NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth

Late miscarriages and preterm births can be caused by a weak (sometimes called an incompetent) cervix that shortens or opens too early in pregnancy. Cervical cerclage involves placing a stitch around the upper part of the cervix. In this procedure, the stitch is placed through the abdomen using a laparoscopic ('keyhole') approach. The aim is to keep the cervix closed to prevent late miscarriages and preterm births.

Contents

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in June 2018 and updated in November 2018.

Procedure name

- Laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth

Specialist societies

- British Society for Gynaecological Endoscopy
- Royal College of Obstetricians and Gynaecologists
- British Maternal and Fetal Medicine Society
- Royal College of Midwives.

Description of the procedure

Indications and current treatment

Cervical incompetence may be caused by a congenital weakness of the cervix, or previous obstetric or gynaecological trauma. It is characterised by painless dilatation of the cervix in the second or third trimester, followed by second trimester miscarriage or premature rupture of the membranes and preterm delivery. The condition is usually diagnosed after 1 or more late second trimester pregnancy losses or early third trimester delivery, and after other causes have been excluded.

Cervical incompetence is traditionally treated by transvaginal cervical cerclage. This involves placing a suture or tape around the cervix, via the vagina, and

tightening it to keep the cervix closed. The procedure is typically done at the end of the first trimester or the beginning of the second trimester. The suture or tape is then usually removed at around 37 weeks of gestation to allow delivery.

Cervical cerclage using a transabdominal approach may be needed if transvaginal cerclage is technically difficult or has proved ineffective. With this approach, caesarean section is necessary to deliver the baby.

What the procedure involves

Laparoscopic cervical cerclage can be done during pregnancy or in women who are not pregnant. Under general anaesthesia, the peritoneal cavity is insufflated with carbon dioxide through a needle inserted into the umbilicus. Several small incisions are then made to provide access for the laparoscope and surgical instruments. In women who are not pregnant, a dilator may initially be inserted into the cervix through the vagina for uterine manipulation. The bladder is dissected away from the uterus and a suture or tape is secured around the cervical isthmus, above the cardinal and uterosacral ligaments. As with the open transabdominal approach, caesarean section is necessary to deliver the baby. The suture may be left in place for future pregnancies

Efficacy summary

Conception rate

In a systematic review of 41 studies on laparoscopic or open abdominal cerclage done before or during pregnancy, the conception rate for patients who had cerclage as an interval procedure was 78% for those who had laparoscopic cerclage (n=511) and 74% for those who had open abdominal cerclage (n=160; p=0.3567).[1]

In a non-randomised comparative study of 49 patients, 12 patients who had robot-assisted transabdominal cerclage could be contacted; 8 out of the 12 were pregnant, 3 were actively pursuing pregnancy and 1 patient chose to postpone pregnancy.[9]

Live birth rate or neonatal survival

In the systematic review of 41 studies, neonatal survival was 89% in both the laparoscopic cerclage (n=621 pregnancies) and the open abdominal cerclage (n=937 pregnancies) groups (p=0.8887).[1] Neonatal survival excluding first trimester loss was 96% (597/621) with laparoscopic cerclage and 91% (853/937) with open abdominal cerclage (p=0.0002).[1]

In a non-randomised comparative study of 38 patients, 94% (17/18) of patients who had laparoscopic cerclage during the first trimester of pregnancy or before pregnancy and 90% (18/20) of patients who had prophylactic transvaginal cerclage had good neonatal outcomes.[5]

In a case series of 225 patients (121 pregnancies), the perinatal survival rate of viable pregnancies was 99% after laparoscopic cerclage, compared with 42% before the procedure.[6]

In a systematic review of 8 studies of robot-assisted transabdominal cerclage during pregnancy, the live birth rate was 90%.[10]

Second or third trimester loss

In the systematic review of 41 studies, the proportion of pregnancies that ended with a second trimester loss was 4% (23/621) in the laparoscopic cerclage group and 8% (73/937) in the open abdominal cerclage group (p=0.001).[1]

In the case series of 225 patients (121 pregnancies), there were 2 fetal losses, which were considered to be cerclage failures. One patient delivered twins at 24 weeks of gestation. Her membranes ruptured and she went into labour and had a caesarean section to deliver the babies. One twin survived and the other died 5 days after birth. In the second patient, the membranes ruptured at 15 weeks of gestation. The cerclage was removed by laparoscopy and the fetus was delivered vaginally.[6]

First trimester loss

In the systematic review of 41 studies, the proportion of pregnancies that ended with a first trimester loss was 7% (43/621) in the laparoscopic cerclage group and 2% (15/937) in the open abdominal cerclage group (p<0.05).[1]

In the non-randomised comparative study of 38 patients, there was 1 miscarriage in the laparoscopic cerclage group at 12 weeks of gestation and no first trimester losses in the transvaginal cerclage group.[5]

Gestational age at delivery

In the systematic review of 41 studies, the proportion of pregnancies that resulted in delivery at gestational age more than 34 weeks was 83% (410/494) in the laparoscopic cerclage group and 76% (710/937) in the open abdominal cerclage group (p=0.0016).[1] The proportion of pregnancies that resulted in delivery between 23 and 34 weeks of gestation was 7% (34/494) in the laparoscopic

cerclage group and 14% (128/937) in the open abdominal cerclage group (p=0.0001).[1]

In the non-randomised comparative study of 38 patients, there were no preterm deliveries in the laparoscopic cerclage group and 2 preterm deliveries in the transvaginal cerclage group (both had a good neonatal outcome).[5]

In the case series of 225 patients (121 pregnancies), 80% of babies were delivered at 34 weeks or more gestation. The mean gestational age at delivery was 35.2 weeks after laparoscopic cerclage insertion (n=121 pregnancies) compared with 23.9 weeks in pregnancies before the procedure (n=402). Before laparoscopic cerclage, 59% (235/402) of pregnancies ended with delivery at between 13 and 24 weeks, compared with 2% (2/121) of pregnancies after laparoscopic cerclage. Eight (7%) deliveries occurred at between 24 and 34 weeks because of preterm labour or preterm pre-labour rupture of the membranes, and the cerclages in these patients were deemed suboptimal.[6]

In the non-randomised comparative study of 49 patients, 5 of the 8 patients who became pregnant after robot-assisted transabdominal cerclage delivered at more than 35 weeks of gestation; 1 had prolapse of the membranes into the cervical canal and delivered at 29 weeks, and the other 2 women await delivery.[9]

In the systematic review of 8 studies of robot-assisted transabdominal cerclage during pregnancy, the median gestational age at delivery was 37 weeks (range 33 to 39).[10]

Safety summary

Overall intraoperative complications

The overall rate of intraoperative complications was 1% (8/728) for patients who had laparoscopic cerclage and 1% (actual numbers not reported) for patients who had open abdominal cerclage in the systematic review of 41 studies (15 studies on laparoscopic cerclage [n=728], 26 studies on open abdominal cerclage [n=1,116]).[1]

Conversions to laparotomy

Conversions to laparotomy were reported in 1% (10/728) of patients who had laparoscopic cerclage in the systematic review of 41 studies; 2 were done before conception and 8 were done during pregnancy.[1]

Conversions to laparotomy were reported in 2 out of 7 patients who had robot-assisted transabdominal cerclage during pregnancy in a case series included in the systematic review of 8 studies (16 patients).[10]

Uterine perforation

Uterine perforation was reported in less than 1% (3/728) of patients who had laparoscopic cerclage in the systematic review of 41 studies.[1]

Uterine fundal perforation was reported in 1 patient in the case series of 225 patients; this was repaired laparoscopically.[6]

Uterine injury was reported in 1 patient who had robot-assisted transabdominal cerclage during pregnancy in the systematic review of 8 studies (16 patients).[10]

Small bowel injury

Small bowel injury was reported in 1 patient who had laparoscopic cerclage in the systematic review of 41 studies.[1]

Bladder perforation

Bladder perforation was reported in 1 patient who had laparoscopic cerclage in the systematic review of 41 studies.[1]

Intraoperative bladder injury was reported in 1 patient in the case series of 225 patients; this was repaired laparoscopically.[6]

Vascular injury

Uterine vein laceration was reported in 1 patient who had laparoscopic cerclage in the systematic review of 41 studies.[1]

Intraoperative uterine vessel injury was reported in 1 patient in a case series of 3 patients; estimated blood loss was 300 ml and transfusion was not needed.[8]

Broad ligament laceration

Broad ligament laceration was reported in 1 out of 7 patients who had robot-assisted transabdominal cerclage during pregnancy in the systematic review of 8 studies (16 patients).[10]

Infection

Pelvic infection was reported in 1 patient who had laparoscopic cerclage in the systematic review of 41 studies.[1]

Wound infection was reported in 1 patient in the case series of 225 patients; this was treated with antibiotics.[6]

Wound infection in 1 of the port sites was reported in 1 patient who had robot-assisted transabdominal cerclage in the non-randomised comparative study of 49 patients.[9]

Perioperative postconceptual miscarriage rate

The perioperative postconceptual miscarriage rate (up to 2 weeks after the cerclage procedure) was 1% (3/211) for patients who had laparoscopic cerclage and 3% (actual numbers not reported) for patients who had open abdominal cerclage in the systematic review of 41 studies.[1]

Long-term complications

Vaginal erosion of cerclage

Vaginal erosion of a cerclage that had been inserted laparoscopically about 7 years previously was described in a case report.[7] The patient had 2 successful pregnancies with caesarean deliveries after the laparoscopic cerclage.[7] Three years after the second delivery, the patient had irregular vaginal discharge, pelvic pressure and fever.[7] The cerclage had eroded though the upper vagina; the vaginal portion of the suture was cut but the suture could not be removed.[7] The patient had oral antibiotics and the remaining cerclage was expelled into the vaginal vault a week later.[7] One month later, the symptoms had resolved.[7]

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, specialist advisers listed no anecdotal adverse events. They considered that the following were theoretical adverse events: general anaesthetic or laparoscopy complications, damage to uterine artery causing bleeding and growth restriction of fetus in future

pregnancies, mesh-related complications, damage to cervix if labour with cerclage in-situ, need for hysterectomy or caesarean section if miscarriage and unable to deliver vaginally (despite removal of cerclage) and increased rate of chorioamnionitis.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth. The following databases were searched, covering the period from their start to 2 October 2018: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with cervical incompetence.
Intervention/test	Laparoscopic cerclage.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 1,021 patients who had laparoscopic cerclage from 2 systematic reviews, 4 non-randomised comparative studies (2 of which were also included in 1 of the systematic reviews), 4 case series (1 of which was also included in 1 of the systematic reviews) and 1 case report; 1 article reported both a case series and a systematic review.[1–10]

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in the appendix.

