

# Cervical cerclage training: Development and assessment of a simulator



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**BACKGROUND:** Cervical cerclage is a mainstay intervention for the prevention of spontaneous preterm birth in high-risk women. Simulation training facilitates high-level skill transfer in a low-consequence environment, and is being integrated into obstetrics and gynecology training.

**OBJECTIVE:** This study aimed to develop a simulator for cervical cerclage, determine its validity as a simulator, and identify parameters suitable as proxy markers for performance.

**STUDY DESIGN:** The 3 aims of this study were achieved, namely: (1) simulator design by obstetricians and a commercial company; (2) survey of obstetricians and gynecologists across a variety of training stages to determine need for and opinion of the simulator; and (3) comparison of novice and expert groups across a variety of proxy markers for successful cerclage insertion.

**RESULTS:** Obstetricians and gynecologists found the simulator to be similar to clinical scenarios and suitable for skill training. Novice

participants stated that the use of the simulator improved their confidence ( $P=.016$ ). In a comparison between 6 expert and 8 novice surgeons, there seemed to be variations across multiple measurements of cerclage placement.

**CONCLUSION:** Simulation is an increasingly prominent training modality for surgical skills. The simulator described herein was considered suitable for training by obstetricians and gynecologists. Further work should focus on the validations of proxy markers of successful insertion, longitudinal assessment of trainees, and correlation of training outcomes with clinical outcomes.

**Key words:** cervical cerclage, cervical stitch, high-risk pregnancy, obstetrics, operative training, preterm birth, simulation, surgical skills, training

## Introduction

Spontaneous preterm birth (sPTB) remains a leading cause of perinatal mortality and morbidity, with severity of outcome inversely related to gestational age at delivery.<sup>1</sup> Cervical cerclage is an established intervention for prevention of sPTB despite a lack of evidence on its mechanism or which subgroups of at-risk women would most benefit from the procedure.<sup>2,3</sup> It is usually used in 1 of 3 circumstances: as a prophylactic measure in women with previous midtrimester losses or preterm births, in response to a sonographically short cervix, or as a “rescue” procedure once the cervix is open and membranes are bulging. Training in the insertion of cervical cerclage is challenging: it is an uncommon procedure with unpredictable surgical difficulty, performed under

regional block, and there is lack of consensus over the optimal technique.

Simulation is increasingly common in operative specialties, including obstetrics and gynecology.<sup>4</sup> Examples of where this has been successfully implemented include management of the impacted head at cesarean delivery and laparoscopic training.<sup>5,6</sup> It has also been used successfully in training for other vaginal procedures, including hysterectomy and apical suspension,<sup>7,8</sup> with an increasing interest in simulation training for vaginal surgery.<sup>9</sup> Here we describe the development of a cervical cerclage simulator and its use as a simulation tool for training doctors in obstetrics and gynecology (Figure 1).

## Materials and Methods

This study was performed in 3 parts: (1) development of the simulator; (2) determination of validity of the model as a simulator; and (3) task-based performance. As per the National Health Service (NHS) Health Research Authority, this study was exempt from ethical approval. Reporting was done per Cheng et al<sup>10</sup> guidelines (extensions to Consolidated Standards of Reporting Trials [CONSORT]

and Strengthening the Reporting of Observational Studies in Epidemiology [STROBE] statements).

## Development of the simulator

The model was developed by obstetricians and a commercial company (Limbs & Things), taking into account likely training needs and clear demarcation of significant anatomic landmarks. Expert opinion was sought and minor revisions were made during the process.

## Determining acceptability of the simulator

Trainees of all grades and consultants in obstetrics and gynecology (equivalent to residents and attendings) were invited to complete a bespoke 42-point questionnaire that included demographic information, previous experience of both cerclage and simulator training, and feedback on the model, including how realistic it was. In cases of participants who never performed any vaginal surgery before, data on how realistic the model was deemed were excluded.

