

# **Research Article**

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# Pre-Pregnancy Transvaginal Double Cervico-Isthmic Cerclage To Treat Women With Previous Conventional Failed Cerclage For Cervical Insufficiency: A Novel Modification of Treatment

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#### Abstract

**Objective:** To report pregnancy outcome following a pre-pregnancy transvaginal cervico-isthmic cerclage using a double non-absorbable synthetic polyester thread in a population of high-risk pregnant women.

**Methods:** A retrospective descriptive study with a continuous series of 76 women presenting with at least one prior prophylactic failure of McDonald cerclage and submitted a pre-gestational transvaginal cervico-isthmic cerclage by the same surgical team between 2010 and 2019. The pregnancy outcome was analyzed for the first subsequent pregnancy of 64 women. The main outcome measure was the overall survival rate.

**Results:** The median age of the patients was 30 years (SD 4.9; range 19-45 years). No intra-operative complication occurred. The median operating time was 39.8 minutes (range 35.5-55.8 min). Cesarean delivery was systematically performed in all patients. The mean gestational age at delivery was 35.5 weeks (SD 5.67; range 16-39 weeks), term birth rate ( $\geq$ 37 weeks) was 64.1%; 84.4% of babies were delivered at  $\geq$ 34.0 weeks gestation. The overall neonatal survival rate was 94%.

**Conclusion:** The pre-conceptional transvaginal cervico-isthimic cerclage here described as Shirodkar-Barini surgery is safe and results in high percentage of live born babies and low prematurity rate on the following pregnancy, in the patients with heavy obstetrics past suggestive of cervical incompetence and previous prophylactic McDonald's failure.

**Keywords:** Cervical cerclage, Cervical incompetence, Cerclage techniques, Pre-pregnancy cerclage, Shirodkar, Spontaneous preterm birth, Transvaginal cerclage.

## 1. Introduction

Uterine cervical incompetence (UCI) is one of the causes of extreme prematurity and perinatal death. It is estimated that 1% of pregnant population have this condition [1]. Classical clinical manifestation includes painless extreme premature delivery of live fetus, painless cervical dilatation during second trimester followed by rupture of membranes, amniotic ascending infection, and delivery. Most women have no history of previous uterine cervical manipulation such as dilatation for curettage, hysteroscopy, and more recently electric loop excision for intraepithelial cervical

pathology. This makes every pregnant woman as a potential carrier for this condition. Special attention for cervical changes during the second trimester of pregnancy should be part of standard prenatal care if one wants to identify undiagnosed cases.

Cervical cerclage has been the primary treatment for UCI, since it was described independently in the late 50's by Shirodkar and MacDonald [2,3]. The main difference between these two technics is that MacDonald suture is placed around the cervix as close as possible to the reflection of vaginal mucosa over the cervix. Shirodkar requires vaginal mucosa dissection and cranial displacement to allow positioning of the sutures as high as the insertion of uterosacral and parametrial ligaments, closely related to the internal cervical opening, with suture of vaginal mucosa. Both technics require suture removal at term to allow vaginal delivery. In women with cervical insufficiency, the recurrence rate of second trimester delivery was estimated in 30% after a prophylactic vaginal cerclage, using the McDonald or Shirodkar techniques [4].

The main objective of this study was to report the outcome of a group of patients that underwent a modified Shirodkar surgery before pregnancy, focusing on those failed cases of at least one cervical cerclage (MacDonald). The authors present a novel surgical technique and propose the cerclage to be performed before pregnancy, with double sutures placed close to the internal os and left totally under the vaginal mucosa. This indicates that delivery should be performed by cesarean section, with the possibility of leaving sutures placed for subsequent pregnancies (originally known as definitive cerclage). Note that all cases must have at least one failed cerclage to eligible for this proposed surgery.

#### 2. Materials and Methods

This retrospective observational study in a consecutive series of women was conducted at the Department of Obstetrics and Gynecology, State University of Campinas (UNICAMP), Campinas (SP, Brazil). Data used for this analysis were extracted using an active search in the medical records of the Clínica Dr. Ricardo Barini (located in the city of Campinas (SP, Brazil) and at the Hospital da Mulher Prof. Prof. Dr. José Aristodemo Pinotti (CAISM) from the State University of Campinas (UNICAMP) for the identification of all patients who underwent preconceptional cerclage by vaginal route. All operations were performed by R.B. and/or I.N.M., who are both experienced in these procedures.

