Cervical cerclage technique: what do experts actually achieve?

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BACKGROUND: Cervical cerclage is a recognized intervention in the management of women at risk of preterm birth and midtrimester loss. The mechanism of action of cerclage is unclear, and the technique has been poorly researched.

OBJECTIVE: This study aimed to evaluate cerclage technique among experienced obstetricians, using a previously developed and evaluated cerclage simulator.

STUDY DESIGN: This prospective experimental simulation and observational study used identical simulators for 28 consultant obstetricians who were asked to perform their normal cerclage. Suture type, height, knot site, and free thread length were recorded. Using computed tomography, depth of bite and tension (by reduction in area of cervix) were calculated.

RESULTS: A total of 52 cervical cerclages were completed (Mersilene tape, n=20; monofilament suture, n=32). Mean suture height was 33 mm (standard deviation, 7.7 mm), greater with monofilament suture than with Mersilene tape, and associated with smaller needle size. Mean depth of bite and mean reduction of starting area did not differ by suture type. Seven procedures showed ≥1 suture bite that had entered the cervical canal once or more.

CONCLUSION: This study assessed cerclage technique of experienced obstetricians using simulators and computed tomography imaging, and demonstrated wide variation in technique; this may affect the efficacy of the procedure. Further work should establish optimal technique and consensus for training and clinical practice.

Key words: cervical cerclage, cervical stitch, high-risk pregnancy, obstetrics, preterm birth, simulation

Introduction

Cervical cerclage is a recognized intervention in the management of women who are at risk of preterm birth and midtrimester loss.[1] The mechanism of action of cerclage is unclear. Furthermore, despite cervical cerclage placement being commonly performed, there is little research or consensus on the optimal technique. Failed cerclage can be associated with fetal membranes prolapsing through a cerclage, or sutures can cut through the cervix; these complications could be related to surgical technique.

Higher suture placement in a short cervix has been associated with lower subsequent odds of preterm birth.[2] It has also been found that a cerclage placed in the distal 10 mm of a closed cervix was associated with the highest risk of preterm birth.[2]

The C-STICH study showed no difference in primary outcome between monofilament and braided sutures, but

EDITOR'S CHOICE

there were higher rates of infection with braided sutures, and more women required anesthetic care for monofilament removal, presumably because of difficulty in locating the threads.[3]

This study aimed to evaluate cerclage technique among experienced obstetricians, using a cerclage simulator that we previously developed and evaluated.[3]

Methods

Simulator/participants

Using the PROMPT Flex Cervical Cerclage Module simulator (Limbs & Things Ltd, Bristol, United Kingdom) (Figure 1, A), 28 consultants from 16 hospitals in 11 UK cities were assessed inserting their "standard" cervical cerclage. Participants responded to an invitation to take part in the study through the UK Preterm Clinical Network, with inclusion criteria comprising National Health Service (NHS) Consultants in obstetrics and gynecology with expertise in cervical cerclage insertion. G.T. and A.H.S. are inventors of the simulator and receive royalties from Limbs and Things Ltd. The remaining authors report no conflicts of interest. Sutures were provided by the participants and were either monofilament or braided-tape. Participants were asked to perform their "normal" cervical cerclage on 2 model cervices. Four participants returned only 1 cervix, resulting in a sample size of 52 procedures. Participants who used both types of sutures were asked to perform 1 procedure with each type of suture. Completed cervical cerclage models and suture packets were returned to the study team, and were then numbered and anonymized. All simulator models were identical, with a 32-mm-diameter cervix and a 6-mm-diameter cervical canal, resulting in a distance of 13 mm from the outer limit of the canal to the surface of the cervix (Figure 1, B).

Ethics

Per the NHS Health Research Authority, this study was deemed exempt from ethical approval. It was registered with the Clinical Effectiveness process review team through the Research & Development department of NHS Fife, and was approved as a service evaluation study by the Clinical Governance of St Thomas' Hospital.

Parameters used

The measurements obtained by external examination of the completed cervical

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AJOG MFM at a Glance

Why was this study conducted?