## Task-based performance

Trainees and consultants were invited to participate in one-on-one testing

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## AJOG MFM at a Glance

**Why was this study conducted?**

Cervical cerclage is a common procedure performed worldwide for women at high risk of preterm birth. Simulation is an important part of modern surgical training, and thus development of a suitable simulator for this procedure is necessary.

**Key findings**

The described simulator is considered to be suitable for training by obstetricians and gynecologists with a range of experience in the procedure. Novice surgeons reported that training on the simulator improved their confidence. Differences were noted in proxy markers of successful insertion between novice and expert groups.

**What does this add to what is known?**

We described a simulator that is acceptable to trainees and trainers, and suggested proxy markers of surgical success that could be used to improve surgical abilities during training.

power calculation was performed because this was an initial exploratory study, performed in a feasible time frame using available participants; therefore, no further statistical analyses were carried out.

**Ethics**

As per the NHS Health Research Authority, this study was exempt from ethical approval.

**Results****Development of the simulator**

The model was developed using silicone rubber. A second model for emergency cerclage was designed with an os dilated to 3 cm and a fluid-filled sac to represent bulging membranes. Cost was reduced and accessibility maximized by designing cervix models that fit into the PROMPT Flex model (Limbs & Things, Bristol, United Kingdom), which is already used by many obstetrics and gynecology departments as part of their simulation training. Previous expert consensus indicates that this model provides realistic access to the cervix. The cost per cervix is £18, and we estimate that each can be used approximately 20 times, amounting to cost per training activity of approximately £0.90 plus sutures and reusable instruments. A head torch was used for lighting.

under the supervision of a research investigator. Given the lack of standardized surgical technique for cerclage, participants were allowed to perform the technique without bladder reflection per personal preference. Those with no operative experience of cerclage performed the procedure on the simulator after a brief training.

Pragmatic proxies for competence were used to determine procedure success: height of knot from external os, circumference of tied loop, suture through the os, and the internal stitch diameter (Figure 2). Other parameters measured included time to complete

procedure, number of bites taken, and knot position.

Comparison was made between an expert group (defined as those who regularly performed the procedure as a lead surgeon and were confident in doing so) and a novice group who had never performed the procedure before.

**Statistical analysis**

Descriptive statistics were used for questionnaire results, with responses to feedback questions compared between novices and experts using the Mann–Whitney *U* test. Standard significance levels were used ( $P < .05$ ). No formal

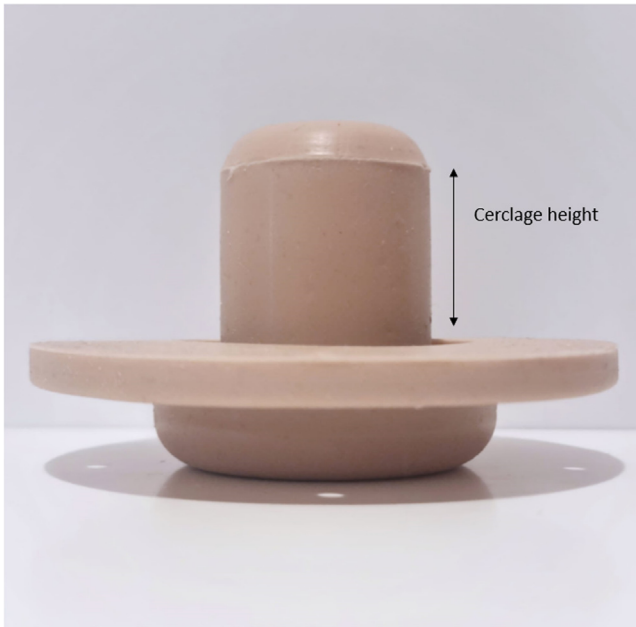
**FIGURE 1**  
**Cervical cerclage simulator**



The cervical simulator model including the PROMPT Flex model. **A**, Closed cervix. **B**, Open cervix with “bulging membranes.” Image supplied by Limbs & Things.