#### 2.1 Inclusion Criteria

• Women with a clinical diagnosis of cervical insufficiency with previous prophylactic classic (McDonald and variations) cerclage failure defined as a history of at least one previous failure of the cervical cerclage to avoid preterm births in the second trimester of gestation, who performed the uterine cerclage outside of a pregnancy by the surgical technique described here, between January 2010 and December 2019, and get pregnancy subsequently. Only data from the first pregnancy after the proposed surgical treatment proposed here was analyzed.

#### 2.2 Exclusion Criteria

Multiple gestation, age younger than 18 years, previous failure emergency cerclage without any prophylactic cerclage failure, previous uterine cervical amputation, lack of delivery information (gestational age at delivery, mode of delivery, obstetrical detailed history, and pregnancy outcomes).

#### 2.3 Ethics

Approval for the study was granted by the Institutional Ethics Committee (CAAE number 1.848.513), and all procedures were performed in accordance with the 1964 Helsinki Declaration. Informed consent was obtained from all study participants.

### 2.4 Description of the surgical technique performed

- All procedures were conducted under regional anesthesia with the patient in the dorsal lithotomy position. Before the procedure, prophylaxis of 1-gram (g) cefazolin sodium was applied, vaginal and perineal chlorhexidine was used for surgical antisepsis. Vaginal valves were used to expose the cervix that was gripped by a Sims retractor.
- After cervical arteries ligation at 3 and 9 hours with Polyglactin threads (Vicryl<sup>™</sup> Ethicon − São Paulo, Brazil), anterior and posterior colpotomy were performed (with semicircular incisions transversally), with mucosal detachment up to the reflection of the bladder mucosa and parametrium levels (Figure 1).
- A non-absorbable synthetic polyester thread Ethibond number 5 (ETHIBOND EXCEL™ Ethicon São Paulo, Brazil) suture was placed around the cervix, with a hysterometer positioned in the cervical cavity. The knot is placed medially at 12 o'clock. A second stitch was placed just above (0.5 − 1.0 centimeters cranially) the first, following the same technique. The sutures were placed at the level of the meeting of the uterosacral ligaments with the cervix, determined by digital palpation (Figure 2).
- Finally, anterior and posterior colporrhaphy with Polyglactin threads 0 (Vicryl<sup>TM</sup> Ethicon São Paulo, Brazil). Transvaginal ultrasound image will show sutures placed at uterine isthmus (Figure 3) Patients were able to attempt pregnancy two months after surgery.

Authors propose this to be called Shirodkar-Barini technic.