Table 2 Summary of key efficacy and safety findings on laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth

Study 1 Moawad GN (2017)

Details

Study type	**Systematic review**
Country	The countries of the individual studies was not reported.
Recruitment period	1998 to 2017
Study population and number	**Laparoscopic cervical cerclage (LCC)**: 15 studies (728 women, 621 pregnancies) • Preconception: 517 patients (71%) • Postconception: 211 patients (29%) **Open abdominal cervical cerclage (OCC)**: 1 systematic review (26 studies, 1,116 patients, 934 pregnancies) • Preconception: 160 patients (19%) • Postconception: 702 patients (81%)
Age	Mean 29 to 35 years
Patient selection criteria	Included: - Paper reporting surgical or pregnancy outcomes of laparoscopic cervical cerclage - Studies reporting on at least 10 patients - Studies reporting on abdominal cerclage placed for expected preterm birth or second trimester losses after previous failed transvaginal cervical cerclage (TVC), congenital or acquired cervical deformity, history of spontaneous preterm birth or second trimester loss, or cervical insufficiency - Inclusion criteria were similar for studies reporting on LCC or OCC - Studies reporting on abdominal cervical cerclage done before pregnancy (preconception) or during pregnancy (postconception) - Studies not differentiating obstetrical outcome based on cerclage timing Excluded: - Studies using duplicate patient population for more than 1 publication - Studies reporting on robotic-assisted cervical cerclage
Technique	Most surgeons used a traditional 3-port laparoscopy approach with a fourth suprapubic assistant port (84% [11/13]), 5 mm Mersilene suture 64% [9/14]), a straight or straightened needle (42% [6/14]) and a uterine manipulator (85% [12/14]). Several different uterine manipulators were used. Most surgeons dissected the uterovesical and paravesical spaces and made a broad ligament window. There was no trend in the direction of suture advancement or anterior versus posterior placement of the knot.
Follow-up	**Not reported**
Conflict of interest/source of funding	One of the authors is a speaker for Intuitive Surgical and Applied Medical. The remaining authors declared they had no conflict of interest.

Analysis

Follow-up issues: Authors who provided different gestational age categories were asked to provide primary data. Two authors failed to respond and were removed from the gestational age and delivery analysis. First and second trimester losses and neonatal survival data were available for all studies.

Study design issues: The authors reported a comprehensive literature review using keywords for open abdominal or laparoscopic cervical cerclage. Two authors assessed each study independently and discrepancies were resolved by a third senior author. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed to report the review. Subgroup analysis was done when possible. Researchers were contacted via email to request obstetrical outcomes data if not provided in the original article.

Primary outcome was the incidence of delivery of a viable infant at 34 weeks or more gestational age. Secondary outcome measures included neonatal survival, neonatal survival excluding first trimester losses, delivery of a viable infant

at less than 34 weeks gestational age, second trimester losses, surgical complications, rate of conception and perioperative pregnancy loss within 2 weeks of abdominal cerclage.

Study population issues: The studies reporting on outcomes of women having OCC had previously been compiled in the systematic review by Burger 2011.

Characteristic of studies reporting on LCC

Author	n	Case series	Age (mean in years)	Inclusion criteria
Burger 2012	66	Retrospective	34.8	Previous failed TVC, extensive cervical surgery
Whittle 2009	65	Prospective	32.6	Presumptive diagnosis of mechanical cervical incompetence (based on Novy criteria)
Sneider 2017 (retracted)	108	Retrospective	32.4	Previous failed TVC, congenital or acquired cervical deformity, previous preterm delivery
Riiskjaer 2012	52	Retrospective	31.8	2 or 3 previous conisations or amputation of the cervix, preterm premature rupture of membranes before 30 weeks, 1 or more second trimester loss or preterm delivery before 30 weeks without uterine contractions, second trimester loss or preterm delivery before 28 weeks with uterine contractions, referred for primary cervical insufficiency
Mingione 2003	11	Retrospective	31.7	Previous failed TVC, history of second trimester loss or preterm delivery, absence or virtual absence of the entire exocervix, congenital or acquired cervical deformity
Luo 2014	19	Prospective	31 (median)	Previous failed TVC, history of cervical incompetence or insufficiency, with or without congenital short cervix or damage rendering the vaginal approach difficult
Liddell 2008	11	Retrospective	32.1	Previous failed TVC, history of cervical surgery, history of preterm delivery or second trimester loss, second trimester loss
Huang 2016	100	Retrospective	31.2	Previous failed TVC
Cho 2003	20	Retrospective	31.1	Previous failed TVC, acquired cervical deformity, history of second trimester loss
Chen 2015	101	Prospective	29.1	Previous failed TVC, spontaneous abortion or preterm delivery in second or third trimester, diagnosed cervical insufficiency
Carter 2009	12	Prospective	31	Previous failed TVC, history of second trimester loss
Ades 2015	51	Prospective	32	Previous failed TVC, previous extensive cervical surgery
Bolla 2015	18	Retrospective	33	Previous failed TVC, patients in whom vaginal insertion was technically difficult or impossible because of an extremely short or absent cervix
Shin 2015	80	Retrospective	31.4	Previous failed TVC, acquired cervical deformity, 1 or 2 successive second trimester losses
Nicolet 2009	14	Retrospective	33.5	Previous failed TVC, recurrent second trimester loss or preterm delivery, severe congenital or acquired cervical deformity

Other issues: It was not possible to differentiate outcomes for patients with preconceptional and those with postconceptional abdominal cerclages due to insufficient information in the evaluated studies. One of the articles included in the review (Sneider et al., 2017) has been retracted at the request of the Editor-in-Chief and the authors as the authors failed to request and receive permission to use the data from the relevant hospital.

Key efficacy and safety findings

Efficacy

Conception rate after preconception cerclage

Timing of cerclage	LCC n=511	OCC n=160	p
Preconceptional	78%	74%	0.3567

Pregnancy outcomes

	LCC	OCC	p
Total pregnancies, n	621	937	-
First trimester loss (≤13 weeks gestational age)	6.9% (43/621)	1.6% (15/937)	<0.05
Second trimester loss (14 to 22 weeks gestational age)	3.7% (23/621)	7.8% (73/937)	0.001
Neonatal survival	89.2% (554/621)	89.4% (838/937)	0.8887
Neonatal survival excluding first trimester loss	96.1% (597/621)	91.0% (853/937)	0.0002
Pregnancies with known gestational age outcome, n	494	937	
Gestational age >34 weeks at delivery	83.0% (410/494)	75.8% (710/937)	0.0016
Gestational age 23 to 33.6 weeks at delivery	6.9% (34/494)	13.7% (128/937)	0.0001
Neonatal survival	89.9% (444/494)	89.4% (838/937)	0.7937

Safety

Complication	LCC	OCC	p
Intraoperative			
Uterine perforation	0.4% (3/728)	NR	NR
Pelvic infection	1/728	NR	NR
Small bowel injury	1/728	NR	NR
Bladder perforation	1/728	NR	NR
Uterine vein laceration	1/728	NR	NR
Insufficient tightening of cerclage	1/728	NR	NR
TOTAL	1.1% (8/728)	1.2%	0.8131
Perioperative			
Perioperative postconceptual miscarriage rate (up to 2 weeks after cervical cerclage)	1.4% (3/211)	3.0%	0.2181^

^reported as p<0.01 in the text of the paper

Conversion to laparotomy: 1.3% (10/728), 2 in the preconception group and 8 in the postconception group**

**7 conversions were from a single study

Abbreviations used: LCC, laparoscopic cervical cerclage; OCC, open abdominal cervical cerclage; NR, not reported; TVC, transvaginal cervical cerclage.

Study 2 Chen Y (2015)

Details

Study type	**Non-randomised comparative study**
Country	China
Recruitment period	Not reported
Study population and number	**n=134** women with cervical insufficiency treated by cervical cerclage - Laparoscopic cerclage placed in first trimester of pregnancy (CPL): 43 women - Laparoscopic cerclage placed in non-pregnant phase (CNL): 58 women - Transvaginal cerclage placed in second or third trimester of pregnancy (TVC): 33 women
Age	**CPL**: mean 29.1±3.8 years **CNL**: mean 29.3±3.3 years **TVC**: mean 29.9±4.0 years
Patient selection criteria	Inclusion criteria: - Medical history of spontaneous abortion or preterm delivery in second or third trimester, diagnosed cervical insufficiency and fertility will. Exclusion criteria for laparoscopic cerclage: - Complications of intrauterine adhesion or uterine myoma in septum or submucosa - Medical history of pelvic surgery, a possibility of pelvic adhesion - Patients with cervical cerclage in first trimester, before this operation, with a medical history of threatened abortion, diagnosed inevitable abortion or medical history of missed abortion. Exclusion criteria for TVC in second or third trimester: - Vaginitis, acute or subacute amnionitis, pelvic inflammation - Premature rupture of fetal membranes
Technique	All laparoscopic procedures were done with the patient under general anaesthesia and used a Mersilene encircling band. Transvaginal cerclage was done under local anaesthesia. In the laparoscopic cerclage group, delivery was by caesarean section, without removing the encircling band. Patients in the transvaginal cerclage group were advised to fully rest after the operation until the delivery. The suture was removed when labour started, and vaginal delivery was recommended.
Follow-up	**Delivery**
Conflict of interest/source of funding	The study was funded by Guangzhou Science Project. The authors declared there were no conflicts of interest.

Analysis

Follow-up issues: None.

Study design issues: The appropriate operation was chosen according to the patients' condition and choice after they were fully informed. TVC was recommended if patients were in the second or third trimester. If patients were in the first trimester, CPL in the first trimester or TVC in the second or third trimester were recommended. If patients were not pregnant, CNL in the non-pregnant phase, CPL in the first trimester, and TVL in the second or third trimester, were all appropriate.

Study population issues: 28% (38/134) of patients had a previous transvaginal cerclage. None of the patients had a previous laparoscopic cervical cerclage.

Other issues: Study is included in the systematic review by Moawad GN et al., 2017 (study 1).