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**FIGURE 2**  
**Cerclage height measurement**



Cerclage height was measured from the external os to the cerclage knot. The exposed parts of the cerclage were then measured. The knot was cut and cerclage removed to determine circumference, and the exposed sections subtracted from this to determine diameter.

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### Acceptability of the simulator

In total, 28 participants evaluated the simulator using a closed cervix: 2 consultants, 21 trainees with >3 years' experience, and 5 trainees with ≤3 years. Furthermore, 15 participants trialed the model with an open cervix, and then again with bulging membranes: 2 consultants, 11 trainees with >3 years' experience, and 2 trainees

with ≤3 years. Only 6 participants had previously performed a cerclage as a lead surgeon, and 10 had never performed the procedure. The Table summarizes the feedback on the simulator, with a higher score (out of 7) indicating a more positive response. All participants had experience in using a medical simulator tool, with one having used a different cervical cerclage model.

Novices (those with no previous experience in performing cervical cerclage; n=8) reported increased confidence in their ability to perform cervical cerclage after using the simulator ( $P=.016$ ). All participants found the simulator useful for teaching and learning, and reported that they would use it again. All trainees reported that they would participate in expert-led sessions using the simulator. In terms of free-text responses, comments were positive and largely related to opportunities to hone technique before performing the procedure on patients; however, 7 participants commented that the simulator material was less compliant than the cervix, and 2 commented that vaginal access was more difficult than in real life.

### Task-based performance

Cerclage parameters were compared in a subgroup of 6 experts and 8 novices. There seemed to be a trend toward smaller cerclage circumference and diameter, greater cerclage height, and certainly more consistent results in the expert group (Figure 3).

## Discussion

### Principal findings

Clinicians are interested in pursuing simulation-based training for development of skills in performing cervical cerclage. The simulator described herein was deemed acceptable in terms of anatomic likeness and ability to replicate clinical procedure. This was true for

**TABLE**  
**Summary of the feedback on the simulator**

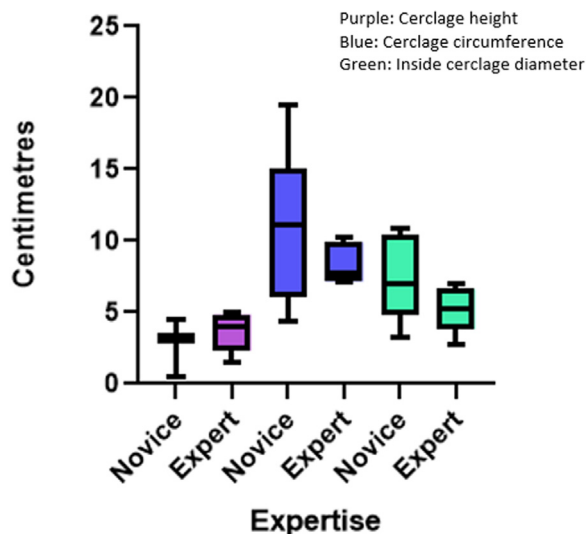
Question	Median score (out of 7) (IQRs)
The simulator is identical to clinical practice	5 (4–5)
The simulator allows for replication of clinical skills used in clinical practice	5 (5–6)
The simulator is anatomically identical to the clinical picture	4.5 (4–6)
The open cervix model allows for replication of clinical skills used in clinical practice	5 (4–6)
The bulging membranes model allows for replication of clinical skills used in clinical practice	5 (4.25–6)

Cerclage simulator user feedback: scores from 1 to 7, with 7 being the highest.

IQR, interquartile range.

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**FIGURE 3**  
**Comparison between novice and expert results**



Proxy markers to assess successful cerclage insertion; comparison between novices and experts. Less variation in inside-stitch diameter and circumference, and a higher cerclage height were noted in the expert group. *Purple* indicates height; *blue* indicates circumference; *green* indicates inside-stitch diameter.

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both closed and open cervix models. A series of proxy markers for successful insertion has been proposed.

