The Cx Device: Benchtop Testing of a Medical Device to Treat Cervical Insufficiency

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Background

- Although cerclage can prevent preterm birth, preterm birth can occur with a cerclage. Also, adverse maternal effects can occur.
- Cervical laceration can occur in the presence of cerclage (1).
- In some clinical studies, a longer cervix after cerclage placement associated with decreased risk of preterm birth (2,3)

Objective

- To address the limitations of a cerclage, a proof-of-principle, medical device was designed, called the Cx Device
- Like a cerclage, the device uses a suture to apply compression.
- Unlike a cerclage, the suture applies compression to polymer plates that act to compress the tissue. As a result, compression stress is distributed over a larger contact area.
- Our objective was to compare the Cx Device to a cerclage suture in benchtop tests of 1) cervical laceration and 2) ultrasound-derived cervical length.

Device Design

- Brainstorming sessions resulted in 32 concepts, from which 8 were explored in detail
- The concepts were assigned relative values using a Pugh matrix, based on these criteria: laceration risk, compression support, cervical length after installation and ease of installation/removal.
- The concept that scored the highest used a suture to apply compression in a circumferential direction with polymer plates (Fig. 1, 2).

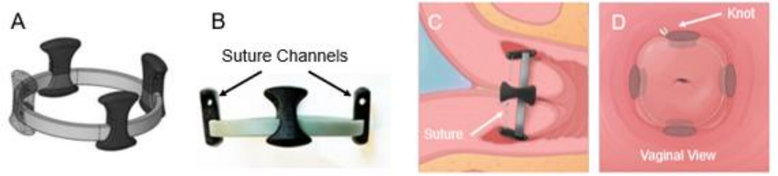


Figure 1: **A**: Computer-aided design (CAD). **B**: 3-D printed prototype showing the channels for compression suture. **C**: Side view with CSD installed. **D**: Vaginal view.

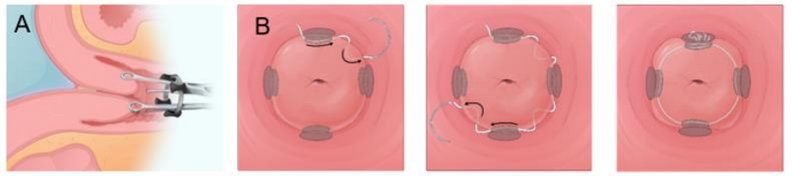
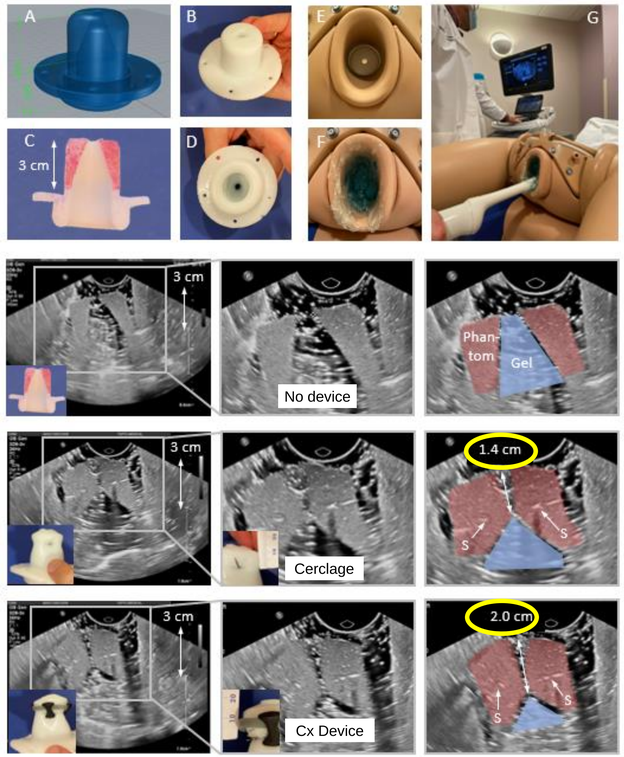


Figure 2 A: The Cx Device is inserted over the cervix using ring forceps. **B**: A purse string suture is localized the device to the correct anatomical position

Methods: Cervical length

A cervix-shaped ultrasound phantom with a funnel (**A, B, C, D**) was constructed using Zerdine hydrogel (CIRS, Norfolk, VA). The phantom was installed on a cerclage trainer (**E, F, G**) (Limbs and Things, Model 80180). Cervical length (yellow circle) was measured with TV ultrasound in three cases

- no device installed (cervical length = 0 cm);
- An O Vicryl cerclage
- The Cx Device installed



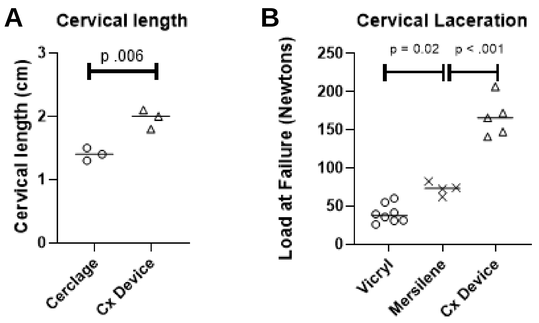
Methods: Cervical Laceration

- A previously described silicone cervix model was used for testing (4).
- Mersilene tape or O Vicryl was sutured to the silicone cervix. The suture was pulled through the silicone until material failure was observed.
- The load at failure was recorded (Newtons).
- For the Cx Device, a polymer plate was sutured to the silicone cervix model and pulled through until failure.
- The peak load at failure was compared for the cerclage sutures and the Cx Device plate

Results

A. Cervical length was significantly longer with the Cx Device.

B. Laceration. The load at failure was significantly higher for the Cx Device compared to suture



Conclusions

- Compared with a cerclage, the Cx Device compressed the cervix over a larger contact area, which significantly decreased laceration risk and improved cervical length in benchtop testing.

References / Acknowledgement

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- 4. BAUMER A, et al., Interface Focus 2019;9:20190009.

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