



Subsequent Pregnancy Outcomes Following Prepregnancy Cerclage in Patients with Absent Ecto-Cervix

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Abstract

Background: We aimed to determine whether the prepregnancy cerclage for women with cervical incompetence with absent ecto-cervix affects the time from surgery to conception and subsequent pregnancy outcome.

Methods: This retrospective study was carried out on patients with at least one previous history of second-trimester abortion and extremely short cervix found by gynecological examination. A total of 40 cases of McDonald's cerclage before pregnancy were performed. The time from surgery to conception and pregnancy outcome were followed up for 4 years. The main outcomes were the time from surgery to conception, and the gestational week of delivery, miscarriage rate, preterm delivery rate.

Results: Between September 2018 and December 2022, 37 women became pregnant following prepregnancy cerclage. In total, 36 babies were born to 37 mothers. The recurrence rate of second-trimester miscarriage was 8.11% (3/37) and the preterm birth rate was 29.73% (11/37). Mean time from surgery to conception was 38w (range 2w-160w). Mean gestational age at delivery was 36 weeks +4 (256 days). The live birth rate was 100%. There were no maternal complications, no intestinal and bladder injuries.

Conclusion: Cervical incompetence patients with absent ecto-cervix may benefit from prepregnancy cerclage without affecting the interpregnancy interval.

Keywords: Ecto-cervix; Prepregnancy cerclage; Pregnancy outcome

Introduction

Preterm delivery (PTB), which is defined as delivery at less than 37 weeks of gestation, happens spontaneously in 10% of pregnancies and is associated with severe infant morbidity and mortality. Cervical incompetence (CIC) is a significant contributor to late miscarriage and preterm delivery. Cervical incompetence is thought to be the cause of 8% of recurrent second trimester abortions and 1% of all pregnancies (1, 2). The cause can be acquired, such as cervical injuries during delivery or cervical surgery, large ring resection of the

transformation zone (LLETZ), cone biopsy, or trachelectomy, or congenital, such as uterine abnormalities and collagen diseases (3, 4). Attempts should be made to rule out other preterm delivery hazards, such as morphological, infectious, placental, and immunological ones, before conducting cervical cerclage.

Shirodkar (5) and McDonald (6) originally developed the transvaginal method for achieving conventional cervical cerclage in 1955 and 1957, respectively. It can be a successful treatment option



for women with a cervical length of less than 25 mm who had two or more second trimester pregnancy losses, and it can also be taken into consideration for twin pregnancies with a cervical length of less than 15 mm (7). In situations where the cervical dilatation is less than 3 cm, emergency cervical cerclage may also be helpful (8, 9). Transvaginal cerclage (TVC) during pregnancy has major challenges and the height of the cerclage is frequently not guaranteed, increasing the risk of late miscarriage and preterm delivery even though it may be low and less effective in women with a congenitally or surgically short cervix. Later, transabdominal cervical cerclage was introduced by Benson and Durfee (10), which has good surgical outcomes but may increase the risk of surgical trauma due to the requirement to re-enter the belly for stitch removal. In comparison to TVC with laparoscopic transabdominal cervical cerclage (LTCC), conventional laparoscopic cervical cerclage has a similar success rate (85%–90%), better pregnancy outcomes, and a decreased risk of infection (11). It was first published in 1998 by Scibetta (12). The removal of the internal loop tie knot, however, has the unavoidable undesirable side effect of necessitating abdominal surgery at full term for an unwarranted cesarean delivery or late abortion (13, 14). This study focuses on a less invasive, lower risk approach with better clinical outcomes and immediate removal.

Cervical cerclage is a major method to treat cervical incompetence, which is one of the leading causes of second-trimester abortion and preterm birth. When the ecto-cervix is absent, transvaginal cerclage is very challenging to perform during pregnancy, and the height of the cerclage is frequently unreliable. As a result, there is a higher risk of late abortion and premature delivery, as

well as an increase in the incidence rate and mortality of newborns.

We aimed to report the use of preconception transvaginal cerclage in a subset of patients at our institution who have a history of late miscarriage and absent ecto-cervix, as well as to preliminarily assess the safety and efficacy of the procedure. The impact on the time to conception and the improvement of pregnancy outcomes and were the main points of attention.