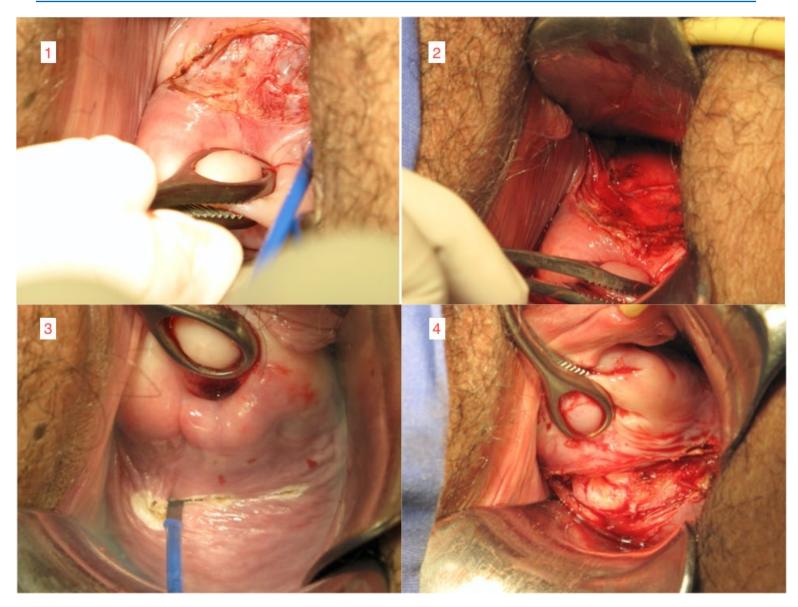


Figure 1

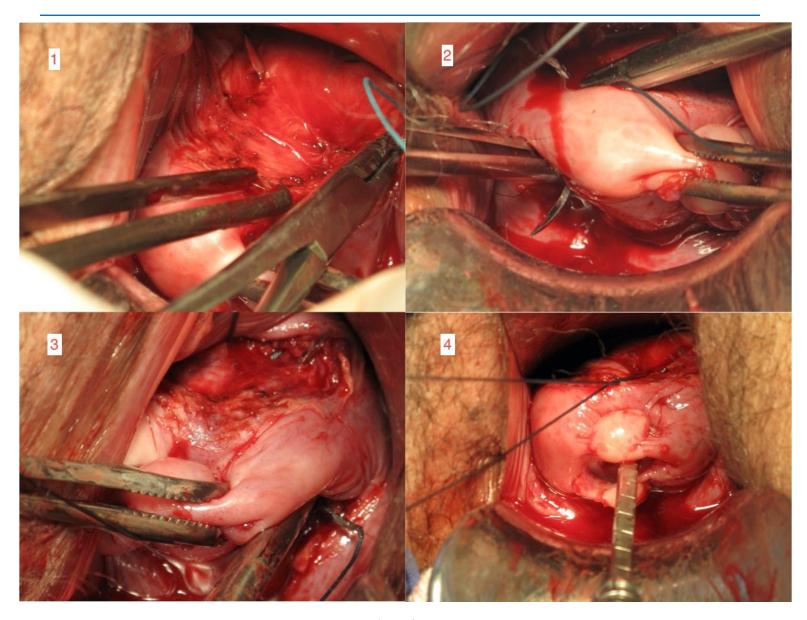


Figure 2

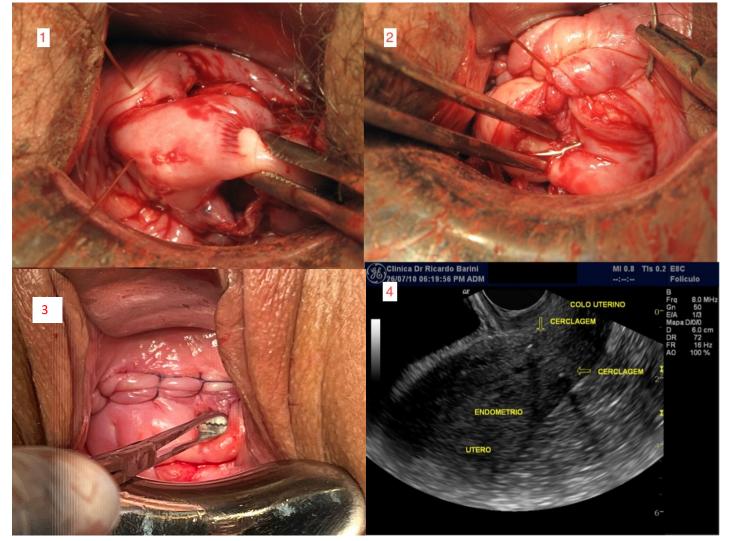


Figure 3

#### 2.5 Outcomes

The primary outcome was neonatal survival, defined as survival 30 days after discharge from hospital. The secondary outcomes were delivery of an infant at ≥34 weeks gestation, gestational age and birth weight at delivery. Surgical morbidity and complications were also evaluated.

During the subsequent pregnancy, the women had their prenatal care and delivery according to their local obstetricians' protocols and maternity hospitals' practices.

#### 2.6 Statistical Analysis

Analysis of the data obtained in the study was made using the SAS System for Windows 13.0 software (Statistical Analysis System; SAS Institute Inc, 2002-2008, Cary, NC, USA). Descriptive statistics of categorical and numerical variables were presented with values of absolute frequency (n), percentage (%), mean values, standard deviation, minimum and maximum values, median and quartiles.

#### 3. Results

After applying the described inclusion and exclusion criteria, the study included a total of 76 women who get pregnant after pre conceptional vaginal cerclage during the study period, at a mean women age of 30 years (SD 4.9; range 19-45 years) at the surgical time. The mean of the time interval between surgery and subsequent pregnancy was 8.7 months (SD 7.1; range 3-40 months).