Cervical cerclage is a common procedure performed worldwide for the prevention of preterm birth, but the mechanism of action is unclear, and surgical technique has been poorly researched.

Key findings

Using a previously described simulator, our study found considerable variation in the height and depth of suture placement and tension of the knot among experienced obstetricians.

What does this add to what is known?

This study highlights wide variation in practice regarding surgical technique and an urgent need to establish optimal practice and consensus for research, training, and clinical practice.

cerclage models were the following: height of each bite from the distal end of the cervix (using calipers directly), number of suture bites, knot position, length of free thread (below the knot), and whether an additional knot was tied to create a loop of thread in the free thread (Figure 2).

Computed tomography imaging

Cerclage models were imaged with the SOMATOM Definition AS+ (Siemens Healthineers, Erlangen, Germany) (Figure 3, C) using an ultrasharp inner-ear program with scanning parameters of 120 kV, 165 mAs, 0.4-mm slide thickness, an algorithm of V80u, and 700/4000 window levels. Images were viewed on Vue PACS Power Viewer version 12.2.1 (Carestream Health, Rochester, NY), from which suture depth was measured. Tension of suture was inferred by measuring the minimum cross-sectional area in comparison with cervices that had not been operated on with a measured area of 814 mm^2 (Figure 3, B).

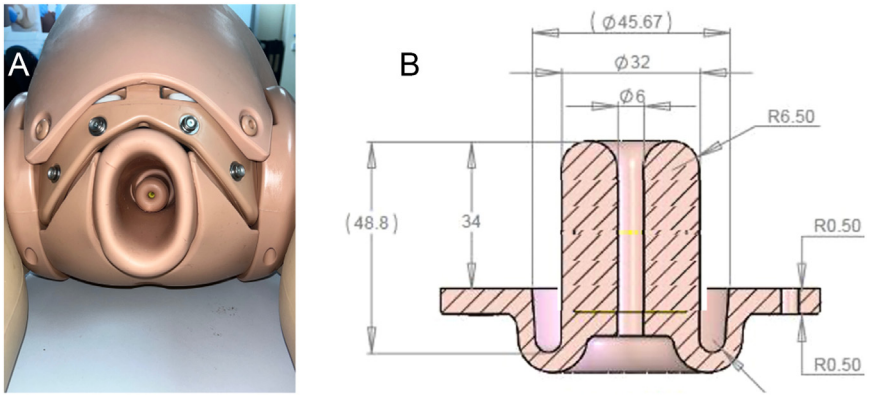
Data

This study recorded information on the following parameters: number of bites, loop present (yes/no), knot position (anterior/posterior), needle type (round-body/cutting needle), needle diameter, mean height (mm), mean depth (mm), tension percentage (reduction in area from control), and length of cut thread arising from the knot. The number and depth of bites varied between cerclages; therefore, mean height and depth were calculated by summing across all height/depth measurements and dividing by total number of bites. There were a small number of looped monofilament "monoloop" sutures, which were classified into the monofilament group for analysis. Tension was inferred by the maximum reduction in cross sectional area of the cervix as measured on the computed tomography (CT) picture archiving and communication system (PACS) viewer, in comparison with a control sample with a measured area of 814 mm^2.

Statistical analysis

The 4 continuous measurements (mean height, mean depth, tension percentage, and thread length) were visualized using bar plots in ascending order, with an overlay of range for height bite and depth. The relationship between tension percentage and mean height was visualized using a scatterplot. Univariable linear mixed-effects (LME) models were applied to assess the dependent variables: mean height, mean depth, tension percentage, and thread length against suture type. Mersilene tape was used as a reference category for comparison of these outcomes with monofilament. Mean height and mean depth were then also compared with needle size, with 31 mm selected as the reference category to compare against the other needle diameters. A univariable LME model compared tension percentage (reduction in area from control) with mean height of suture. A random effect of participant ID was included in each model to account for the within-participant variation. This approach was adopted because the data were not independent owing to the repeated measures from 24 participants. Estimates (beta coefficients) and 95% confidence intervals (CIs) are presented for all fixed effects. Summary characteristics of all cerclages are presented for each parameter, including number of bites, loop present (created by 2 knots) (yes/no), knot position (anterior/posterior/

FIGURE 1
PROMPT Flex Cervical Cerclage Simulator, Limbs & Things Ltd



A, Model cervix in situ in the training model (with perineum removed) and **B,** dimensions.