Materials and Methods

This was a retrospective study. A total of 40 individuals with cervical incompetence, one or more previous late miscarriages, and a very short vaginal section of the cervix on inspection participated in the study. They were monitored for a total of 4 years; 1 had her stitches removed prior to becoming pregnant due to a reaction to the stitches, 2 were lost to follow-up, 37 became pregnant during the subsequent follow-up period, and 37 experienced pregnancy outcomes. All of the patients information was de-identified.

Study population

Women with the following indications were included based on the ACOG and SOGC criteria for cerclage surgery: At least one spontaneous mid-trimester fetal loss or preterm labor following painless cervical dilation, congenitally short or surgically amputated cervix (physical examination shows that the vaginal segment of cervix < 1.0 cm), severe cervical laceration, individuals with a history of unsuccessful transvaginal cerclage implantation were also included. Exclusion criteria: abortion caused by anatomical factors, infection and fetal death, which is not suitable for patients under general anesthesia. The following flow diagram indicated the process in our study (Fig. 1).

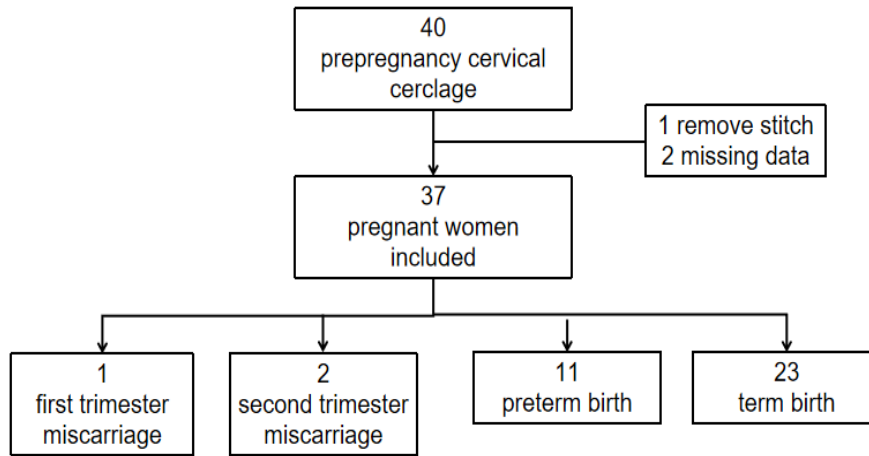


Fig. 1: Study progress

Preoperative preparation

With the approval of the Ethics Committee of the second affiliated hospital of Soochow University, the risks of prepregnancy cerclage were described in detail, and informed consent was obtained (JD-LK-2018-030-03). This study conforms to the STROBE guidelines (15). Prepregnancy cerclage was selected for admission to the hospital. Before the operation, the doctor trained the leucorrhea secretion for each patient, and treated them according to the results.

Surgical procedure

All participants received general anesthesia, and the operation method was modified McDonald's cerclage. All operations were performed by the same doctor. Cefazolin 1.0 g intravenous drip was administered prophylactically about half an hour before surgery, and azithromycin 0.5g intravenous drip was administered once for those allergic to cephalosporins.

General anesthesia was used, the vulva, vagina and cervix were routinely disinfected. The anterior and posterior lips of the cervix were tractioned with a mouse-tooth forceps, the cervical fascia was incised at the anterior and posterior walls of the vaginal segment of the cervix at a distance of about 1.5 cm from the external cervix, and at the folds of the vaginal wall, the cervical fascia was

incised near the vaginal wall, and the bladder was pushed up on the anterior wall to the level of the isthmus of the uterine bladder in the retroflexed peritoneal line, and the fascia was pushed up on the posterior wall to the level of the isthmus of the uterosacral ligament. The fascia on both sides of the uterine cervix is not incised and freed. The needle is inserted at a depth of approximately 1/3 of the thickness of the cervical wall when suturing the anterior wall cervical tissue, at a height close to the reflex line, on both sides to avoid the lower branches of the uterine artery crossing the tissue of the lateral wall of the uterine cervix. At a distance of 2.5 cm from the edge of the cervix, the cervix was closed with counterclockwise circular sutures, none of which could penetrate the cervical canal, which could be confirmed with a catheter before the sutures passed through the cervical wall but were not withdrawn. A catheter was placed in the cervical canal, sutured and knotted, the cervical length was 2.0 cm below the cervical suture line, the catheter was removed, the uterine orifice was allowed to be about 0.5 cm, and 2-0 absorbable sutures were used to close the cervical bladder gap and the cervico-rectal gap. Postoperatively, all participants were followed up weekly to monitor symptoms of vaginal infection, abnormal discharge, uterine or vaginal bleeding and dyspareunia. The primary outcomes were the

time from surgery to conception and pregnancy outcomes, especially incidence of live birth, pre-term delivery rate, delivery mode, neonatal survival were reviewed as the secondary outcomes.