Key efficacy and safety findings

Efficacy

n= CPL 43 women, **CNL** 58 women, **TVC** 33 women

Main outcomes

	CPL (n=43)	CNL (n=58)	TVC (n=33)
Not pregnant	-	14% (8/58)	-
Currently pregnant	40% (17/43)	28% (16/58)	0
Abortion	1/43	3% (2/58)	30% (10/33)
Delivery	58% (25/43)	55% (32/58)	67% (23/33)

Comparison of pregnancy outcomes among 3 groups

				p value		
Data	**CPL (n=26)**	**CNL (n=34)**	**TVC (n=33)**	**CPL vs CNL**	**CPL vs TVC**	**CNL vs TVC**
First trimester spontaneous abortion	1/26	1/34	1/33	NR	NR	NR
Second trimester spontaneous abortion	0	1/34	27% (9/33)	NR	NR	NR
Premature delivery	1/26	12% (4/34)	24% (8/33)	NR	NR	NR
Term delivery	92% (24/26)	82% (28/34)	45% (15/33)	0.459	<0.001	0.002
Fetal salvage rate	100% (25/25)	97% (32/33)	72% (23/32)	0.569	0.012	0.014
Mean gestational age if pregnancy lasted ≥14 weeks	37.9±0.8	36.7±4.5	32.9±7.2	0.434	<0.001	<0.001
Mean gestational age for all pregnancies	36.7±5.9	35.7±7.2	31.3±7.9	0.521	<0.001	<0.001
Mean birth weight (g)	3,006.0±402.9	2,885.9±437.4	2,762.5±591.1	0.713	0.553	0.767
Weeks of pregnancy gained	16.0±2.0	14.6±5.6	10.7±5.9	0.065	<0.001	0.001

Safety

There were no complications such as bleeding, infection or injury of peripheral organs.

For the neonates in each group, there was no need for intensive care, there were no neonatal deaths, and no sequelae of prematurity.

Abbreviations used: CNL, laparoscopic cerclage placed in non-pregnant phase; CPL, laparoscopic cerclage placed in first trimester of pregnancy; NR, not reported; TVC, transvaginal cerclage.

Study 3 Huang X (2016)

Details

Study type	**Case series**
Country	China
Recruitment period	2010 to 2015
Study population and number	**n=100** women having laparoscopic cervical cerclage between pregnancies
Age	Mean 31.2±3.9 years (range 23 to 40)
Patient selection criteria	Women with cervical incompetence who did not have a live birth after a previous transvaginal cerclage.
Technique	All patients had pelvic ultrasonography and hysteroscopy prior to the operation. All procedures were done under general anaesthesia and cerclage used a Mersilene 5 mm tape. A simplified technique was used in which a vaginal cup was used to elevate the cervix and there was no need to dissect the bladder away from the lower segment of the uterus before inserting the suture. Transvaginal ultrasound was done after the procedure to confirm the position of the suture at the cervico-isthmic junction.
Follow-up	**19.7±10.1 months**
Conflict of interest/source of funding	The study was supported by "Sea Poly Project of Beijing Overseas Talents".

Analysis

Follow-up issues: Follow-up was done at regular 3 to 6 months intervals with clinical visit or telephone contact.

Study design issues: The main outcome of interest was the result of subsequent pregnancy. Information on surgical outcomes such as estimated blood loss, operation time and complications was also recorded.

Study population issues: All women had previously had a failed transvaginal cervical cerclage. The mean number of second trimester pregnancy losses was 2.9±1.2 (range 2 to 7). The mean gestational age of previous second trimester miscarriage was 20.1±3.6 (range 13 to 27) weeks. There were 3 women who had term delivery before laparoscopic cervical cerclage. Four women had cervical conisation because of cervical intraepithelial neoplasia. None of the women had evidence of structural uterine anomaly other than the arcuate variant.

Of the 100 women having laparoscopic cervical cerclage, 42 had concomitant procedures including dye test (n=14), excision of endometriosis (n=8), ovarian cystectomy (n=7), ovarian drilling (n=1), adhesiolysis (n=7), myomectomy (n=5) and transcervical resection of uterine polyp (n=8).

Other issues: Study is included in the systematic review by Moawad GN et al., 2017 (study 1).

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>

n=100

Mean duration of laparoscopic cervical cerclage in patients that did not have concomitant procedures: 26±4.7 minutes (range 20 to 40)

Mean blood loss: 11.9 ml (range 5 to 50)

Pregnancy outcomes

<table>
<tr><th></th><th>Prior to surgery</th><th>After surgery</th></tr>
<tr><td colspan="3">Including all pregnancies</td></tr>
<tr><td>Number of patients</td><td>100</td><td>100</td></tr>
<tr><td>Number of patients who conceived</td><td>100</td><td>82</td></tr>
<tr><td>Number of pregnancies</td><td>340</td><td>85</td></tr>
<tr><td>Number of ongoing pregnancies</td><td>0</td><td>17</td></tr>
<tr><td>Number of first trimester miscarriage <13 weeks</td><td>39</td><td>12</td></tr>
<tr><td>Number of ectopic pregnancies</td><td>0</td><td>1</td></tr>
<tr><td>Number of mid-trimester losses (14 to 27 weeks)</td><td>291</td><td>2</td></tr>
<tr><td>Number of preterm deliveries (28 to 33 weeks)</td><td>7</td><td>2</td></tr>
<tr><td>Number of preterm deliveries (34 to 36 weeks)</td><td>0</td><td>9</td></tr>
<tr><td>Number of term deliveries (≥37 weeks)</td><td>3</td><td>42</td></tr>
<tr><td colspan="3">Including only pregnancies which progressed beyond the first trimester and in which the final outcome was confirmed.</td></tr>
<tr><td>Number of pregnancies</td><td>301</td><td>55</td></tr>
<tr><td>Number of mid-trimester losses</td><td>96.7% (291/301)</td><td>3.7% (2/55)*</td></tr>
<tr><td>Number of preterm deliveries (28 to 36 weeks)</td><td>2.3% (7/301)</td><td>20% (11/55)</td></tr>
<tr><td>Number of term deliveries</td><td>1% (3/301)</td><td>76.4% (42/55)</td></tr>
<tr><td>Number of live births</td><td>1% (3/301)</td><td>96.4% (53/55)</td></tr>
<tr><td>Mean± SD gestation weeks</td><td>20.5±4.1</td><td>37.5±1.8</td></tr>
</table>

*There were 2 cases of mid-trimester losses after the procedure: 1 premature rupture of membranes and inevitable miscarriage at 18 gestational weeks, which needed laparoscopic removal of the cerclage (the patient had ultrasonographic features of adenomyosis) and 1 premature rupture of membranes with uncontrolled uterine contractions at 24 gestational weeks, which needed emergency caesarean section but the baby did not survive.

</td><td>

Perforation of the uterus: 1/100

</td></tr>
</table>

Study 4 Ades A (2015)

Details

Study type	**Non-randomised comparative study**
Country	Australia
Recruitment period	1995 to 2014
Study population and number	**n=69 (51 laparoscopic cervical cerclage, 18 open abdominal cervical cerclage)** Women with cervical incompetence treated by cervical cerclage before or during pregnancy
Age	Median 32.0 years (laparoscopy) versus 33.5 years (laparotomy), p=0.816
Patient selection criteria	Eligible women had a diagnosis of cervical incompetence and a transvaginal cerclage was deemed to be unsuitable or to pose too high a risk. The main reasons were previous extensive cervical surgery or previous failed or suboptimal transvaginal cerclage. Women with a suboptimal transvaginal cerclage had a surviving infant, but needed prolonged bed rest or hospitalisation during pregnancy, or had premature deliveries despite the transvaginal cerclage. One pregnancy that was terminated because of fetal abnormalities and 1 that ended before 20 weeks because of non-cerclage-related causes (17-week entangled monochorionic monoamniotic twins) were excluded from the study.
Technique	In the laparotomy group, all cerclages were inserted by 1 operator between 1995 and 2011. In the laparoscopy group, all cerclages were inserted by 1 operator between 2007 and 2013. In the laparotomy group, 6 (33%) cerclages were inserted during pregnancy, all between 10 and 11 weeks of gestation. In the laparoscopy group, 8 (16%) cerclages were inserted during pregnancy at an average gestation of 9.2 weeks. 11 patients in the laparoscopy group had a concomitant procedure, including excision of endometriosis, dye studies, adhesiolysis, and myomectomy.
Follow-up	**Not reported**
Conflict of interest/source of funding	Not reported.

Analysis

Study design issues: A cohort of consecutive pregnancies beyond 12 weeks in patients with laparoscopic cerclage was compared with a historical control group of 29 pregnancies in women who had a cerclage placed by laparotomy. The primary outcome was neonatal survival to 28 days of life. The secondary outcome was delivery of an infant at more than 34 weeks of gestation.

Study population issues: Before the abdominal cerclage, women in the laparotomy group had lost 25 babies, and 63 babies had been lost in the laparoscopy group. There were no statistically significant differences between the 2 groups with regard to age, the median gestation of previous deliveries or in the proportion of successful pregnancies.

Other issues: Study is included in the systematic review by Moawad GN et al., 2017 (study 1).

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 69 (51 versus 18)

Median length of hospital stay (days)
• Laparoscopy=0
• Laparotomy=4, p<0.001

Pregnancy outcomes after cerclage insertion
<table>
<tr><th></th><th>Cerclage insertion by laparoscopy</th><th>Cerclage insertion by laparotomy</th><th>p value</th></tr>
<tr><td>Gestation at delivery, weeks</td><td>37.0 (34.7 to 38.0)</td><td>36.9 (35.0 to 37.3)</td><td>0.230</td></tr>
<tr><td>Total number of pregnancies (number of babies)</td><td>54 (56)</td><td>29 (30)</td><td></td></tr>
<tr><td colspan="4">Gestation at delivery, weeks</td></tr>
<tr><td>13 to 25 +6</td><td>1 (1.9%)</td><td>0 (0%)</td><td>0.964</td></tr>
<tr><td>26 to 33 +6</td><td>8 (14.8%)</td><td>3 (10.3%)</td><td></td></tr>
<tr><td>34 to 36 +6</td><td>11 (20.4%)</td><td>7 (24.1%)</td><td></td></tr>
<tr><td>≥37</td><td>34 (63.0%)</td><td>19 (65.5%)</td><td></td></tr>
<tr><td>Number of neonates survived</td><td>55 (98%)</td><td>30 (100%)</td><td>0.542</td></tr>
<tr><td>Birthweight of neonates survived, g</td><td>3,062 (2,227 to 3,400)</td><td>3,097 (2,595 to 3,635)</td><td>0.290</td></tr>
</table>
8 women in the laparotomy group and 3 women in the laparoscopy group had consecutive pregnancies with the same cerclage left in situ.</td><td>Complications
• Laparoscopy=2.0% (1/51)
• Laparotomy=22.2% (4/18), p=0.004

Complication in laparoscopy group: 1 bladder perforation, which was repaired laparoscopically at the time of surgery.