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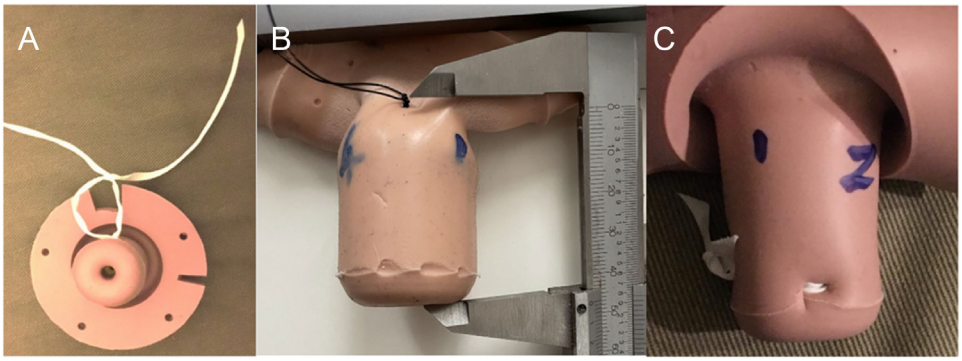
FIGURE 2
Sutured cerclage models



A, Example of a suture tied with an extra knot to create a loop with long cut length. **B,** Measurement of height. **C,** Example of a bite placed low down.

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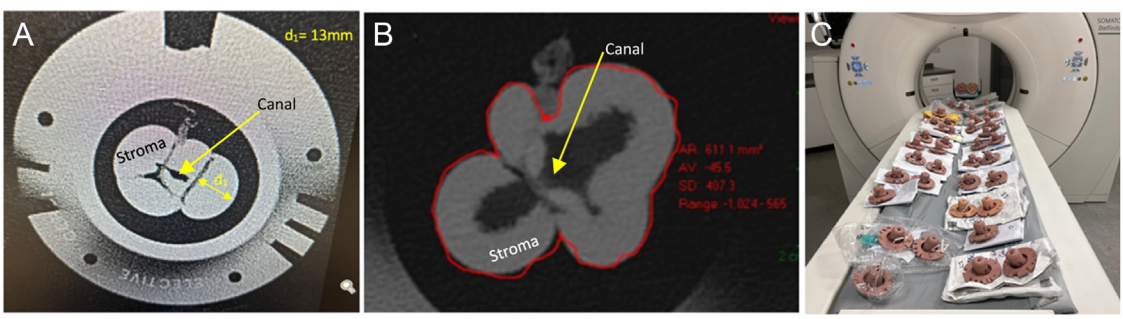
lateral), needle type (round-body/cutting needle), mean height (mm), mean depth (mm), tension percentage, and thread length. Statistical analysis was conducted with R, version 4.2.0 (R Core Team, Vienna, Austria), and all plots were made using the ggplot2 R-package.

Results

A total of 52 cervical cerclages were completed with 20 Mersilene tape and 32 monofilament sutures, of which 28 were single-thread and 4 looped-thread. There were 48 round-body and 4 cutting needles. Monofilament needle diameters were 31 to 48 mm (31 mm, n=8; 40 mm, n=8; 45 mm, n=4; and 48 mm, n=14), whereas all 20 Mersilene tape sutures had a 48-mm needle. The median number of bites was 4 (range, 2−5); 42 knots were tied anteriorly (80%) vs 10 (20%) posteriorly, with a loop tied in 50% of sutures. None were lateral (Table 1).

