

# FIGO good practice recommendations on cervical cerclage for prevention of preterm birth

Andrew Shennan<sup>1</sup> | Lisa Story<sup>1</sup> | Bo Jacobsson<sup>2,3,4</sup> | William A. Grobman<sup>5</sup> |  
the FIGO Working Group for Preterm Birth

<sup>1</sup>Department of Women and Children's Health, King's College London, London, UK

<sup>2</sup>Department of Obstetrics and Gynecology, Institute of Clinical Science, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

<sup>3</sup>Department of Obstetrics and Gynecology, Sahlgrenska University Hospital, Gothenburg, Sweden

<sup>4</sup>Department of Genetics and Bioinformatics, Domain of Health Data and Digitalization, Institute of Public Health, Oslo, Norway

<sup>5</sup>Department of Obstetrics and Gynecology, Feinberg School of Medicine, Northwestern University, Chicago, Illinois, USA

## Correspondence

Andrew Shennan, Department of Women and Children's Health, St Thomas' Hospital, London SE1 7EH, UK.  
Email: andrew.shennan@kcl.ac.uk

## Funding information

This work has been supported by grants from March of Dimes.

## Abstract

Cervical cerclage is an intervention which when given to the right women can prevent preterm birth and second-trimester fetal losses. A history-indicated cerclage should be offered to women who have had three or more preterm deliveries and/or mid-trimester losses. An ultrasound-indicated cerclage should be offered to women with a cervical length <25 mm if they have had one or more spontaneous preterm birth and/or mid-trimester loss. In high-risk women who have not had a previous mid-trimester loss or preterm birth, an ultrasound-indicated cerclage does not have a clear benefit in women with a short cervix. However, for twins, the advantage seems more likely at shorter cervical lengths (<15 mm). In women who present with exposed membranes prolapsing through the cervical os, a rescue cerclage can be considered on an individual case basis, taking into account the high risk of infective morbidity to mother and baby. An abdominal cerclage can be offered in women who have had a failed cerclage (delivery before 28 weeks after a history or ultrasound-indicated [but not rescue] cerclage). If preterm birth has not occurred, removal is considered at 36–37 weeks in women anticipating a vaginal delivery.

## KEYWORDS

cerclage, intra-abdominal cerclage, preterm birth, prevention

## 1 | INTRODUCTION

Cervical cerclage is a commonly performed intervention in the care of women at risk of preterm birth and second-trimester fetal loss. A suture is placed in the cervix to prevent preterm dilatation. There remains uncertainty surrounding the population of women who are most likely to benefit and the optimal surgical techniques to be used. Several randomized controlled trials (RCTs) and meta-analyses have been undertaken to help provide an evidence-based approach to management.

### 1.1 | Type of cerclage

Cerclages can be categorized by the indication for insertion:

1. History-indicated, performed in asymptomatic women with risk factors in the obstetric or gynecologic history that increase the risk of preterm birth.
2. Ultrasound-indicated, performed on asymptomatic women with cervical shortening.
3. Rescue cerclage, where the cervix is already open and the fetal membranes exposed.

\* The Members of the FIGO Working Group for Preterm Birth, 2018–2021 are listed at the end of the article.

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Vaginal cerclage insertion, either ultrasound- or history-indicated, is not associated with an increased risk of preterm prelabor rupture of membranes, chorioamnionitis, or cesarean section.<sup>1-3</sup>

## 2 | ASYMPTOMATIC WOMEN WITH A PREVIOUS HISTORY OF PRETERM BIRTH

History-indicated cerclages have been shown to be beneficial in specific populations. A pre-specified subgroup analysis of an international multicenter trial encompassing 1292 women indicated benefit from a cerclage, inserted prophylactically during the first trimester, in women who had undergone three or more previous preterm births and/or second-trimester losses. The preterm birth rate before 33 weeks of gestation was halved in women who had undergone cerclage (15% vs 32%). This effect was not observed in women with two or fewer previous preterm deliveries. Where women had had one previous preterm birth, the rate of preterm birth before 33 weeks was 14% versus 17% in the expectant group. Where women had undergone two previous preterm deliveries, the rate of preterm birth was 12% in the cerclage group versus 14% in the expectant group.<sup>1</sup>

*Recommendation: A history-indicated cerclage should be offered in women who have had three or more preterm deliveries and/or mid-trimester losses.*