Statistical analysis

The descriptive statistics for the continuous variables in our study were expressed as mean, standard deviation, and minimum and maximum values; the categorical variables were expressed as numbers and percentages. SPSS (IBM SPSS for Windows, version 26) statistical package software was used for the statistical calculations.

Results

Of the 40 patients we followed up after performing prepregnancy cervical cerclages, 2 were lost to follow up. One patient required stitch removal after cerclage due to a reflecting knot. There were

32 nulliparous and 8 multiparous women. The women in pregnant group had an average age of 31.85 ± 2.24 years. The demographics of the women who became pregnant are presented in Table 1. Maternal age ranged from 18 to 45 years, with a mean age of 31.85 years (SD: 2.24 years). The mean BMI was 24.68, (SD: 5.35). 80% of women (32/40; 80%) were nulliparous. Women had 1-4 second-trimester pregnancy losses, with 8 having already experienced one, 22 having already had two, 2 having already experienced three, and 5 having already experienced four. Average gestational week of previous miscarriage was 22.08 ± 1.28 weeks. Fourteen people had a prior failed transvaginal cerclage (TVC). Upon gynecological examination, it was discovered that 4 women had severe cervical lacerations, 9 had shallow or absent vaginal vault, and 21 had short vaginal segment of cervix.

Table 1: Clinical and demographic characteristics of 37 cerclage women

<i>Characteristics</i>	<i>Results</i>
Age at cerclage (mean±sd),y	31.85±2.24
BMI (mean±sd),kg/m2	24.68±5.35
Number of second-trimester miscarriage	
1 miscarriage	8(21.62%)
2 miscarriages	22(59.46%)
3 miscarriages	2(5.41%)
4 miscarriage	5(13.51%)
Average gestational week of previous miscarriage(w)	22.08±1.28
prior failed TVC	14(37.83%)
Short vaginal segment of cervix	21(56.76%)
shallow or absent vaginal vault	9(24.32%)
severe cervical laceration	4(10.81%)
surgically amputated cervix	9(24.32%)

Data are presented as number (%) unless otherwise indicated. Percentages were calculated as number of subjects positive for the variable divided by number of subjects with data available for that specific variable. TVC: transvaginal cerclage.

Operative and clinical information characteristics are presented in Table 2. The mean time from

surgery to conception was 38 weeks (2-160 weeks).

Table 2: Operative and clinical information characteristics

<i>Surgical outcomes</i>	<i>Results</i>
Hospital stay(mean±sd),day	4.22±1.35
Procedure time(mean±sd),min	39.54±10.12
Estimated blood loss(mean±sd),ml	5.12±1.14
Mean time from surgery to conception(w)	38

Overall, 32 women had natural conception, 2 woman had taken Leletrozole for ovulation induction and 2 women had undergone in-vitro fertilization treatment. The mean gestational week of delivery was 36weeks+4, 35 women delivered 36 healthy infants.

Details of pregnancy outcomes are outlined in Table 3. One woman had an early missed abortion, 2 cases had a second-trimester abortion, and 1 woman had a 26weeks+ gestational abortion with a birth weight of 800 g. The aborted baby

was resuscitated and survived, and the stitches were removed during the inevitable abortion. Eleven women were delivered prior to 37 weeks' gestation. Among the women who experienced live birth, 25 of 36 women underwent cesarean section, while 11 women had a vaginal delivery. The incidence of premature rupture of membranes was 1/36(2.78%). One of the patients did not remove the stitches after the first cesarean delivery and had another pregnancy 2 years later and another preterm cesarean delivery.