Complications in laparotomy group: 3 intraoperative haemorrhage (no transfusions were needed) and 1 wound infection.

There were no conversions to laparotomy in the laparoscopy group.

There were no long-term complications in either group.

No perioperative miscarriages were recorded in any of the 14 patients who had cerclages inserted during pregnancy. One patient in the laparotomy group, who had fetal heart activity confirmed before discharge on postoperative day 2, was diagnosed with a miscarriage at her nuchal scan 3 weeks later. Fetal loss was estimated at 1 to 2 weeks after cerclage insertion.</td></tr>
</table>

Study 5 Bolla D (2017)

Details

Study type	**Non-randomised comparative study**
Country	Switzerland
Recruitment period	2008 to 2015
Study population and number	**n=38 (18 laparoscopic cerclage, 20 transvaginal cerclage)** **Women who had a prophylactic cerclage for cervical insufficiency**
Age	Median age: 33 years (laparoscopic group); 34 years (transvaginal group), p=not significant
Patient selection criteria	Inclusion criteria for transvaginal group: patients with a singleton pregnancy who had a prophylactic transvaginal cerclage with a McDonald suture because of cervical insufficiency. In the laparoscopic group, patients having cerclage during the first trimester of pregnancy or before pregnancy were included. The indication for laparoscopic cerclage was a history of failed transvaginal cerclage. All patients had a history or more than 2 second trimester pregnancy losses or preterm births before 34 weeks of gestation. Exclusion criteria were past pregnancy losses or preterm births caused by infection and multiple twin gestations.
Technique	Transvaginal cerclage was done using a McDonald suture with 5 mm Mersilene tape. Laparoscopic cerclage was done using a 5 mm Mersilene tape.
Follow-up	**To delivery**
Conflict of interest/source of funding	None

Analysis

Study design issues: Retrospective, non-randomised comparative study. The study focused on sonographic changes in cervical length.

Study population issues: In the laparoscopic group, 6 women had the procedure before pregnancy. For the procedures that were done during pregnancy, the mean gestational age at the time of cerclage was 11.4±1.6 weeks in the laparoscopic group and 17.5±3.2 weeks in the transvaginal group (p=0.005). 94% (17/18) of women in the laparoscopic group had a history of early miscarriage compared with 60% (12/20) of patients in the transvaginal group. 11% (2/18) of women in the laparoscopic group had a history of preterm delivery compared with 55% (11/20) of women in the transvaginal group. Prior to cerclage placement, the cervical length was similar between the 2 groups (28.6±11 mm in the laparoscopic group and 26.6±7 mm in the transvaginal group, p=not significant).

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: 38 (18 versus 20) After cerclage placement, the distance between the tape and the external os was statistically significantly shorter in the transvaginal group compared with the laparoscopic group (13.5±4.9 mm versus 31.5±8.8 mm, p<0.0001). During pregnancy, the cervical length decreased significantly after cerclage placement in the transvaginal group (from 26.6±7 mm to 13.2±7 mm at delivery, p<0.0001) but not in the laparoscopic group. 94% (17/18) of women in the laparoscopic group had an uncomplicated pregnancy course and delivered by caesarean section at 37.6±2 weeks of gestation, with a good neonatal outcome. In 1 woman, an additional transvaginal cerclage was done because of bulging of the membranes through the cervical canal after laparoscopic cerclage placement. This pregnancy ended in a miscarriage at 12 weeks of gestation. 90% (18/20) of women in the transvaginal cerclage group had an uncomplicated pregnancy and delivered spontaneously (56%) or by caesarean section (44%) at 37.2±4 weeks of gestation with good neonatal outcomes. There were 2 preterm deliveries, both with a good neonatal outcome.	

Study 6 Ades A (2018)

Details

Study type	**Prospective case series**
Country	Australia
Recruitment period	2007 to 2017
Study population and number	**n=225 patients; 121 pregnancies** **Women who had a pre-pregnancy laparoscopic cerclage for cervical insufficiency**
Age	34 years
Patient selection criteria	Indications for laparoscopic cerclage were 1 or more of the following: previous failed transvaginal cerclage (defined as a pregnancy loss despite insertion of a transvaginal cerclage), previous suboptimal transvaginal cerclage (defined when the pregnancy resulted in a live birth, but at a high personal cost – prolonged hospitalisation and bed rest during pregnancy or admission of the baby to neonatal intensive care), absent or very short cervix after surgery (<25 mm), patient request after 1 or more mid-trimester losses or extreme prematurity with a history of cervical insufficiency. Women who were pregnant at the time of the cerclage were excluded.
Technique	The laparoscopic cerclage was done using a Prolene suture (monofilament non-braided). All procedures were done with the patient under general anaesthetic.
Follow-up	**30 days after discharge**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: There were 141 recorded pregnancies in 126 women: 7 pregnancies were excluded because they ended for reasons not related to the cerclage and 13 women were pregnant at the time of submission for publication.

Study design issues: Prospective observational study in a consecutive series of women. All laparoscopic cerclages were inserted by a single surgeon. The primary outcome was neonatal survival, defined as survival 30 days after discharge from hospital. A secondary outcome was delivery of an infant >34 weeks of gestation. Surgical morbidity and complications were also reviewed.

Study population issues: The primary indication was a failed transvaginal cerclage in 66 (29.3%) patients, a suboptimal transvaginal cerclage in 32 (14.2%) patients, cervical surgery and failed transvaginal cerclage in 18 (8%) patients, cervical surgery and suboptimal transvaginal cerclage in 16 (7.1%) patients, cervical surgery and mid-trimester loss in 33 (14.7%) patients, cervical surgery without loss or cerclage in 23 (10.2%) patients, mid-trimester loss(es) with no transvaginal cerclage in 34 (15.1%) patients and preterm birth alone (≥24 weeks with surviving baby).

Key efficacy and safety findings

Efficacy

The cerclage could not be inserted in 2 patients: 1 patient had extensive endometriosis and the other had severe adhesions after an abdominal trachelectomy.

Perinatal survival rate of viable pregnancies = 98.5% (mean gestation age of 35.2 weeks at delivery)

Babies delivered at ≥34 weeks of gestation = 79.7%

Pregnancy outcomes before and after laparoscopic transabdominal cerclage insertion

Outcome	Before laparoscopic cerclage (n=402)	After laparoscopic cerclage (n=121)
Delivery 13 to 24 weeks, n (%)	235 (58.5%)	2 (1.6%)
Delivery ≥24.1 weeks, n (%)	167 (41.5%)	119 (98.4%)
Mean gestational age (weeks)	23.9±9.3	35.17±5.57
Distribution of gestational age at delivery, n (%)		
≤24 weeks	235 (58.5%)	2 (1.6%)
24.1 to 28 weeks	37 (9.2%)	4 (3.3%)
28.1 to 34 weeks	30 (7.5%)	11 (9.1%)
34.1 to 37 weeks	20 (4.9%)	41 (33.9%)
>37.1 weeks	80 (19.9%)	63 (52.1%)
Perinatal survival rate	41.5%	98.4%
Delivery after 34 weeks	24.9%	79.7%
Increase in gestational age	-	11.27 weeks

There were 2 fetal losses, which were considered to be cerclage failures. One patient delivered twins at 24 weeks of gestation. Her membranes ruptured and she went into labour and had a caesarean section to deliver the babies. One twin survived and the other died 5 days after birth. In the second patient, the membranes ruptured at 15 weeks of gestation. The cerclage was removed by laparoscopy and the fetus was delivered vaginally.

8 deliveries occurred between 24 and 34 weeks duration because of preterm labour or preterm pre-labour rupture of the membranes and the cerclages were deemed suboptimal. Nine patients had premature deliveries because of other identifiable obstetric causes.

Safety

There were no conversions to laparotomy.

Overall complication rate=1.3%

Complications

- Postoperative wound infection, n=1 (treated with antibiotics)
- Intraoperative bladder injury, n=1 (repaired laparoscopically)
- Uterine fundal perforation, n=1 (repaired laparoscopically)

Study 7 Hawkins E (2014)

Details

Study type	**Case report**
Country	US
Recruitment period	Not reported
Study population and number	**n=1** **Woman with a long-term complication of a successful laparoscopic abdominal cerclage**
Age	37 years
Patient selection criteria	Not applicable
Technique	A transabdominal laparoscopic cerclage was placed using a braided polyester suture, before conception.
Follow-up	**7 years**
Conflict of interest/source of funding	None

Case report: Vaginal erosion of abdominal cerclage

A 37-year old woman presented for laparoscopic cerclage as an interval procedure. She had previously had a transvaginal rescue cerclage placed during the early second trimester because of cervical insufficiency, which was subsequently complicated by an intra-amniotic infection and the pregnancy was terminated. With her next pregnancy, a prophylactic transvaginal cerclage was placed at 12 weeks of gestation and the pregnancy was carried to 36 weeks of gestation, but there were episodes of preterm labour and significant early cervical shortening.

On examination, before her next conception, the cervix was found to be flush with the vaginal apex. A laparoscopic cerclage was placed using a braided polyester suture. The subsequent pregnancy carried to 37 weeks of gestation and the baby was delivered by caesarean section. Three years later the woman had another successful pregnancy with caesarean delivery at 39 weeks of gestation, and the cerclage was left in place.

Three years after the second delivery, and approximately 7 years after the laparoscopic cerclage procedure, the patient reported irregular vaginal discharge, pelvic pressure and subjective fevers. On examination, erosion of the cerclage through the upper vagina was evident, with associated mucopurulent discharge. An ultrasound scan showed a complex collection measuring 2x3 cm between the junction of the lower uterine segment, the cervix and the bladder, with elements of the cerclage extending into the collection.

The vaginal portion of the suture was cut, but the suture could not be removed. The patient had oral antibiotics. Laparoscopic removal of the cerclage and drainage of the abscess was considered but the patient preferred conservative management. After 1 week, the entire remaining cerclage was expelled into the vaginal vault. A repeat ultrasound scan 1 month later showed complete resolution of the collection and symptoms had resolved.