Across all samples, mean suture height was 33.0 mm (SD, 7.7 mm) and mean depth of bite 7.5 mm (SD, 2.9 mm). The mean reduction in area was 126 mm^2 (interquartile range [IQR], 79−184 mm^2) or 15.4% (IQR, 9.7%−22.6%) of starting area, with a range from 0% to 42% because 1 case had no tension at all (the knot was completely undone). Free thread length showed a mean of 45.5 mm (IQR, 33.0−55.0 mm) across all cerclages with a range of 10 to 158 mm. Mean height and depth varied considerably between cerclages, as did the heights and depths of individual bites for any one cerclage (Figure 4). Seven procedures showed ≥1 bite with a depth of ≥13 mm and entered the cervical canal during procedure, in 4 of which the mean depth was also ≥13 mm and the cervical canal was thus entered more than once (Figure 3, A). Tension and cut thread length also varied greatly (Figure 5).

FIGURE 3
Computed tomography imaging of cerclage models



CT scan of cervix: **A,** measuring depth of bite, with 1 bite passing through the cervical canal and **B,** area measurement. **C,** Model cervices undergoing CT imaging.

CT, computed tomography.

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TABLE 1
Summary characteristics

Cerclage characteristic	All cerclage (n=52)
Number of bites	4 (2–5)
Loop present	
No	26 (50%)
Yes	26 (50%)
Knot position	
Anterior	42 (81%)
Posterior	10 (19%)
Needle type	
Round-body	48 (92%)
Cutting needle	4 (8%)
Mean suture height (mm)	32.9 (7.5), (15.6–48.1)
Mean suture depth (mm)	7.5 (2.9), (4.2–18.6)
Cerclage tension (%)	15.4 (9.7–22.6), (0–50.0)
Free thread length (mm)	45.5 (33–55), (10.0–158.0)

Mode presented for number of bites. Mean (SD) presented for mean height, mean depth, tension percentage, and thread length. Maximum and minimum presented for all numeric parameters.

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Univariable LME models showed mean height to be greater with monofilament suture than with Mersilene tape (β=3.1; 95% CI, 1.3–6.3; P=.005) (Table 2), although no difference was found for mean depth, tension, or free thread length. The smallest needle diameter (31 mm) was associated with a higher mean placement in comparison with other needle sizes (31 vs 40 mm: β=−6.5; 95% CI, −13.0 to −0.02; 31 vs 45 mm: β=−3.2; 95% CI, −11.0 to −4.6; and 31 vs 48 mm: β=−5.7; 95% CI, −9.9 to −1.5; with global P value=.058). There was no clear relationship between mean depth of bites and needle size (Table 3).

Of the 7 samples that contained ≥1 bite that were deep enough to enter the cervical canal (≥13 mm), 2 were done with a 31-mm needle and 5 with a 48-mm needle.

To assess if people who placed their suture higher also tied it tighter, tension vs height was analyzed and showed a positive estimate with increased mean height of suture (β=0.42; 95% CI, −1.1 to 0.83); however, as shown in the scatterplot in Figure 6, there was considerable variability between cerclages (Table 3; Figure 6).

Comment

Principal findings

This study examined the cerclage technique of experienced obstetricians using a simulator and CT imaging. Our data demonstrated considerable variation in cerclage placement, which may result in variable efficacy of the procedure. We found that cerclage height is related to suture type, with monofilament cerclage being placed higher. We also found that height was related to needle size, and the smallest needle had significantly higher placement. Monofilament sutures have a range of smaller needle sizes, which may explain the effect on suture height. There was considerable variation in tension, depth, and length of suture left. Of concern, several bites were deep enough to have included the cervical canal, which is likely to influence efficacy.