## 3 | ASYMPTOMATIC WOMEN WITH A SHORT CERVIX

Where high-risk women undergo ultrasound surveillance of cervical length and cervical shortening <25 mm is identified, a cerclage has been found to be beneficial when inserted at gestations less than 24 weeks. A meta-analysis including data from four RCTs indicated that an ultrasound-indicated cerclage for a cervical length <25 mm in women who had had one or more spontaneous mid-trimester losses or preterm births reduced the incidence of birth before 35 weeks (RR 0.57; 95% CI 0.33–0.99 in women who had a previous second-trimester loss, and RR 0.61; 95% CI 0.4–0.92 in women with a previous preterm birth before 36 weeks of gestation).<sup>2</sup>

*Recommendation: An ultrasound-indicated cerclage should be offered to women with a cervical length <25 mm if they have had one or more spontaneous preterm birth and/or mid-trimester loss.*

## 4 | ASYMPTOMATIC WOMEN WITH OTHER RISK FACTORS OR MÜLLERIAN ABNORMALITIES

The role of history- or ultrasound-indicated cerclage is less evident in other high-risk groups such as women with Müllerian abnormalities or cervical surgery, as there have been only preliminary studies to inform practice.<sup>4</sup> A meta-analysis of 27 retrospective cohort studies showed an increased risk of preterm birth <37 weeks of gestation

when cold knife conization was compared with no treatment (14% vs 5%; RR 2.59; 95% CI 1.8–3.72) and LLETZ versus no treatment (11% vs 7%; RR 1.24; 95% CI 1.14–1.35).<sup>5</sup> In women with a short cervix and history of cervical surgery, management should be individualized, but some clinicians consider cerclage with a cervical length <25 mm. There is a lack of randomized controlled trials to support the use of either ultrasound- or history-indicated cerclage in women with multiple pregnancies<sup>6</sup> without additional risk factors. If cerclage is considered in a twin pregnancy, observational evidence suggests that benefit is more likely with a shorter cervix (<15 mm).<sup>7</sup> If a cervix is incidentally noted as short in a low-risk population, no benefit appears to be conferred from an ultrasound-indicated cerclage.<sup>4-8</sup>

*Recommendation: In high-risk women who have not had a previous mid-trimester loss or preterm birth, an ultrasound-indicated cerclage does not have a clear benefit in women with a short cervix but can be considered on an individual case basis. For twins, the advantage seems more likely at shorter cervical lengths (<15 mm).*

## 5 | WOMEN WITH CERVICAL SHORTENING AND DILATATION THAT HAVE ALREADY RESULTED IN FETAL MEMBRANE EXPOSURE

Where cervical shortening and dilatation have already resulted in fetal membrane exposure, the insertion of a rescue cerclage can be considered before 24 weeks of gestation, where it may delay birth compared with expectant management/bed rest alone. Overt infection (intra-amniotic infection and/or inflammation) or active labor are contraindications to insertion. Infection and inflammation can first be explored under particular circumstances with amniocentesis, but a non-invasive test is warranted and needs to be developed.<sup>9-11</sup> A systematic review, including one RCT and prospective and retrospective cohort studies, has indicated insertion of a rescue cerclage is associated with increased neonatal survival and prolongation of pregnancy. Birth at all gestations after 24 weeks was reduced.<sup>12</sup> Further prospective RCTs are required to evaluate the risks and benefits of rescue cerclage.

*Recommendation: In women who present with exposed membranes prolapsing through the cervical os, a rescue cerclage can be considered on an individual case basis, taking into account the high risk of infective morbidity to mother and baby.*

## 6 | ASYMPTOMATIC WOMEN WITH PREVIOUS UNSUCCESSFUL CERCLAGE

In high-risk women who have previously undergone an unsuccessful cerclage, a transabdominal cerclage can be inserted in situations with adequate operative resources. The suture is inserted via the abdomen, more proximally. Its use is supported by evidence from a multicenter RCT of transabdominal cerclage versus a vaginally placed high or low cervical cerclage that rates of preterm birth <32 weeks of gestation and fetal losses were lower (8% vs 33%; RR 0.33; 95% CI 0.07–0.76)

in women who received transabdominal cerclage.<sup>13</sup> There were also fewer fetal losses (3% vs 21%; RR 0.12; 95% CI 0.016–0.93). In this trial preterm birth rates <32 weeks were similar in women receiving high or low vaginal cerclage (38% vs 33%). This can be placed either at laparotomy or laparoscopy.<sup>14</sup> Pre-conceptual insertion should be considered when possible due to reduced anesthetic risks and the technical advantages of operating on a non-pregnant uterus. There is no evidence that pre-conceptual placement has a detrimental effect on fertility or the management of early miscarriage. A link to a video of the procedure is given in Suff et al.<sup>15</sup>