Study 8 Gallot D (2003)

Details

Study type	**Case series**
Country	France
Recruitment period	Not reported
Study population and number	**n=3** **Women with a history of recurrent miscarriage and failed vaginal cerclage**
Age	26, 35 and 29 years
Patient selection criteria	Not applicable
Technique	All procedures were done under general anaesthesia before pregnancy as an interval procedure.
Follow-up	**To delivery**
Conflict of interest/source of funding	Not reported

3 case reports (including 1 report of uterine vessel injury)

1. 26 year old woman with a history of 1 first trimester pregnancy loss followed by 2 mid-trimester pregnancy losses (18 and 23 weeks) despite a vaginal cerclage for the last pregnancy. The operation lasted 80 minutes and blood loss was less than 100 ml. The bifurcation of the uterine artery was located by transillumination of the broad ligament using an endoscope with cold light inserted through a lateral port. The patient became pregnant within 4 months and delivered a healthy baby by caesarean section at 38 weeks of gestation.

2. 35 year old woman with a history of 5 first trimester pregnancy losses followed by 2 mid-trimester pregnancy losses despite 2 vaginal cerclages. During the laparoscopic cerclage, the bifurcation of the uterine artery was located by dissection of the anterior face of the broad ligament with a laparoscopic dissector. On 1 side, this dissection induced a vessel injury (300 ml blood loss) because of poor visualisation. The operation lasted 110 minutes, but transfusion was not needed. The patient became pregnant within 3 months. She had 2 episodes of vaginal bleeding during the first trimester. The patient was on bed rest between 33 and 38 weeks of gestation because of uterine contractions. The accurate position of the suture was checked by vaginal ultrasonography. She gave birth to a healthy baby at 38 weeks by caesarean section.

3. 29 year old woman with a history of 3 mid-trimester pregnancy losses despite 1 vaginal cerclage. The bifurcation of the uterine artery was located by dissection of the posterior face of the broad ligament just above the uterosacral ligament. The operation lasted 25 minutes and blood loss was less than 100 ml. The patient has not yet conceived.

Study 9 Moore ES (2012)

Details

Study type	**Non-randomised comparative study**
Country	US
Recruitment period	2009 to 2011
Study population and number	**n=49 (24 robotically-assisted transabdominal cervical cerclage versus 25 laparotomy transabdominal cervical cerclage)** **Women who are not pregnant who have cervical insufficiency or history of previous pregnancy loss (for robotically-assisted procedure)**
Age	Mean 33.1 years (robotically-assisted procedure)
Patient selection criteria	At least 1 of the following: previous pregnancy loss because of cervical insufficiency; a previous failed transvaginal cerclage; extreme cervical shortening with cervical insufficiency or deep cervical lacerations with cervical insufficiency.
Technique	The da Vinci Surgical System (Intuitive Surgical, US) was used for robot-assisted transabdominal cervical cerclage.
Follow-up	**Not reported**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Patients in the robotically-assisted group were followed up at least 2 months after the procedure (n=18); 12 women were contacted.

Study design issues: Non-randomised comparative study. The primary focus of the study was on the feasibility and technical details of the procedure. Limited pregnancy results were reported.

Study population issues: Four patients in the robotically-assisted group had not had a previous pregnancy loss, but elected for the procedure because of previous preterm deliveries or an extremely short (<2 mm) forniceal recess. None of the patients who had robotically-assisted cervical cerclage were pregnant at the time of the procedure. The laparotomy group included non-pregnant patients and those with singleton pregnancies, who had their procedure during the study period. The mean BMI of patients in the robotically-assisted group was 29.7±5.9 kg/m^2.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 49 (24 versus 25)

Comparison of surgery variables
<table>
<tr><td></td><td colspan="2">Robotically-assisted TAC (n=22)*</td><td colspan="2">Laparotomy TAC (n=24)**</td><td></td></tr>
<tr><td>Surgery variable</td><td>Mean</td><td>SD</td><td>Mean</td><td>SD</td><td>p value</td></tr>
<tr><td>Anaesthesia time (h:min)</td><td>2:35</td><td>00:21</td><td>1:43</td><td>00:20</td><td><0.001</td></tr>
<tr><td>Procedure time (h:min)</td><td>1:58</td><td>00:22</td><td>1:07</td><td>00:19</td><td><0.001</td></tr>
<tr><td>Length of hospital stay (h:min)^</td><td>21:28</td><td>16:33</td><td>50:08</td><td>5:31</td><td><0.001</td></tr>
<tr><td>Estimated blood loss (ml)^</td><td>50.0</td><td>50.0</td><td>150.0</td><td>100.0</td><td><0.001</td></tr>
</table>
* 2 patients were excluded: 1 procedure was converted to laparotomy and 1 patient had concurrent myomectomy
1** patient was excluded: the membranes ruptured 2 days after the procedure resulting in fetal loss, and the hospital stay included management of this situation.
^ length of stay and estimated blood loss reported as median (interquartile range)

Pregnancy status – robotically-assisted TAC
Of the 12 women in the robotically-assisted group who could be contacted, 8 were pregnant, 3 were actively pursuing pregnancy and 1 woman chose to postpone pregnancy. One pregnancy resulted in a spontaneous loss at 5 weeks; the patient has since become pregnant again.
On average, pregnancy occurred at 3.11±1.73 months after the procedure.
Of the 8 women who were pregnant, 5 had an uncomplicated pregnancy and delivered at >35 weeks of gestation, 1 had prolapse of the membranes into the cervical canal and delivered at 29 weeks, and the other 2 women await delivery.</td><td>1 robotically-assisted procedure was converted to laparotomy because of an inability to adequately insufflate the abdomen because of adhesions.

1 patient in the robotically-assisted group had postoperative pain and she stayed in hospital for 2 days. At follow-up, the patient had adhesiolysis and had treatment for a wound infection at 1 of the port sites.

1 patient in the laparotomy group had rupture of the membranes 2 days after the procedure, which resulted in fetal loss. There was another fetal loss within 9 days of the procedure.</td></tr>
<tr><td colspan="2">Abbreviations used: SD, standard deviation; TAC, transabdominal cerclage</td></tr>
</table>

Study 10 Zeybek B (2016)

Details

Study type	**Case series and systematic review**
Country	US
Recruitment period	2010 to 2016
Study population and number	**Case series: n=6; systematic review: n=16 (8 studies)** **Women who are pregnant who had robot-assisted abdominal cerclage**
Age	Case series: median 34 years (range 28 to 37); systematic review: median 31.5 years (range 25 to 37).
Patient selection criteria	Patients were offered the procedure if abdominal cerclage was indicated per the American College of Obstetricians and Gynaecologists guidelines. In 5 patients, the indication was failed vaginal cerclage in a previous pregnancy. In the remaining patient, a scarred and shortened cervix was the indication. For the systematic review, articles describing robotic cerclage in non-pregnant patients and traditional laparoscopic cerclage were excluded. Only articles published in English were included. The major indication in most of the published articles was previous failed transvaginal cerclage.
Technique	Robot-assisted transabdominal cervical cerclage. Studies included in the systematic review described the following technological advancements: indocyanine green, needleless, using a Koh cup as a vaginal fornices delineator, and transvaginal ultrasound guidance.
Follow-up	**To delivery**
Conflict of interest/source of funding	None

Analysis

Study design issues: The primary outcome measure was defined as delivery of a viable infant at 34 weeks of gestational age or more. Secondary outcome measures were gestational age at delivery, preterm labour, premature rupture of the membranes, neonatal survival after the procedure, failed abdominal cerclage, and surgical complications. Failure was defined as second trimester or any perioperative pregnancy loss within 2 weeks of the procedure.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: 6 (case series); 16 (systematic review) **Case series (n=6)** Median operating time=159.5 minutes (range 124 to 204) Median estimated blood loss=25 ml (range 10 to 25) All patients were discharged on postoperative day 1. Median gestational age at delivery=37.5 weeks (range 22 to 39) 5 patients delivered at between 36 and 39 weeks. 1 patient went into preterm labour at 22 weeks and had cerclage removal by minilaparotomy. The patient was found to have a uterine rupture close to the right uterine artery under the cerclage suture. The cerclage suture was removed and the rupture site was repaired. The patient gave birth vaginally 3 hours after the procedure but the infant did not survive because of cardiorespiratory failure. **Systematic review (n=16)** Median gestational age at delivery=37 weeks (range 33 to 39). Live birth rates=90% Rates of third-trimester delivery=90%	There were no complications in the case series. None of the procedures were converted to laparotomy. In the systematic review, 6 of the 8 articles reported no complications. In the remaining 2 articles, the following complications were reported: • 1 uterine injury in a report of 2 patients. • Conversion to laparotomy in 2 out of 7 patients. • Difficulty in accessing lower uterus in 1 out of 7 patients. • Broad ligament laceration in 1 out of 7 patients.

Validity and generalisability of the studies

- No randomised controlled trials were identified.
- There are variations in technique, including some reports of a robot-assisted procedure. Different materials may be used for the cerclage.
- The systematic review by Moawad GN et al. (2018) did not include robot-assisted cerclage placement because the authors considered the data to be too limited.[1]
- In some studies, laparoscopic cervical cerclage was done as an interval procedure in women who were not pregnant and in others it was done during pregnancy.
- Two studies compare post-procedural obstetric outcomes with pre-procedural ones. This comparison is difficult to interpret outside the context of a controlled trial, as "regression to the mean" phenomenon may be partly responsible.[3,6]
- Some studies included women who did not have a history of mid-trimester loss or premature delivery. It is possible that these patients would not have suffered loss of pregnancy, even without any cerclage. It is also possible that the outcomes may vary according to whether the procedure is done as a primary procedure (as an alternative to vaginal cerclage in women who have never had a cervical cerclage) or as a secondary procedure (after previously failed vaginal cervical cerclage).

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

NICE guidelines

- Preterm labour and birth. NICE guideline 25 (2015). Available from http://www.nice.org.uk/guidance/NG25
- Ectopic pregnancy and miscarriage: diagnosis and initial management. NICE clinical guideline 154 (2012). Available from http://www.nice.org.uk/guidance/CG154

Additional information considered by IPAC

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Three Specialist Advisor Questionnaires for laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme did not seek patient commentary for this procedure.

Issues for consideration by IPAC

None other than those described above.