Table 3: Pregnancy outcomes of patients

<i>Pregnancy outcomes</i>	<i>Results</i>
Mean GA at delivery(weeks)	36 ⁺⁴
Distribution	
first trimester miscarriage	1(2.70%)
14~27+6weeks	2(5.41%)
28~33+6weeks	1(2.70%)
34~36+6weeks	10(27.03%)
term labor	23(62.16%)
Live births	36(100%)
Approach of conception	
natural conception	32(88.89%)
Pregnant with ART	4(11.11%)
Mode of delivery	
vaginal delivery	11(30.56%)
cesarean section	25(69.44%)
PPROM	1(2.78%)
Birth weight(mean ±sd),kg	3.18±0.63

Discussion

This study examined subsequent pregnancy outcomes in 37 women who had experienced pre-pregnancy cerclage. Among 37 women who became pregnant in the study period 2018-2022, the recurrence rate of second-trimester miscarriage

was 8.11% (3/37) and the preterm birth rate was 29.73% (11/37). Mean time from surgery to conception was 38w (range 2w-160w). The benefit of cervical cerclage remains controversial, and the management of patients with extremely short vaginal segments, often with a history of at least one late miscarriage and often a previous history

of failed transvaginal cervical cerclage, is often more challenging. The current recommended indications for transabdominal cerclage include a history of a previous failed transvaginal cerclage, but the disadvantages of transabdominal cerclage are obvious, such as the fact that it is not removable and the uncertainty as to whether it will have an effect on the prolongation of the next interval between pregnancies. Laparoscopic cerclage may be safer than open TAC in the management of cervical insufficiency because a statistically significant lower incidence of fetal loss, blood loss, and rate of hemorrhage in the laparoscopic cerclage group were found (16). However, there is no evidence to compare the benefits of laparoscopic cerclage and transvaginal cerclage in women with absent ecto-cervix. These adverse effects make this option unacceptable for some women with absent ecto-cervix and increase their anxiety about preparing for pregnancy.

A proportion of studies have shown a benefit of progestogen use in women at high risk of preterm delivery with short cervix (17,18). In addition, another study by Enakpene et al. in a small group of women with a very short cervix showed a clear benefit (19), so in this post-pregnancy follow-up we also recommend the use of progestogen for a combination of treatments. The role of vaginal pessary is questionable due to the lack of significant extra-cervical, variable results from small studies and randomized controlled trials (20,21). Therefore, the present study was not designed as a cohort study of pessary comparison.

A highlight of the current study was the enhanced preconception counseling with a review of medical history, cervical examination and ultrasound assessment measurements during the non-pregnancy period, which led to the decision to perform a preconception circumcision. In particular, the physical examination is an indispensable step for the cervix. The current scoring for the cervix is mainly the bishop score for induction of labor, which predicts the success of induction based on the maturity of the cervix and is not applicable for patients with CIC. In our examination, we focused on the texture of the cervix, the length of the vaginal segment of the cer-

vix, the presence of laceration up to the fornix. These indicators are often not obtained under ultrasound.

In this study, we used Johnson MB66 non-absorbable thread, which is not only tougher and frequently used in orthopedic surgery to suture ligaments, but also has a greater contact area to reduce the risk of cutting the cervix owing to intraoperative suturing. None of the 40 patients in this group had complications such as infection and bleeding, except for one case in which the suture was removed after a reaction to a node that developed hyperplasia and bleeding. Two second-trimester miscarriages occurred during the subsequent follow-up, and the transvaginal removal was very smooth. Currently, there is an option to remove or not remove the sutures as needed in a cesarean section. And in this study, there was one patient who had a need for another birth after a single cesarean delivery and had already had subsequent pregnancy and a second cesarean delivery without removing the sutures after the cesarean delivery, and the sutures had been present in the body for 4 years.

Whether surgery affects time to conception was also initially explored in this study, and there is controversy regarding the optimal interpregnancy interval (IPI) after a midterm abortion. Some clinicians believe that there is little justification for delaying the next pregnancy after a single failed pregnancy, as an increase in IPI is unlikely to improve birth outcomes (22,23), whereas a new pregnancy and the birth of a child may give women new hope (24). Current WHO guidelines recommend that women should wait at least 6 months before trying again (25). Our findings show that these women had a median time to conception of 38 weeks. Edlow found no significant effect of IPI on pregnant women with previous miscarriage or preterm delivery in midterm pregnancies, but a 10-fold increased risk of preterm delivery or miscarriage among pregnant women with previous full-term deliveries with IPI <6 months (26). An evaluation of the optimal timing for pregnancy after cervical conization found that patients who have fertility desire with cervical intraepithelial neoplasia (CIN) were rec-