*Recommendation: In women who have had a failed cerclage (delivery before 28 weeks after a history- or ultrasound-indicated [but not rescue] cerclage), an abdominal cerclage can be offered.*

## 7 | OTHER ISSUES REGARDING CERCLAGE

### 7.1 | Surgical technique

The choice of cerclage material and specific technique of insertion should be at the discretion of the surgeon. There is currently insufficient evidence to support any particular technique. However, randomized comparisons of vaginal cerclage (Shirodkar versus McDonald) have shown similar outcomes.<sup>13,16</sup> However, they should be placed as high as practically possible.<sup>17</sup> Abdominal cerclage can be performed preconceptually or laparoscopically, although there is no evidence to support a specific technique or timing. Infertility is not affected by abdominal cerclage.

### 7.2 | Perioperative considerations

Regional or general anesthesia is required for cerclage insertion (including abdominal cerclage). There is no evidence that a specific anesthetic has any advantage. Routine catheterization is not required and depends on the anesthetic and surgeons' discretion. Vaginal cerclage can usually be removed without additional anesthesia unless buried or high. Vaginal cerclage can be performed as a day case, but inpatient management may be required if sepsis is suspected following rescue cerclage. A retrospective survey of 226 women compared inpatient vs. outpatient management; there was no benefit in inpatient procedures with 48 h of admission.<sup>18</sup>

### 7.3 | Cerclage removal

If preterm birth has not occurred, removal is considered at 36–37 weeks in women anticipating a vaginal delivery. With preterm rupture of membranes, there is no evidence that the suture will improve outcomes, so removal is at the discretion of the clinician and patient taking into account the potential balance of prolonging the gestation with the potential risk of chorioamnionitis.

## 7.4 | Adjuvant/alternative therapy

Several different therapies have been advocated before or at the time of cerclage. These include tocolysis (usually indomethacin), antibiotics, and amnioreduction. All these interventions lack high-quality prospective evidence of benefit and can be considered on an individual case basis. Multiple studies have compared different agents (progesterone, pessaries, and cerclage) to prevent preterm birth. Several randomized controlled trials are in progress comparing the three treatments.<sup>19,20</sup> There is also currently no evidence to support the use of these interventions simultaneously.<sup>21</sup>

### CONFLICTS OF INTEREST

Andrew Shennan reports payment/honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from Manipal India; support for attending meetings and/or travel from Hologic; leadership or fiduciary roles in the HTA Commissioning Board UK and Action on Pre-eclampsia charity. Lisa Story reports receipt of equipment, materials, drugs, medical writing, gifts or other services from Clinical Innovations. Bo Jacobsson reports research grants from Swedish Research Council, Norwegian Research Council, March of Dimes, Burroughs Wellcome Fund and the US National Institute of Health; clinical diagnostic trials on NIPT with Ariosa (completed), Natera (ongoing), Vanadis (completed) and Hologic (ongoing) with expenditures reimbursed per patient; clinical probiotic studies with product provided by FukoPharma (ongoing, no funding) and BioGaia (ongoing; also provided a research grant for the specific study); collaboration in IMPACT study where Roche, Perkin Elmer and Thermo Fisher provided reagents to PLGF analyses; coordination of scientific conferences and meetings with commercial partners as such as NNFM 2015, ESPBC 2016 and a Nordic educational meeting about NIPT and preeclampsia screening. Bo Jacobsson is also Chair of the FIGO Working Group for Preterm Birth and the European Association of Perinatal Medicine's special interest group of preterm delivery; steering group member of Genomic Medicine Sweden; chairs the Genomic Medicine Sweden complex diseases group; and is Swedish representative in the Nordic Society of Precision Medicine. William Grobman reports no conflicts of interest.

### AUTHOR CONTRIBUTIONS

All authors and the FIGO Working Group for Preterm Birth drafted the concept of the paper. AS and LS wrote the first version of the manuscript. BJ and WAG revised various versions of the manuscript. All authors and Working Group members commented on the manuscript and approved the final version.

### MEMBERS OF THE FIGO WORKING GROUP FOR PRETERM BIRTH, 2018–2021

Joe Leigh Simpson, Jane Norman, Ana Bianchi, Stephen Munjanja, Catalina María Valencia González, Ben W. Mol.

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**How to cite this article:** Shennan A, Story L, Jacobsson B, Grobman WA; the FIGO Working Group for Preterm Birth. FIGO good practice recommendations on cervical cerclage for prevention of preterm birth. *Int J Gynecol Obstet.* 2021;155:19–22. <https://doi.org/10.1002/ijgo.13835>