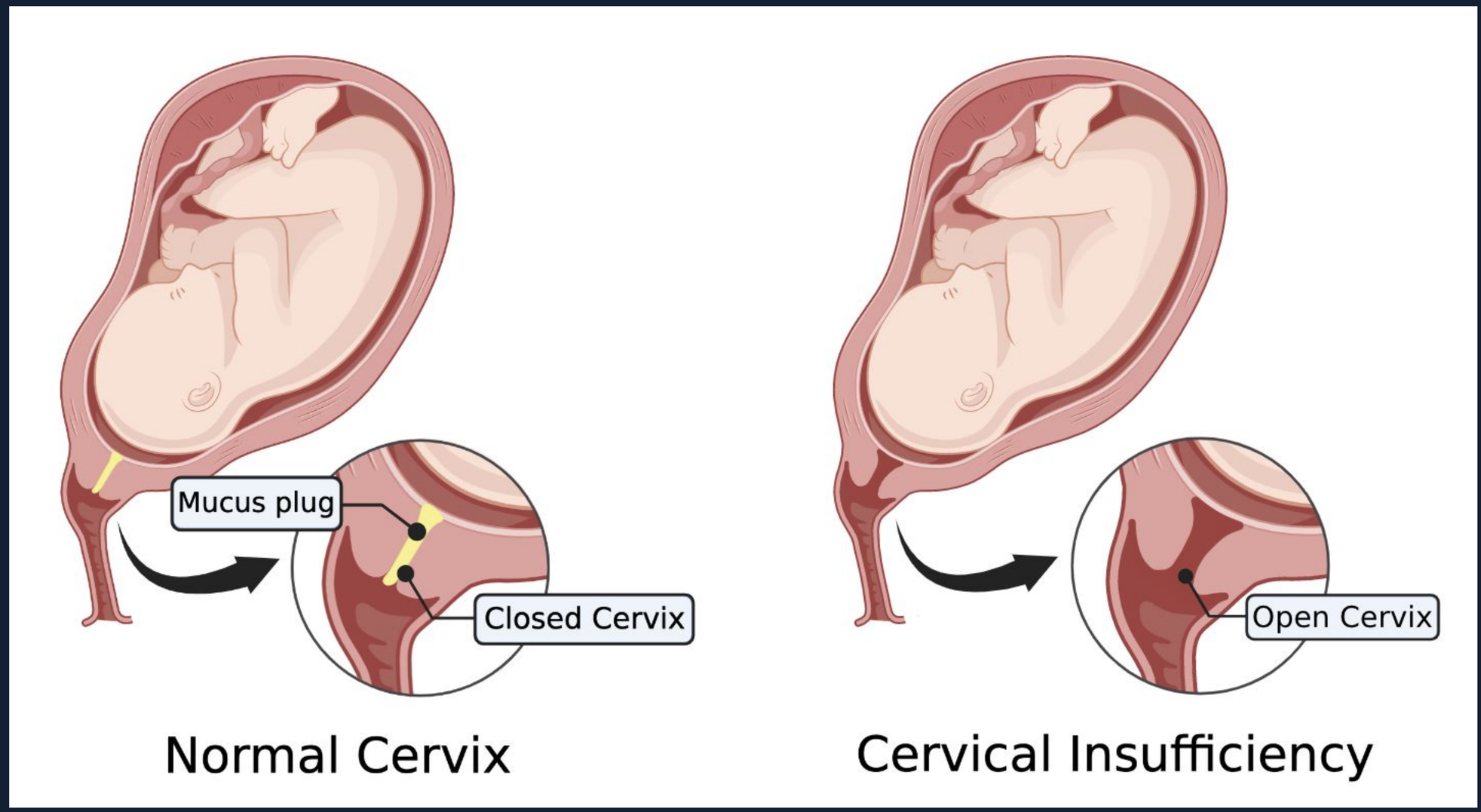
[1] M. Thakur and K. Mahajan, "Cervical Incompetence," in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2022. Accessed: Oct. 04, 2022. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK525954/
[2] A. Roman, A. Suhag, and V. Berghella, "Overview of Cervical Insufficiency: Diagnosis, Etiologies, and Risk Factors," *Clinical Obstetrics & Gynecology*, vol. 59, no. 2, pp. 237–240, Jun. 2016, doi: 10.1097/GRF.0000000000000184.



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