Results in the context of what is known

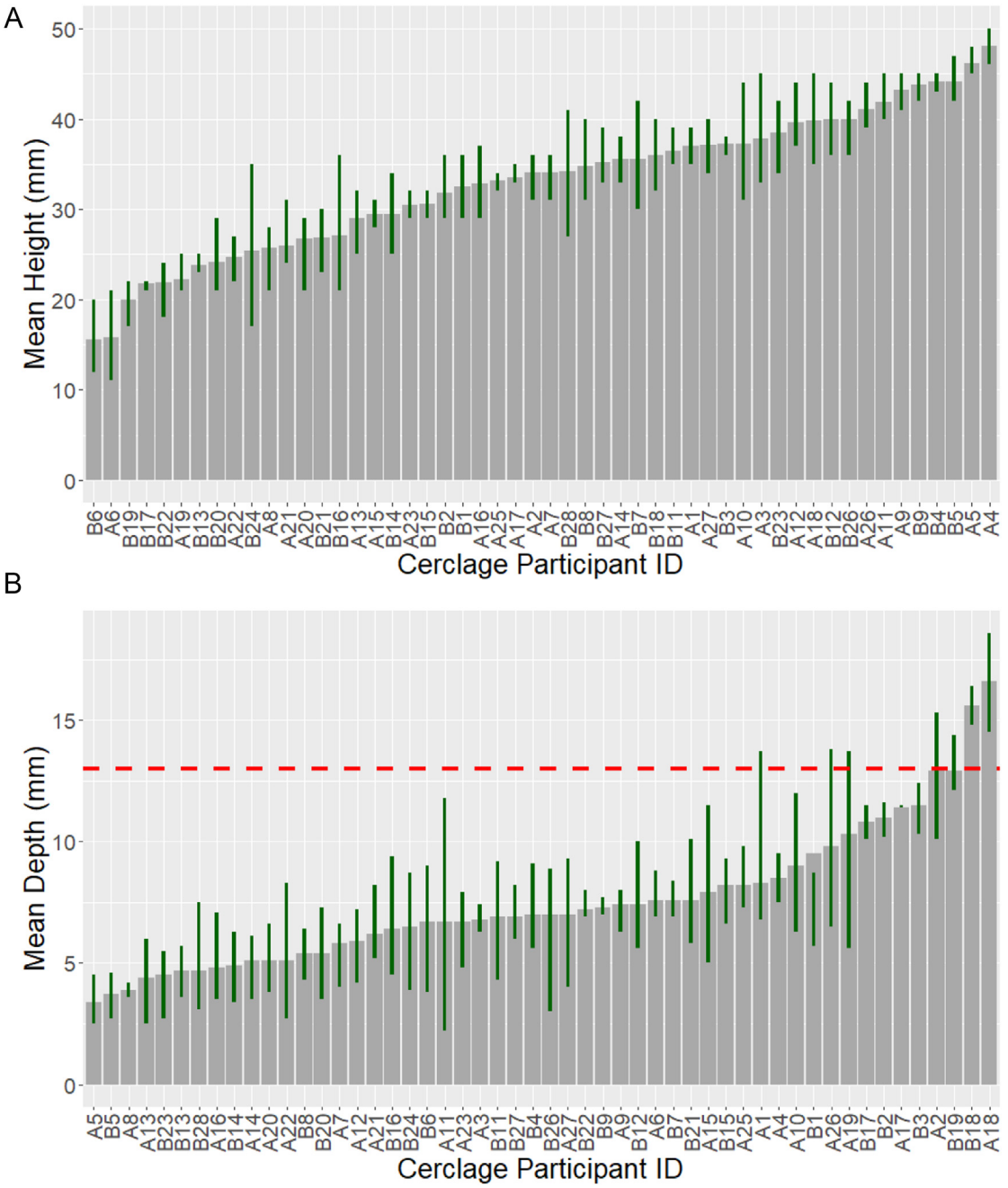
Although optimal cerclage technique is not known, original description of cerclage emphasized high cerclage placement.[4,5] In the 1950s, the original cerclage sutures were described as purse-string sutures placed at the level of the internal os so that "the cervical canal is reformed and practically closed by unabsorbed sutures."[6] Short cervices (<25 mm) with higher cerclage placement were associated with lower odds of preterm birth, and cerclage placed in the distal 10 mm had the highest risk of preterm birth.[2] Suture height in our study included sutures placed as low as 11 mm from the external os (ie, 37 mm from the top of the cervix), and only 48 suture bites (25% of all suture bites) were within 10 mm of the top of the cervix.