The clinical characteristics of the study population are shown in Table 1. Most of the patients recruited had no children alive (89%; n=67) and 76.7% (n=58) of the patients had a medical history of at least one previous late miscarriage (the others 23.3% had deliveries at the beginning of the third trimester). The mean of the gestational age of births (abortions and premature deliveries) of the previous pregnancies was 21.5 weeks (SD 3.24; range 12-30 weeks).

The median operating time was 39.8 minutes (range 35.5-55.8 minutes), and hospitalization time was 24 hours for all women. A total of 7 complications were identified during surgeries (9.58%), with no need for further interventions or increased length of

hospital stay: 2 cases of utero-vesical hematoma; 2 cases with abnormal bleeding during anterior or posterior colpotomy; 1 retro cervical hematoma, 1 urinary retention, 1 vaginal wall suture required. No bowel or bladder injuries, infection or abnormal/long

vaginal bleeding were reported in the postoperative period. No serious adverse events (no cases of intensive care unit admission, sepsis, or cardiorespiratory distress) occurred. The length of hospitalization was one day for all the women.

Numerical variable	Mean	Standard Deviation	Minimum	Maximum
Age at the surgical time	30.42	4.97	19	45
Body Mass Index (BMI)	26.44	4.84	18.9	40.68
Previous abortions	1.53	1.25	0.0	7.0
Parity	1.01	0.95	0.0	4.0
Living children	0.1	0.3	0.0	1.0
Previous cerclages	1.3	0.57	1.0	4.0

Table 1: Descriptive analysis of the study population (n=76).

Of the total 76 pregnant women, 9 ended in first trimester miscarriages (11.8%). Two of 67 women underwent cesarean delivery at 28- and 29-weeks' gestation due to severe pre-eclampsia (1 associated with severe fetal growth restriction and 1 associated with HELLP Syndrome). Other C-section was indicated for an ARS (acute respiratory syndrome) maternal complication at 35 weeks of gestation. The 9 abortions and the 3 elective preterm deliveries were further excluded from the sample.

Among clinical complications during pregnancies, it was observed 3 cases of gestational diabetes, 3 of hypertensive disorders, 3 of urinary tract infection, in addition to the case already excluded from Covid-19 infection.

The mean gestational age at delivery for the 64 remaining pregnancies included in the final analysis was 35.5 weeks (SD 5.67; range 16-39 weeks). The gestational age at delivery birth

occurred at full-term ( $\geq$ 37 weeks) in 41 patients (64.1%) and after 34 weeks in 54 patients (84.4%).

Of the 64 total pregnancies outcome, 61 deliveries were cesarean sections, 1 vaginal delivery and 2 late abortions. The mean birth weight was 2766 gram (SD 860; range 200-4045 gram), with 48 newborns weighing more than 2500 gram (78.7%).

In this group, urgent cerclage after shortening of the cervix was subsequently required in 6 pregnancies (9.4%), 3 of them managed to carry the pregnancy to the end of the third trimester (35, 37 and 38 weeks of gestation), 1 prolonged the pregnancy for 5 weeks (from 23 to 28 weeks of gestation) and the remaining 2 pregnancies ended soon after the rescue cerclage (19 and 24 weeks of gestation). The summary of the 10 pregnancies with births below 34 weeks, considered as surgical treatment failure rate (15.6%), is presented in Table 2. The overall neonatal survival rate was 95.3% (61/64).

Number case	Year (Surgery)	Gestational age	Clinical appearance	Neonatal outcome
		<= 28 weeks		
1	2014	16	PROM	Late abortion
2	2015	19	Cervical Shortening + Emergency Cerclage + PROM	Late abortion
3	2013	24	Prolapse of the membranes + Emergency Cerclage + PROM	Neonatal death, 600g
4	2017	25	PROM (22 weeks)	C-section, 930g, alive.
5	2016	28	Prolapse of the membranes + Emergency Cerclage (18 weeks)	C-section, 1120g, alive.
		29-33 weeks		
6	2013	29	Cervical Shortening (22 weeks)	C-section, 1445g, alive.
7	2015	31	PROM 31 weeks	C-section, 1595g, alive.
8	2012	31	Preterm labor	C-section, 1610g, alive.
9	2017	32	PROM 28 weeks	C-section, 1680g, alive.