References

1. Moawad GN, Tyan P, Bracke T et al. (2018) Systematic Review of Transabdominal Cerclage Placed via Laparoscopy for the Prevention of Preterm Birth. Journal of Minimally Invasive Gynecology 25: 277–86
2. Chen Y, Liu H, Gu J et al. (2015) Therapeutic effect and safety of laparoscopic cervical cerclage for treatment of cervical insufficiency in first trimester or non-pregnant phase. International journal of clinical and experimental medicine 8: 7710–18
3. Huang X, Ma N, Li TC et al. (2016) Simplified laparoscopic cervical cerclage after failure of vaginal suture: technique and results of a consecutive series of 100 cases. European Journal of Obstetrics, Gynecology, & Reproductive Biology 201: 146–50
4. Ades A, Dobromilsky KC, Cheung KT et al. (2015) Transabdominal Cervical Cerclage: Laparoscopy Versus Laparotomy. Journal of Minimally Invasive Gynecology 22: 968–73
5. Bolla D, Gasparri ML, Badir S et al. (2017) Cervical length after cerclage: comparison between laparoscopic and vaginal approach. Archives of Gynecology & Obstetrics 295: 885–90
6. Ades A, Parghi S, Aref-Adib M (2018) Laparoscopic transabdominal cerclage: Outcomes of 121 pregnancies Australian & New Zealand Journal of Obstetrics & Gynaecology 23: 1–6
7. Hawkins E, Nimaroff M (2014) Vaginal erosion of an abdominal cerclage 7 years after laparoscopic placement. Obstetrics and Gynecology 123: 420–23
8. Gallot D, Savary D, Laurichesse H et al. (2003) Experience with three cases of laparoscopic transabdominal cervico-isthmic cerclage and two subsequent pregnancies. BJOG: an International Journal of Obstetrics and Gynaecology 110: 696–700
9. Moore ES, Foster TL, McHugh K et al. (2012) Robotic-assisted transabdominal cerclage (RoboTAC) in the non-pregnant patient. Journal of Obstetrics & Gynaecology 32: 643–7
10. Zeybek B, Hill A, Menderes G et al. (2016) Robot-Assisted Abdominal Cerclage During Pregnancy. Journal of the Society of Laparoendoscopic Surgeons 20: 4 e2016.00072

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	01/10/2018	2018, Issue 9
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	01/10/2018	2018, Issue 9
HTA database (Cochrane Library)		-
MEDLINE (Ovid)	02/10/2018	1946 to October 01, 2018
MEDLINE In-Process (Ovid) &	02/10/2018	October 01, 2018
Medline ePub ahead (Ovid)	02/10/18	October 01 , 2018
EMBASE (Ovid)	01/10/2018	1974 to 2018 Week 40

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Cerclage, Cervical/
2	(cervi* adj4 (suture* or stitch*)).tw.
3	Sutures/
4	cerclag*.tw.
5	or/1-4 (
6	Uterine Cervical Incompetence/
7	(cervi* adj4 (incompeten* or weak* or short* or damage* or insufficien*)).tw.
8	exp Pregnancy Trimester, Second/
9	(trimest* adj4 second*).tw.
10	midtrimest*.tw.
11	Obstetric Labor, Premature/
12	Premature Birth/
13	((prematur* or preterm*) adj4 (birth* or deliver* or labo?r*)).tw.
14	abortion, spontaneous/ or abortion, habitual/
15	(abort* adj4 (spontan* or habitual*)).tw.
16	Miscarriag$.tw.
17	(pregnan$ adj4 loss$).tw.
18	or/6-17

19	5 and 18
20	animals/ not humans/
21	19 not 20

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Aboujaoude R, Maloof P, Alvarez M et al. (2007) A novel method for laparoscopic abdominal cerclage utilizing minimally invasive hydrodissection: a case report. Journal of Reproductive Medicine 52: 428–30	Case report n=1	A laparoscopic approach to cerclage in patients diagnosed with cervical incompetence can be done with minimal risks to the gravid uterus.	Case report without any unique adverse events.
Ades A, Aref-Adib M, Parghi S, et al. (2018) Laparoscopic transabdominal cerclage in pregnancy: A single centre experience Australian & New Zealand Journal of Obstetrics & Gynaecology 09: 09.	Case series n=18	Of 19 women who underwent laparoscopic transabdominal cerclage in pregnancy, at 6-11 weeks gestation, the perinatal survival rate was 100%. There were no complications. The average gestational age at delivery was 37.1 weeks. Sixteen women delivered after 34 weeks.	Larger studies are included.
Ades A, May J (2014) Laparoscopic transabdominal cerclage: Successful term pregnancy following radical trachelectomy. Journal of Gynecologic Surgery 30: 165-167	Case report n=1	Laparoscopic transabdominal cerclage has shown good pregnancy outcomes in patients with cervical insufficiency. This procedure can be an effective option for patients who have had trachelectomy.	Case report without any unique adverse events.
Ades A, May J, Cade TJ et al. (2014) Laparoscopic transabdominal cervical cerclage: a 6-year experience. Australian & New Zealand Journal of Obstetrics & Gynaecology 54: 117–20	Case series n=64	The perinatal survival rate was 96% with a mean gestational age at delivery of 35.8 weeks. 83% of women delivered at ≥34 weeks of gestation. There was 1 adverse intra-operative event (bladder injury), with no postoperative sequelae.	Likely to be extensive patient overlap with Ades A et al., 2015, which is included in table 2 (study 4).
Ades A, Hong P (2015) Successful laparoscopic transabdominal cerclage in uterus didelphys. BMJ Case Reports 17	Case report n=1	Laparoscopic transabdominal cerclage can be done successfully in women with uterus didelphys and a satisfactory obstetric outcome can be achieved.	Case report without any unique adverse events.

Agdi M, Tulandi T (2008) Placement and removal of abdominal cerclage by laparoscopy. Reproductive Biomedicine Online 16: 308-10	Case report n=1	This is the first reported laparoscopic abdominal cerclage and its removal by laparoscopy at 19 weeks of gestation.	Case report without any unique adverse events.
Al Fadhli R, Tulandi T. (2004) Laparoscopic abdominal cerclage. Obstetrics & Gynecology Clinics of North America 31 (3): 497–504.	Case reports n=2	One woman achieved a term pregnancy. The second woman had not yet achieved pregnancy 2 months after laparoscopic cerclage.	2 case reports without any unique adverse events.
Barmat L, Glaser G, Davis G et al. (2007) Da Vinci-assisted abdominal cerclage. Fertility & Sterility 88: 1437.e1-3	Case report n=1	Abdominal cerclage was successfully placed using the da Vinci robot. The patient had minimal blood loss and was discharged to home on the same day as surgery.	Case report without any unique adverse events.
Bolla D, Raio L, Imboden S et al. (2015) Laparoscopic Cerclage as a Treatment Option for Cervical Insufficiency. Geburtshilfe und Frauenheilkunde 75: 833–38	Case series n=18	Doing a laparoscopic cervical cerclage using a blunt grasper device with a flexible tip does not increase intraoperative complications, particularly in early pregnancy.	Small case series, which is included in the systematic review by Moawad et al, 2017 (study 1).
Brolmann HAM, Oei SG. (2000) The laparoscopic approach of the transabdominal cerclage of the uterine cervix in case of cervical incompetence. Gynaecological Endoscopy 9 (3): 191–4.	Case report n=1	The patient conceived some months later and had an uneventful pregnancy. A caesarean section was done at 37 weeks because of suspected impairment of fetal growth, a high flow resistance in the placental bed and changes on cardiocartography. A live baby was delivered (low birthweight for gestational age). The band was removed during the caesarean section as the patient did not desire any future pregnancies.	Case report without any unique adverse events.
Burger NB, Brolmann HA, Einarsson JI et al. (2011) Effectiveness of abdominal cerclage placed via laparotomy or laparoscopy: systematic review. Journal of Minimally Invasive Gynecology 18: 696–704	Systematic review 6 studies (n=135) on the laparoscopic approach, and 26 (n=1116) on the open abdominal approach	Delivery of a viable infant at 34 weeks of gestation or more varied from 78.5% (laparoscopic) to 84.8% (abdominal). Second-trimester fetal loss occurred in 8.1% (laparoscopic) vs 7.8% (abdominal), with no reported third-trimester losses (laparoscopic) vs 1.2% (abdominal). Severe bleeding (>400 ml or needing blood transfusion) did not occur in the laparoscopic groups. We conclude that abdominal cerclage is associated with excellent results as treatment of cervical incompetence, with high fetal survival rates and minimal complications during surgery and pregnancy. Further studies are	A more recent systematic review is included (Moawad et al, 2017; study 1).

		needed to differentiate which method is superior.	
Carter JF, Soper DE, Goetzl LM et al. (2009) Abdominal cerclage for the treatment of recurrent cervical insufficiency: laparoscopy or laparotomy? American Journal of Obstetrics & Gynecology 201: 111.e1-4	Non-randomised comparative study n=19	Operative laparoscopy is a safe and effective alternative to laparotomy for the placement of abdominal cerclage.	Small comparative study, which is included in the systematic review by Moawad et al, 2017 (study 1).
Cho CH, Kim TH, Kwon SH, et al. (2003) Laparoscopic transabdominal cervicoisthmic cerclage during pregnancy. Journal of the American Association of Gynecologic Laparoscopists 10 (3): 363–6.	Case series n=20	Live birth rate=95% One loss occurred after premature rupture of the membranes at 19 weeks of gestation. The fetus and products of conception were successfully removed by dilatation and curettage after the cerclage was removed laparoscopically.	Small case series, which is included in the systematic review by Moawad et al, 2017 (study 1).
Clark NV, Einarsson JI. (2016) Laparoscopic Abdominal Cerclage. Current Obstetrics and Gynecology Reports 5: 348–54	Review	Laparoscopic cerclage is a highly successful intervention for the treatment of cervical insufficiency. Continued research is needed to further define the surgical and obstetric benefits of this method.	A more recent systematic review is included (Moawad et al, 2017; study 1).
Cronin C, Hewitt M, Harley I et al. (2012) Robot-assisted laparoscopic cervical cerclage as an interval procedure. Gynecological Surgery 9: 317-321	Case reports n=2	2 women had robot-assisted laparoscopic cervical cerclage as an interval procedure, with successful pregnancies and neonatal outcomes.	2 case reports without any unique adverse events.
DaCosta V, Wynter S, Harriott J et al. (2011) Laparoscopic cervicoisthmic cerclage for the treatment of cervical incompetence: case reports. West Indian Medical Journal 60: 590–3	Case reports n=2	Laparoscopic cervicoisthmic cerclage costs less, is less invasive, has fewer complications and should replace the traditional laparotomy technique.	2 case reports without any unique adverse events.
Darwish AM, Hassan ZZ. (2002) Feasibility of laparoscopic abdominal cerclage in the second trimester. Gynaecological Endoscopy 11 (5): 327–9.	Case report n=1	Patient had an unremarkable pregnancy course and delivered a healthy baby at 37 weeks by repeat caesarean. The stitch was left in place.	Case report without any unique adverse events.
El-Nashar SA, Paraiso MF, Rodewald K et al. (2013) Laparoscopic cervicoisthmic cerclage: technique and systematic review of the literature. Gynecologic & Obstetric Investigation 75: 1-8	Case series (n=4) and systematic review (25 studies)	Laparoscopic cervicoisthmic (LCC) is feasible during and in between pregnancies as well as in congenitally malformed uteri. Current evidence suggests that LCC might be of benefit in selected cases of cervical insufficiency with short cervices.	A more recent systematic review is included (Moawad et al, 2017; study 1).
Fechner AJ, Alvarez M, Smith DH et al. (2009) Robotic-assisted laparoscopic cerclage	Case report n=1	A woman who was pregnant who had no vaginal portion of the cervix had a robotic-assisted laparoscopic	Case report, included in the systematic