Clinical and research implications

Mersilene tape was only available with the largest needle diameter (48 mm); the observed significant association of both monofilament and smallest needle size with higher placement may have been due to smaller needles being available with monofilament sutures only. It is interesting that some clinicians chose to use a monofilament with a large needle when smaller ones were available. Availability of a range of needles and production of smaller needles for Mersilene tape may facilitate higher placement of cerclage.

Suture depth varied considerably, with some sutures placed so deep that they entered the cervical canal (Figure 3, A), resulting in suture bites that provide no support in preventing dilation of the cervix. Although the mechanism is not known, as in the original descriptions of the technique, we can postulate that where cerclage is effective, it works by a circumferential "purse-string" pressure around the cervix. Therefore, an additional potential harm of deep suture placement is that less cervix is incorporated within the circumference of the suture, which may be less effective because any tissue outside this circumference is not being constricted and prevented from dilating. In the model, the cervical canal was of a uniform 6-mm diameter along its length, and 7 sutures actually entered the canal, with several more only 1 or 2 mm away. In real cases

FIGURE 4
Suture height and depth



Ordered bar plots of **A,** mean height and **B,** mean depth, with the range overlaid. The horizontal line at 13 mm represents the depth of the outer limit of the cervical canal. Participants are numbers 1 to 28, with A/B where they performed 2 procedures.

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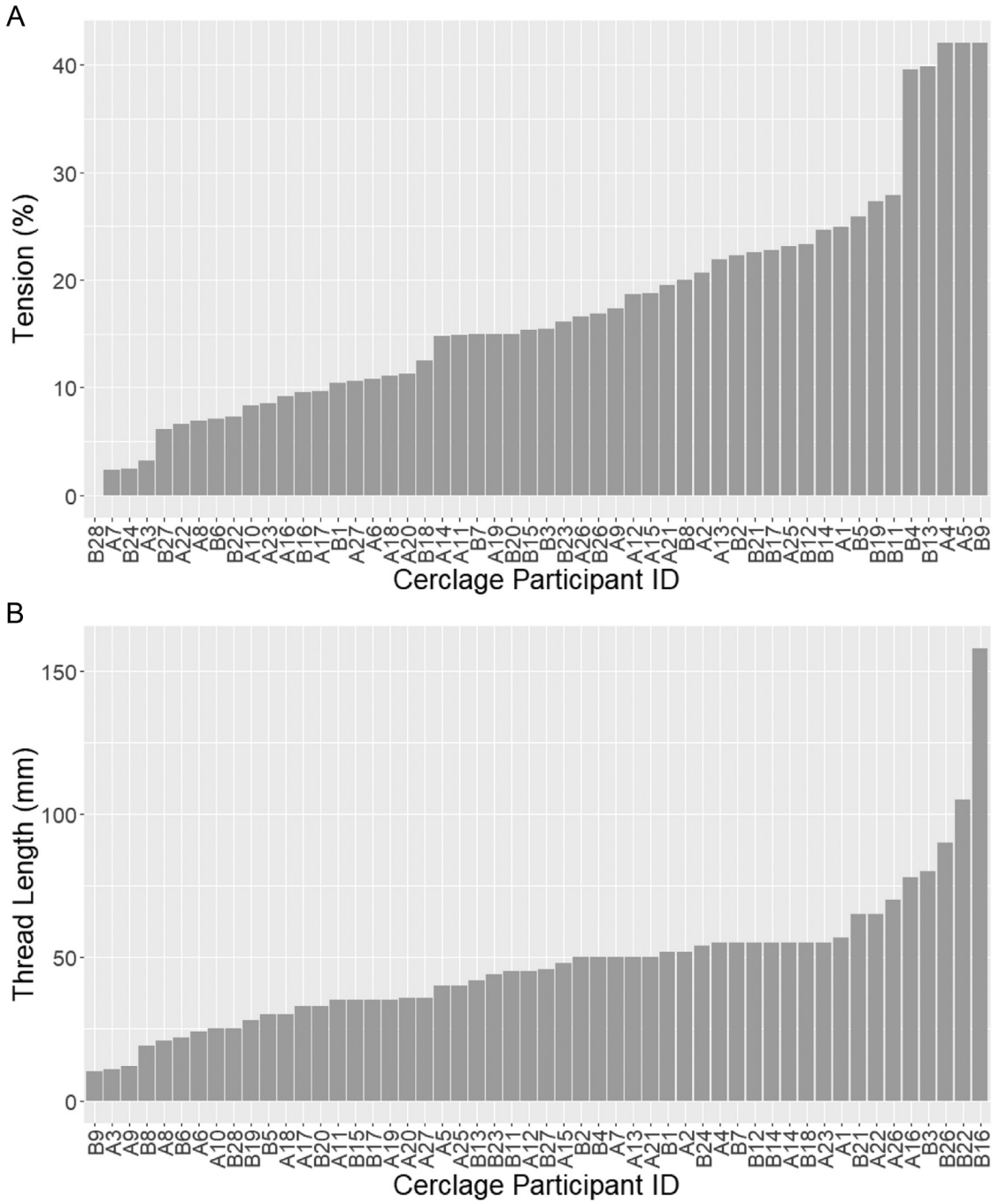
FIGURE 5
Suture tension and thread length