10	2011	33	Gestational diabetes >> fetal macrossomia >> Preterm labor	C-section, 4045g, alive.
			111111111111111111111111111111111111111	

PROM: Premature Rupture of Membranes

Table 2: Description of the pregnancy's cases with premature births below 34 weeks (n=10).

#### 4. Discussion

Despite more than 70 years of the original surgical description of cervical cerclage there is no consensus in the literature regarding diagnosis of cervical incompetence, surgery indication, surgical technic and pregnancy outcome for patients treated surgically for cervical incompetence. Cochrane review indicates that although cervical cerclage seems to reduce preterm birth and neonatal death, there is still no definite answers when compared to clinical interventions, either progesterone or pessary [5]. Supported by some authors and in agreement with Canadian Fetal Maternal Committee, our position is in favor of indicating surgery intervention to prevent preterm birth [6].

There is also a great disagreement in the literature regarding diagnosis of cervical incompetence. While some claim that clinical history remains gold standard, others consider that cervical measurement, painless passing of Hegar number seven device through the cervix to the most important diagnostic tool. Nowadays, transvaginal ultrasound during pregnancy has added one more way to identify cervical incompetence, whether by cervix length or by confirming cervical morphologic changes of its internal opening.

The group we present in this study has restrictively been recruited based on clinical history of previous extreme preterm delivery, especially with live born fetus, painless cervical dilatation and at least one previous loss with the use of cerclage during pregnancy. We understand that this strict patient selection excludes other confounding preterm birth causes and segregates a more homogeneous population and a higher risk preterm birth group of patients. Besides, we would like to emphasize the fact that all patients included had a previous history of cervical cerclage and one quarter of this group had more than one procedure without success. Previous studies with this same selected population (failures in previous cerclages) had been published, both differ from ours in the technique and surgical time. They included transvaginal cervical-isthmic cerclage with polypropylene sling placement, or a single polypropylene tape and classic McDonald technique, but all of them described cerclage outcome performed during gestation [7-9].

As our primary outcome, the data obtained in this study demonstrated a total postnatal survival of 95% after Shirodkar-Barini surgery conducted because of cervical incompetence with prior prophylactic McDonald cerclage failure. This rate is comparable to the overall survival rate of 94% after a cervical-isthmic cerclage with a polypropylene sling placed during pregnancy for both women with (n=44) and without (n=10) previous failed cerclage [7]. The rate found is also comparable

to a take-home baby rate of 95% after abdominal cerclage during pregnancy (4) and 98% reported for a pre-pregnancy abdominal laparoscopic cerclage study [10]. A survival rate of 100% was achieved after pre-pregnancy transabdominal cerclage in a series of 37 non-selected women group (patients with a single second trimester loss, even in the absence of a history typical for cervical incompetence or without a prior transvaginal cerclage [11].

One can argue what the pros and cons of both methods. Abdominal route requires perform two laparotomies (one to place the cerclage and another in the time of cesarean section), besides additional intrinsic risks of fetal loss related to the procedure. Pre-pregnancy laparoscopic cerclage requires general anesthesia and one may not be sure of the strength that can be placed to the knots when placing cervical sutures, leading to dysmenorrhea, infertility, and technical difficulties for emptying uterine contents in the case of early abortion. In contrast, pre-pregnancy vaginal procedure can have an hysterometer inserted to make sure internal cervical opening will not be closed or too open, avoiding the disadvantages mentioned above. Other concerns to be discussed are related to health-economic impact and associated morbidity.

As primary outcome, our take-home baby rate of 95% was higher than one showed for a transvaginal cervical-isthmic cerclage during pregnancy study of 77% [9]. In this aforementioned study, 4 out of 6 cases of perinatal deaths (67%) were associated with chorioamnionitis, demonstrating a possible superiority of pregestational techniques regarding infectious risks.

There was no serious adverse outcome in this group of patients, either for the surgery itself (intraoperative), nor for the next to the procedure pregnancy (immediate postoperative). Such non-serious above-mentioned adverse events have never been described in previous studies, in which only severe complications were reported. The 24-hours length of hospital stay could be considered an important advantage over other techniques. The surgical time of 39.8 minutes (range 35-55 minutes) was very similar to that described for other transvaginal cervical-isthmic cerclages but carried out during pregnancy (36.9 minutes in Moez 2015; 31 minutes in Deffieux 2011 [7,9]. From a surgical technique point of view, our results showed that this new surgical approach was safe and feasible to be used in this group of patients.