in a pregnant patient. American Journal of Obstetrics & Gynecology 200: e10-1		cerclage at 12 weeks of gestation and ultimately delivered a healthy infant at term.	review by Zeybek et al., 2016 (study 9).
Foster TL, Addleman RN, Moore ES et al. (2013) Robotic-assisted prophylactic transabdominal cervical cerclage in singleton pregnancies. Journal of Obstetrics & Gynaecology 33 821-2	Case series n=7	6 patients successfully completed their pregnancy and there was 1 fetal loss. There were 2 conversions to laparotomy. The authors noted there was a consistent problem with access to the upper cervix beyond the extremely soft, enlarged uterus. The study was stopped and the authors noted that robot-assisted transabdominal cervical cerclage should be approached cautiously during pregnancy.	Small case series, which is included in the systematic review by Zeybek et al., 2016 (study 9).

Gibb D, Saridogan E. (2016) The role of transabdominal cervical cerclage techniques in maternity care. The Obstetrician & Gynaecologist 18:117–25	Review and case series (n=32)	There were no surgical complications and there was no conversion to laparotomy. There was 1 mid-trimester pregnancy loss and 1 intrauterine death. Laparoscopic cerclage before pregnancy probably offers similar chances of success compared with the open approach and has the general advantages of minimal access surgery.	A more recent systematic review is included (Moawad et al, 2017; study 1).
Ghomi A, Rodgers B (2006) Laparoscopic abdominal cerclage during pregnancy: A case report and a review of the described operative techniques. Journal of Minimally Invasive Gynecology 13: 337–41	Case report (n=1) and systematic review	Laparoscopic transcervical abdominal cerclage approach is safe and effective to pregnant patients when abdominal cerclage is recommended and offers faster patient recovery.	A more recent systematic review is included (Moawad et al, 2017; study 1).
Gremeau AS, Corvaisier M, Bourdel N, et al. (2018) Laparoscopic cervico-isthmic cerclage: About 25 cases Journal of Gynecology Obstetrics and Human Reproduction 07: 07.	Case series n=25	3 minor intraoperative complications (12%) with haemorrhage <300 ml were noted and managed intraoperatively. 21 pregnancies (68% of patients) were recorded after cerclage including 5 early miscarriages and 16 caesarean deliveries with an average time taken to conceive of 11.8 months. The overall neonatal survival rate after cerclage was 76% versus 16% before surgery ($p<0.0001$), with a 100% neonatal survival rate beyond the 1st trimester as compared to 22% before cerclage ($p<0.0001$).	Larger studies are included.
Gocmen A, Sanlikan F (2013) Two Live Births following Robotic-Assisted Abdominal Cerclage in Nonpregnant Women. Case Reports in Obstetrics and Gynecology 256972	Case reports n=2	Robotic assisted abdominal cerclage is a good alternative surgical method with successful pregnancy outcomes.	2 case reports without any unique adverse events.
Gowda SL (2016) Transabdominal cervical cerclage: Laparoscopy or laparotomy. World Journal of Laparoscopic Surgery 9: 78-81	Review 15 articles	The review concludes that if transabdominal cervical cerclage is preferred then laparoscopic approach is superior to laparotomy as it is as effective as open method with fast postoperative recovery.	A more recent systematic review is included (Moawad et al, 2017; study 1).
Gungor M, Afsar S, Ozbasli E et al. (2016) The interval robotic transabdominal cerclage in a morbidly obese patient. Journal of Robotic Surgery 10: 69-72	Case report n=1	We report the use of interval robotically assisted transabdominal cerclage procedure in a morbidly obese patient and ultimately she delivered a healthy infant at 38 weeks 2 days.	Case report without any unique adverse events.

Karaman Y, Bingol B, Gunenc Z. (2007) Laparoscopic transabdominal isthmic cerclage in a case of cervical agenesis and a successful pregnancy with ICSI. Gynecological Surgery 4: 45-48	Case report n=1	To the best of our knowledge, this is the first report of laparoscopic isthmic cerclage for the prevention of a clinical condition similar to cervical insufficiency in cervical agenesis that has resulted in a term pregnancy after ICSI.	Case report without any unique adverse events.
Kjollesdal M, Nielsen S, Stjerndahl JH, et al. (2005) Laparoscopic cervico-uterine cerclage using polypropylene mesh for the treatment of cervical incompetence. Acta Obstetricia et Gynecologica Scandinavica 84 (8): 823–4.	Case report n=1	Patient became pregnant shortly after laparoscopic cerclage was done and was able to maintain a normal level of activity during the pregnancy. Elective caesarean was done at 37 weeks gestation.	Case report without any unique adverse events.
Lee R, Biats D, Mancuso M (2017) Robotic transabdominal cerclage: a case series illustrating costs. Journal of Robotic Surgery 26	Case reports n=3	3 patients had robotically placed cerclage done before pregnancy and the results suggest it is a viable and less invasive alternative to the traditional transabdominal cerclages.	3 case reports without any unique adverse events
Lesser KB, Childers JM, Surwit EA. (1998) Transabdominal cerclage: a laparoscopic approach. Obstetrics & Gynecology 91(5 Pt 2): 855–6.	Case report n=1	A healthy baby girl was delivered by repeat caesarean at 35 weeks gestation after onset of regular contractions and the stitch was removed. The procedure was complicated by a small amount of venous bleeding from beneath the right uterine artery, which was controlled by clips and packing'	Case report without any unique adverse events.
Liddell HS, Lo C. (2008) Laparoscopic cervical cerclage: a series in women with a history of second trimester miscarriage. Journal of Minimally Invasive Gynecology 15: 342-5	Case series n=11	A laparoscopic cervical cerclage was placed before pregnancy. No intraoperative or postoperative complications were experienced. Ten of 11 women subsequently became pregnant and all delivered live babies by caesarean section in the third trimester. Laparoscopic cervical cerclage is feasible and effective.	Small case series, which is included in the systematic review by Moawad et al, 2017 (study 1).
Luo L, Chen SQ, Jiang HY et al. (2014) Successful treatment of cervical incompetence using a modified laparoscopic cervical cerclage technique: a cohort study. European Journal of Obstetrics, Gynecology, & Reproductive Biology 179: 125-9	Non-randomised comparative study n=44	This modified technique for laparoscopic cervical cerclage demonstrates good obstetric outcomes with low risk of adverse events, which may provide a reasonable alternative to achieve pregnancy success in patients with cervical incompetence.	Small comparative study, which is included in the systematic review by Moawad et al, 2017 (study 1).
Meglic L, Cavic M, Tomazevic T et al. (2017) Laparoscopic	Case series n=3	Radical vaginal trachelectomy was done in 15 patients and laparoscopic abdominal cerclage in	Larger case series are included.

abdominal cerclage after radical vaginal trachelectomy. Clinical and Experimental Obstetrics and Gynecology 44: 343-346		3 of them (21.5%). All 3 patients became pregnant and after 36 weeks of gestation delivered by caesarean section.	
Menderes G, Clark L, Azodi M. (2014) Robotic-assisted abdominal cerclage: a case report and literature review. Journal of Robotic Surgery 8: 195-200	Case report n=1	Abdominal cerclage was safely and successfully placed at 13 weeks with robotic assistance. The patient had an otherwise uncomplicated antenatal course and was delivered via primary caesarean section at 38 weeks.	Case report, included in the systematic review by Zeybek et al., 2016 (study 9)
Mingione MJ, Scibetta JJ, Sanko SR, et al. (2003) Clinical outcomes following interval laparoscopic transabdominal cervico-isthmic cerclage placement: case series. Human Reproduction 18 (8): 1716–9.	Case series n=11	Live birth rate = 83% (10/12) In 1 woman, the procedure was complicated by an initially unrecognised penetrating small bowel injury that occurred during lysis of extensive adhesions involving the bowel and uterus. Subsequently, the patient developed a pelvic abscess that was treated with CT-guided drainage and intravenous antibiotics.	Small case series, which is included in the systematic review by Moawad et al, 2017 (study 1).
Moawad GN, Abi Khalil ED, Samuel D. (2016) Robotic Cerclage in Advanced-stage Endometriosis. Journal of Minimally Invasive Gynecology 23: 1026-1027	Case report n=1	A robotic-assisted abdominal cerclage can be done safely and effectively in patients with advanced-stage endometriosis.	Case report, included in the systematic review by Zeybek et al., 2016 (study 9)
Moria A, Aljaji N, Miner L et al. (2012) Abdominal cerclage after failed transvaginal cervical cerclage. Gynecological Surgery 9: 219-222	Non-randomised comparative study n=20	Of 18 pregnancies, 16 resulted in a live birth (89%). Abdominal cerclage in women who have failed a transvaginal cervical cerclage is associated with a high live birth rate.	Larger or more recent studies are included.
Murray A, Hutton J. (2011) Successful tubal blastocyst transfer after laparoscopic cervical cerclage: cesarean delivery of a live very low-birth-weight infant and later hysterectomy for uterine rupture. Fertility & Sterility 96: 895-7	Case report n=1	An intrauterine pregnancy occurred after blastocyst intrafallopian transfer, but there was uterine herniation necessitating premature delivery of a very low-birth-weight infant that had lung problems but is now healthy. The mother later developed a haematometra that ruptured, needing an emergency hysterectomy from which her recovery was protracted.	Case report of tubal blastocyst transfer after laparoscopic cerclage.
Pawlowicz P, Ordon W, Malinowski A. (2009) Laparoscopic abdominal cervical cerclage before conception--case report. Ginekologia Polska 80: 949-52	Case reports n=2	Laparoscopic cervical cerclage is a less invasive technique with acceptable outcome, which could replace the traditional laparotomy technique.	2 case reports without any unique adverse events.
Pawlowicz P, Uchman-Musielak M, Hincz P et al.	Case report	A 38-year-old patient with a history of recurrent miscarriages, with the	Case report without any

(2012) Preconception laparoscopic transabdominal cervicoisthmic cerclage (TAC) placed in older women. Przeglad Menopauzalny 16: 51-53	n=1	diagnosis of cervical incompetence, in whom transvaginal cerclage was not technically possible had a preconception laparoscopic transcervical abdominal cerclage. The patient became pregnant 2 months later and she gave birth at term by caesarean section to a healthy baby girl.	unique adverse events.