Ordered bar plots of **A,** tension (%) and **B,** thread length. Participants are numbers 1 to 28, with A/B where they performed 2 procedures.

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TABLE 2
Univariable linear mixed-effects model results for fixed effects with estimates and 95% confidence intervals for height (mm), depth (mm), tension (reduction in area [%]), and free thread length (mm) compared with suture type (Mersilene tape reference category)

	Estimates, 95% CI, and *P* value							
Suture type	Height (mm)		Depth (mm)		Tension (%)		Free thread length (mm)	
Mersilene tape (reference)	—		—		—		—	
Monofilament	3.1 (1.3–6.3)	.005	−0.6 (−1.6 to 0.5)	.257	−1.9 (−7.6 to 3.7)	.489	−10.4 (−23.3 to 2.4)	.105

CI, confidence interval.

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TABLE 3
Univariable linear mixed-effects model results for fixed effects with estimates and 95% confidence intervals for height (mm) and depth (mm) outcomes compared with needle size (31-mm reference category)

Needle size	Height (mm)		Depth (mm)	
31 mm (reference)	—		—	—
40 mm	−6.5 (−13.0 to −0.02)	.049	0.4 (−2.0 to 2.8)	.737
45 mm	−3.2 (−11.0 to 4.6)	.405	1.6 (−1.4 to 4.5)	.276
48 mm	−5.7 (−9.9 to −1.5)	.010	1.4 (−0.1 to 2.9)	.071

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where funneling may be present and the canal diameter greater, inadvertent rupture of membranes or increased chance of ascending infection may be likely if sutures are placed deeply, as demonstrated in our model.

The C-STICH trial reported more difficulty in removing a monofilament suture, with additional requirement for regional anesthesia at removal. Shorter thread length and the finer suture in monofilament sutures may contribute to greater difficulty for clinicians removing the cerclage.[7] In this study, some sutures were left with only a 10-mm free length of thread, which is difficult to locate, especially in women with a monofilament cerclage and those in labor. A loop was tied in 50% of cerclages involving 2 knots. This can create confusion because the person removing the suture may believe that they have divided the cerclage when they have actually only cut the loop.

Drugs are highly regulated for use in clinical trials (through Clinical Trials of an Investigational Medicinal Product [CTIMPs]) and subsequent clinical use, with extensive surveillance of impact and side effects. All CTIMPs have investigational brochures with pharmacokinetics and other relevant measures that could affect efficacy. In stark contrast, surgical interventions have far less scrutiny and variation in actual techniques, and are rarely evaluated. We can hypothesize that outcomes could be related to variation in technique. This study shows that a simulator may allow some objective measure of surgical interventions and assist in standardization and evaluation in trials. Given that numbers needed to treat are high with vaginal cerclage (>30), most women will do well even with an ineffective cerclage. This may mask poor technique in clinical practice but also explain why failed sutures occur.