ommended for pregnancy at 6 and 9 months after LEEP and cold knife conisation (CKC) (27). The cesarean section rate was high in this group at 69.44% (25/36). This may be due to the fact that women pay closer attention after miscarriage and Chinese women have a habit of staying in bed. Some women may be influenced by this habit, and prolonged bed rest during pregnancy can result in a loss of muscle strength, which is why most women opt for the cesarean section method.

Following their pregnancies, all women were tracked down, scrutinized, and their gestational weeks for delivery were meticulously documented. During delivery, the stitches were removed or not depending on whether there was a need for the next pregnancy, and one woman had subsequent pregnancy 2 years after the cesarean delivery and had a live cesarean delivery again. Moreover, Except for one missed abortion in the first trimester of pregnancy and two patients who had miscarriage in the second trimester of pregnancy, all the other pregnant patients were given live labor, including one patient who had inevitable miscarriage in the second trimester of pregnancy. Overall prognosis for these patients with absent ecto-cervix was favorable. This reflection of a good prognosis might be a reflection of the sample size of the particular community, however the study's drawbacks include its small sample size, use of a single operator, and absence of randomization. In conclusion, prepregnancy cerclage has favorable pregnancy outcomes and does not prolong the time to conception.

Conclusion

Preconception counseling should be intensified in patients with a history of at least one previous late miscarriage. For patients with a combined short vaginal segment of the cervix or cervical agenesis, prepregnancy cerclage may be considered. There is no significant effect on the time to conception, and pregnancy outcome is significantly improved.

Its suitability can be further explored, especially when abdominal cerclage procedures are not readily available. Further research given ethical considerations is needed in this area.

Journalism Ethical considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

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Conflict of Interest

The authors declare that there is no conflict of interest.

Abbreviations and acronyms

<i>Abbreviations and Acronyms</i>	<i>Full name</i>
CIC	Cervical incompetence
PTB	Preterm birth
TVC	Transvaginal cerclage
BMI	Body mass index
LEEP	Loop Eelectrosurgical Excision Procedure
IPI	interpregnancy interval
CIN	cervical intraepithelial neoplasia

CKC	cold knife conisation
PPROM	preterm premature rupture of membranes
GA	Gestational age
ART	Assisted reproduction technology
ACOG	American College of Obstetricians and Gynecologists
LTCC	laparoscopic transabdominal cervical cerclage
LLETZ	large ring resection of the transformation zone
SOGC	The Society of Obstetricians and Gynaecologists of Canada