## Results

Systematic review—level evidence supports the use of simulation training for high-level skill transfer across general surgical specialties.<sup>11</sup> Repetitive, deliberate practice of skills is integrated into all major surgical training theories,<sup>12</sup> and simulation-based training facilitates this in a low-consequence environment. We have demonstrated enthusiasm across all training grades for the use of simulation training for cervical cerclage.

In obstetrics, simulator programs have been described for a variety of scenarios, including cesarean delivery, management of the impacted fetal head, and invasive fetal medicine procedures.<sup>5,13,14</sup> In all cases, simulation is demonstrated to be acceptable to trainees as an adjunct to clinical training, particularly in less commonly performed procedures. This study also supports the use of cerclage simulators for obstetrics and gynecology training.

One study presented a cervical cerclage simulator using bovine tissue, although there are obvious limitations in using fresh animal tissue, and the study had a small sample size (n=10), with most junior users being final-year maternal—fetal medicine trainees.<sup>15</sup> A more recent study of 20 obstetrics and gynecology residents demonstrated increased comfort in performing cervical cerclage after simulation training, with a decline in perceived need for clinical support and further training. However, no attempt was made to determine any markers of successful cerclage placement.<sup>16</sup> We have proposed a series of proxy markers for successful insertion.

## Clinical and research implications

Similarly to previous studies, we demonstrated the perceived educational value of simulation-based surgical training for obstetrics and gynecology trainees. The positive response of expert practitioners suggests that this model may have a role for refinement of technique as well as for initial

training. However, there is generally a lack of high-quality work investigating the translation of operative simulation training into real-life scenarios.

Further research should first focus on validation of the metrics that we have described as proxy markers for successful cerclage placement. Further metrics, such as anterior-posterior cerclage length, could also be considered. Initially, this may be achieved by validating differences noted between experts and novices. This can then be used to provide further training in increasingly complex scenarios. A comparative study between this and other training modalities (eg, video training) would be of value. The final stage of validation of this model is translating skills into clinical practice where markers such as total stitch length and stitch height can be determined, but actual success can also be studied. Throughout all stages, there is capacity for ongoing qualitative assessment of the simulator so that it can be improved upon. After completion of validation, including transition into clinical practice, the role of simulation within a formal training curriculum can be considered.

Of course, in the case of cervical cerclage, a second role for a simulator is determining optimal technique for cerclage insertion. Given that there is currently no consensus on either cerclage material or surgical technique, this model provides an opportunity for experts' techniques to be compared as described herein, or perhaps with the additional use of imaging, to determine the most successful techniques. This would aid in the development of a Delphi consensus on cerclage techniques.

## Strengths and limitations

We designed and refined the model on the basis of expert and novice feedback. The simulator was considered realistic and valuable for training by the participants. We demonstrated varying outcomes according to level of expertise, which suggests that the simulator could be used by trainees for technique improvement.

The most significant limitation of this study is the need for proxy markers for



successful insertion. The development of a consensus on cerclage technique will reduce this limitation, as will translation into clinical practice where pregnancy outcomes can be assessed. Any significance in data derived from this study is inherently limited because of small sample numbers, but the set could be used to power a larger study of markers. The cohort was derived from a single UK center that has a large preterm birth surveillance service, so there may be an artificial inflation in the number of actual procedures that trainees have performed as compared with the average. Improvement in individuals over time was not assessed and should be investigated in future research. Although the simulator was considered to be realistic, there were concerns that the material used for the vagina was too rigid.

## Conclusion

Cervical cerclage remains an important intervention in obstetrics, but one with limited training opportunities. We present a cervical cerclage simulator model that obstetricians and gynecologists perceive as a realistic and valuable training tool. Further research is required to validate proxy markers of successful placement, high-level outcomes such as translation into clinical performance, and the role of the model within formalized training curricula. This simulator should also be used for the development of a Delphi consensus on surgical technique. ■

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