Pereira RM, Zanatta A, de Mello Bianchi PH et al. (2009) Successful interval laparoscopic transabdominal cervicoisthmic cerclage preceding twin gestation: a case report. Journal of Minimally Invasive Gynecology 16: 634-8	Case report	A 36-year-old patient, gravida 1, para 0, aborta 1, had interval laparoscopic cerclage after a previous failed transvaginal emergency cerclage done in the second trimester. Hysteroscopic metroplasty was concomitantly done for an incomplete septate uterus. The patient became pregnant with twins 3 months later after in vitro fertilization. The gestational course was uneventful, and the patient delivered 2 healthy neonates at 38 weeks gestation by elective caesarean section. The cerclage tape was left in situ.	Case report without any unique adverse events.
Raghuwanshi SR, Shashikala ST, Rao KA. (2011) Repeat Transabdominal Laparoscopic Encerclage. International Journal of Infertility and Fetal Medicine 2: 81-84	Case report n=1	Repeat laparoscopic abdominal encerclage can be done safely in a patient who had term pregnancy following laparoscopic abdominal cerclage using a simple instrument suture passer without any postoperative complication or discomfort to the patient.	Case report without any unique adverse events.
Reid GD, Wills HJ, Shukla A et al. (2008) Laparoscopic transabdominal cervico-isthmic cerclage: a minimally invasive approach. Australian & New Zealand Journal of Obstetrics & Gynaecology 48: 185-8	Case series n=3	Laparoscopic cervical cerclage proved technically feasible and safe for a surgeon trained in laparoscopic suturing methods.	Larger case series are included.
Riiskjaer M, Petersen OB, Uldbjerg N et al. (2012) Feasibility and clinical effects of laparoscopic abdominal cerclage: an observational study. Acta Obstetricia et Gynecologica Scandinavica 91: 1314-8	Case series n=52	Laparoscopic abdominal cerclage is a feasible and safe procedure. Obstetrical outcomes are encouraging but prospective studies are needed to define the effectiveness of the laparoscopic cerclage compared with the traditional transvaginal approach.	Retrospective case series, which is included in the systematic review by Moawad et al, 2017 (study 1).
Scibetta JJ, Sanko SR, Phipps WR (1998) Laparoscopic transabdominal cervicoisthmic cerclage. Fertil Steril 1998; 69:161–3	Case report n=1	Patients believed to need a transabdominal cerclage may have a laparoscopic interval procedure, obviating the need for a laparotomy before or during pregnancy.	Case report without any unique adverse events.
Shaltout MF, Maged AM, Elsherbini MM et al. (2017) Laparoscopic transabdominal cerclage: new approach. The Journal of Maternal-Fetal & Neonatal Medicine 5: 600–4	Case series n=15	A modified laparoscopic technique was used. There were no intraoperative or postoperative complications. 12 patients delivered vaginally with the removal of the cerclage, 2 had caesarean sections because of breech presentation and 1 had surgical evacuation. The modified technique was considered to be a good alternative to the traditional one.	Larger case series are included.

Shin JE, Kim MJ, Kim GW et al. (2014) Laparoscopic transabdominal cervical cerclage: Case report of a woman without exocervix at 11 weeks gestation. Obstetrics & Gynecology Science 57: 232-5	Case report n=1	Laparoscopic cervical cerclage during pregnancy can be safe and effective treatment for well-selected patients with cervical incompetence and eliminates the need for open laparotomy.	Case report without any unique adverse events.
Shin SJ, Chung H, Kwon SH et al. (2015) The Feasibility of a Modified Method of Laparoscopic Transabdominal Cervicoisthmic Cerclage During Pregnancy. Journal of Laparoendoscopic & Advanced Surgical Techniques. Part A 25: 651-6	Case series n=80	The successful pregnancy rate was 90% (72/80 pregnancies), with a mean gestational age of 36.3+/-2.7 weeks.	Retrospective case series, which is included in the systematic review by Moawad et al, 2017 (study 1).
Sifakis S, Kaminopetros P, Kappou D et al. (2012) Successful term pregnancy in a patient with cervicovaginal fistula managed with transabdominal laparoscopic cervical cerclage. Journal of Obstetrics and Gynaecology 32: 700-701	Case report n=1	The patient had a successful term pregnancy outcome, after cervicovaginal fistula was detected in the first trimester and managed with laparoscopic transabdominal cervical cerclage.	Case report without any unique adverse events.
Singh SS, Mayo JP, Leyland NA (2008) Laparoscopic cervical cerclage. Journal of Obstetrics & Gynaecology Canada: JOGC 30: 459	Case report n=1	The patient had an interval (non-pregnant) laparoscopic cervical cerclage and delivered a healthy infant by caesarean section a year later. The cerclage remains in place.	Case report without any unique adverse events.
Sneider K, Christiansen OB, Sundtoft IB et al. (2017) Recurrence rates after abdominal and vaginal cerclages in women with cervical insufficiency: a validated cohort study. Archives of Gynecology & Obstetrics 295: 859-866	Non-randomised comparative study n=140 (20 abdominal cerclage)	Abdominal cerclage was associated with a lower rate of preterm delivery than a prophylactic vaginal cerclage in the second and third pregnancies.	Results were not presented separately for laparoscopic cerclage.
Tulandi T, Alghanaim N, Hakeem G et al. (2014) Pre and post-conceptional abdominal cerclage by laparoscopy or laparotomy. Journal of Minimally Invasive Gynecology 21: 987-93	Review 16 studies	The rates of third-trimester delivery and live birth after laparoscopic cerclage are high and comparable to those by laparotomy. The efficacy of the procedure done either before or during pregnancy is similar. Abdominal cerclage done before conception is more practical than after conception. With the inherent advantages of laparoscopy over laparotomy, abdominal cerclage done by laparoscopy is preferable, in particular when done in women who are not pregnant.	A more recent systematic review is included (Moawad et al, 2017; study 1).

Tusheva OA, Cohen SL, McElrath TF et al. (2012) Laparoscopic placement of cervical cerclage. Revue Obstetricale et Gynecologique 5: e158-65	review	A laparoscopic approach may be superior to the transabdominal approach in terms of surgical outcomes, cost, and postoperative morbidity.	A more recent systematic review is included (Moawad et al, 2017; study 1).
Vissers J, van Kesteren PJM, Bekedam DJ. (2017) Laparoscopic abdominal cerclage during pregnancy: Report on two cases using a McCartney tube. Journal of Obstetrics and Gynaecology 37: 383-384	Case reports n=2	Laparoscopic cerclage during pregnancy is a challenging procedure and use of a McCartney tube for uterine manipulation may increase its feasibility.	2 case reports without any unique adverse events.
Vousden NJ, Carter J, Seed PT et al. (2017) What is the impact of preconception abdominal cerclage on fertility: evidence from a randomized controlled trial. Acta Obstetricia et Gynecologica Scandinavica 96: 543-546	RCT (19 transabdominal versus 48 transvaginal cerclage)	There was no significant difference in the time taken to conceive following transabdominal cerclage compared to controls.	It is unclear how many, if any, of the transabdominal procedures were done by laparoscopy.
Whittle WL, Singh SS, Allen L et al. (2009) Laparoscopic cervico-isthmic cerclage: surgical technique and obstetric outcomes. American Journal of Obstetrics & Gynecology 201: 364.e1-7	Cohort study n=65	The findings suggest that the cervico-isthmic cerclage placed laparoscopically compares favourably with the traditional laparotomy approach.	Study is included in the systematic review by Moawad et al, 2017 (study 1).
Wolfe L, DePasquale S, Adair CD et al. (2008) Robotic-assisted laparoscopic placement of transabdominal cerclage during pregnancy. American Journal of Perinatology 25: 653-5	Case reports n=2	Two women had successful treatment with robotic-assisted laparoscopic placement of transabdominal cerclage in pregnancy.	2 case reports, included in the systematic review by Zeybek et al., 2016 (study 9).
Zanatta A, de Carvalho BR, Amaral K et al. (2015) Laparoscopic interval isthmocervical cerclage with cardiac tape in a patient with previous cervical amputation. Journal of Minimally Invasive Gynecology 22: 536-7	Case report n=1	Cotton cardiac tape is feasible for laparoscopic cerclage and can be used as an alternative to the commonly used Mersilene tape (Ethicon). Laparoscopy safely allows tape placement medial to the uterine vessels.	Case report without any unique adverse events.
Zanconato G, Bergamini V, Baggio S et al. (2015) Successful Pregnancy Outcome after Laparoscopic Cerclage in a Patient with Cervicovaginal Fistula. Case Reports in Obstetrics and Gynecology 784025	Case report n=1	The report describes a successful term pregnancy in a patient with a history of recurrent late miscarriage due to a large cervical fistula of traumatic origin, connecting the uterine cavity and the posterior vaginal fornix. A combined approach of laparoscopic cerclage and transvaginal fistula repair effectively restored cervical	Case report without any unique adverse events.

		competence and created the conditions for a viable birth in a subsequent pregnancy.	
Zeybek B, Borahay M, Kilic GS (2016) Overcoming the obstacles of visualization in robotically assisted abdominal cerclage using indocyanine green. Journal of Robotic Surgery 10: 361-364	Case report n=1	A near infrared camera system was used, which is a relatively new modality in robotics. Indocyanine green dye was used to help to visualise vascular anatomy during a robotic cerclage procedure in a pregnant patient.	Case report, included in the systematic review by Zeybek et al., 2016 (study 9).