References

- Alfirevic Z, Stampalija T, Medley N (2017). Cervical stitch (cerclage) for preventing preterm birth in singleton pregnancy. *Cochrane Database Syst Rev*, 6: CD008991.
- Shennan A, Story L, Jacobsson B, Grobman WA (2021). FIGO Working Group for Preterm Birth (2021). FIGO good practice recommendations on cervical cerclage for prevention of preterm birth. *Int J Gynaecol Obstet*, 155(1): 19-22.
- Sundtoft I, Langhoff-Roos J, Sandager P, et al (2017). Cervical collagen is reduced in non-pregnant women with a history of cervical insufficiency and a short cervix. *Acta Obstet Gynecol Scand*, 96(8): 984-90.
- Hamou B, Sheiner E, Coreanu T, et al (2020). Intrapartum cervical lacerations and their impact on future pregnancy outcome. *J Matern Fetal Neonatal Med*, 33(5): 883-7.
- V S (1955). A new method of operative treatment for habitual abortions in the second trimester of pregnancy. *Antiseptic*, 52: 299-300.
- McDonald IA (1957). Suture of the cervix for inevitable miscarriage. *J Obstet Gynaecol Br Emp*, 64(3): 346-50.
- Owen J, Hankins G, Iams JD, et al (2009). Multicenter randomized trial of cerclage for preterm birth prevention in high-risk women with shortened midtrimester cervical length. *Am J Obstet Gynecol*, 201(4): 375.e1-8.
- Namouz S, Porat S, Okun N, et al (2013). Emergency cerclage: literature review. *Obstet Gynecol Surv*, 68(5): 379-88.
- Wierzchowska-Opoka M, Kimber-Trojnar Z, Leszczyńska-Gorzela B (2021). Emergency Cervical Cerclage. *J Clin Med*, 10(6):1270.
- Benson RC, Durfee RB (1965). Transabdominal Cervico Uterine Cerclage during Pregnancy for the Treatment of Cervical Incompetency. *Obstet Gynecol*, 25: 145-55.
- Witt MU, Joy SD, Clark J, et al (2009). Cervicoisthmic cerclage: transabdominal vs transvaginal approach. *Am J Obstet Gynecol*, 201(1): 105.e1-4.
- Scibetta JJ, Sanko SR, Phipps WR (1998). Laparoscopic transabdominal cervicoisthmic cerclage. *Fertil Steril*, 69(1): 161-3.
- Ades A, Aref-Adib M, Parghi S, Hong P (2019). Laparoscopic transabdominal cerclage in pregnancy: A single centre experience. *Aust N Z J Obstet Gynaecol*, 59(3): 351-5.
- Moawad GN, Tyan P, Bracke T, et al (2018). Systematic Review of Transabdominal Cerclage Placed via Laparoscopy for the Prevention of Preterm Birth. *J Minim Invasive Gynecol*, 25(2): 277-86.
- von Elm E, Altman DG, Egger M, et al (2007). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Epidemiology*, 18(6): 800-4.
- Marchand GJ, Masoud AT, Galitsky A, et al (2021). Complications of Laparoscopic and Transabdominal Cerclage in Patients with Cervical Insufficiency: A Systematic Review and Meta-analysis. *J Minim Invasive Gynecol*, 28(4): 759-768.e2.
- Jarde A, Lutsiv O, Beyene J, McDonald SD (2019). Vaginal progesterone, oral progesterone, 17-OHPC, cerclage, and pessary for preventing preterm birth in at-risk singleton pregnancies: an updated systematic

- review and network meta-analysis. *BJOG*, 126(5): 556-67.
18. EPPPIC Group (2021). Evaluating Progestogens for Preventing Preterm birth International Collaborative (EPPPIC): meta-analysis of individual participant data from randomised controlled trials. *Lancet*, 397(10280): 1183-94.
 19. Enakpene CA, DiGiovanni L, Jones TN, et al (2018). Cervical cerclage for singleton pregnant patients on vaginal progesterone with progressive cervical shortening. *Am J Obstet Gynecol*, 219(4): 397.e1-397.e10.
 20. Dugoff L, Berghella V, Sehdev H, et al (2018). Prevention of preterm birth with pessary in singletons (PoPPS): randomized controlled trial. *Ultrasound Obstet Gynecol*, 51(5): 573-9.
 21. Norman JE, Marlow N, Messow CM, et al (2016). Vaginal progesterone prophylaxis for preterm birth (the OPPTIMUM study): a multicentre, randomised, double-blind trial. *Lancet*, 387(10033): 2106-16.
 22. Goldstein RR, Croughan MS, Robertson PA (2002). Neonatal outcomes in immediate versus delayed conceptions after spontaneous abortion: a retrospective case series. *Am J Obstet Gynecol*, 186(6): 1230-4.
 23. Basso O, Olsen J, Knudsen LB, et al (1998). Low birth weight and preterm birth after short interpregnancy intervals. *Am J Obstet Gynecol*, 178(2): 259-63.
 24. Cuisinier M, Janssen H, de Graauw C, et al (1996). Pregnancy following miscarriage: course of grief and some determining factors. *J Psychosom Obstet Gynaecol*, 17(3): 168-74.
 25. World Health Organization (2007). Report of a WHO technical consultation on birth spacing. <https://www.who.int/publications/i/item/WHO-RHR-07.1>
 26. Edlow AG, Srinivas SK, Elovitz MA (2007). Second-trimester loss and subsequent pregnancy outcomes: What is the real risk? *Am J Obstet Gynecol*, 197(6): 581.e1-6.
 27. Zhang X, Tong J, Ma X, et al (2020). Evaluation of cervical length and optimal timing for pregnancy after cervical conization in patients with cervical intraepithelial neoplasia: A retrospective study. *Medicine (Baltimore)*, 99(49): e23411.