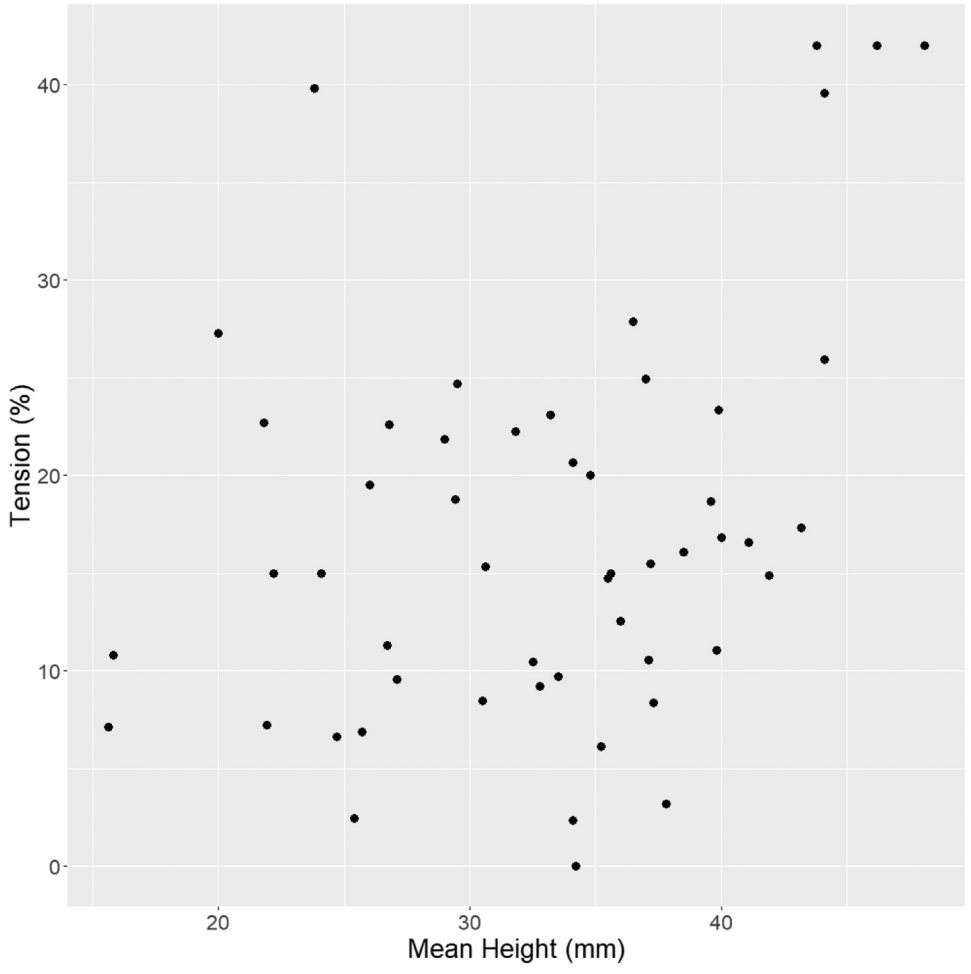
Strengths and limitations

A key strength of our study was that all cervical cerclages were performed on identical model cervices and by experienced consultants. Strengths also include the wide geographic spread across the United Kingdom and response level for repeated measures from most participants. However, a limitation of this study was the small sample size, which limited the opportunity for multivariable analysis and the ability to provide further insight into differences between parameter measurements and participants. Comparisons between suture types and needle sizes were calculated for exploratory purposes of these observation data. Data on participants' years of experience and number of cerclages performed each year were not available. A further limitation of this study is that it was not an in vivo study; human studies could be used to confirm our findings.

Conclusions

We have demonstrated wide variation in technique for cervical cerclage among experienced obstetricians using a standardized simulator. Further research needs to evaluate whether these variations affect the efficacy of the procedure. The simulator can allow obstetricians to become competent in cerclage placement, and it be used as a tool to standardize the technique both for clinical trials and clinical practice. There is wide variation among experienced obstetricians, and there is an urgent need for establishing how technique affects outcomes and for consensus on training and clinical practice. ■

FIGURE 6
Scatterplot of tension (%) compared with mean height (mm)



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