Regarding the gestational age at delivery, for this group of 64 patients, the mean gestational age at delivery was 35.5 weeks, with a success rate in preventing preterm delivery of 64% (≥37 weeks). This is comparable to the 66% and 69% of term-delivery rate reported on 45 classic McDonald technique and 85 cervical-isthmic cerclages with polypropylene sling, respectively [8]. A worse term

delivery rate of 57% was showed for the 26 transvaginal singletape cervical-isthmic cerclages placed during pregnancy described by Moez et al. 2015 [9].

Deliveries after 34 weeks occurred in 84.4% in our cases, which could mean that the procedure was effective in preventing extreme pre-term births. Reported rate of 54% of deliveries after 34 weeks for women with high vaginal cerclage and 61% for low vaginal cerclage, both placed during pregnancy were shown [12]. The same rate of 54% was found in a large and national tertiary fetal-maternal medicine unit for 39 patients who had prophylactic cerclage between 9 and 24 weeks of gestation [13]. Comparing with the pre-pregnancy abdominal laparoscopic cerclage, the reported rate reached 79%, which can be considered very similar to our results [10].

Ten patients delivered before 34 weeks and need further consideration. Nine of them can be considered absolute failure of the procedure, due to cervical dilatation, membranes exposure to vaginal ambience, ascending inflammation, or infection, with consequent rupture of membranes. Despite the failure, six patients in this group had a live born take-home baby. The remaining case in this group was a patient that developed gestational diabetes and fetal macrossomia, delivering a very large for gestational age by with 4045 g at 33 weeks' gestation after preterm labor onset. This macrossomia could be isolated considered a strong risk factor for prematurity, and not be considered a "real failure" of the proposed surgical procedure.

Three patients ended pregnancy at second trimester and those are the ones that didn't have a surviving infant. All of them required removal of the sutures to allow uterine evacuation, which was achieved spontaneously soon after it. All patients recovered without permanent health issues due to the sequence of procedures. All were advised to attempt pregnancy and undergo abdominal cerclage during nest pregnancy. One of them opted for uterine surrogacy and two of them went pregnant with abdominal cerclage during pregnancy with live born babies.

Closer examination of the results revealed these 3 non-live babies (2 stillborn and 1 neonatal death) are included in cases whose pregestational surgeries were performed in the first half of the study (2013, 2014 and 2015). In addition, in the last 2 years of the study (and in fact, so far) we have not had any births <34 weeks and we have had no fetal or neonatal loss in the last 6 years, which is likely to be associated with greater team surgical experience.

Regarding the need for subsequent rescue cerclage, our results (9.4%) were similar to those observed in a group with high vaginal cerclage technique published in a recent multicenter study (10.2%) [12].

It must also be emphasized that most pregnancies evaluated were not under medical supervision by the same staff that assisted surgical procedures during the subsequent pregnancy studied here. Which means that the prenatal follow-up of patients included in this study was neither homogeneous nor controlled, and it can be pointed out as a possible uncontrolled bias.

Another point to be observed is that after our vaginal Shirodkar-Barini surgery a c-section delivery is mandatory. This is also true for all other abdominal technics. Although not evaluated, most woman refer to be more confident with a previous procedure then a during pregnancy one. It can also be argued that in some cases cervical cerclage can be left on site for more than one pregnancy if sutures are in position and no cervical dilatation occurred before birth.

We do need to acknowledge some limitations in our study. First, we recognize that it was an observational study. However, a randomized controlled trial comparing the results of this surgery with no intervention is an ethical challenge, considering that the recurrence rate of untreated cervical insufficiency may be as high as 72% [4]. Another limitation is the lack of data about progesterone supplementation, ethnicity, social class, alcohol, and smoking habits. They could be pointed as potential confounders. Finally, while our study included a relatively few patients, we believe that the strict selection of our cases, decreasing possible bias related to the validity of our results.

As another consideration to be discussed is the fact that all the operations were performed by the same surgeons. This provides consistency of surgical technique and expertise. However, we are not able to assess the outcomes of the procedure by multiple surgeons or institutions. In addition, we have not compared the use of different types of sutures, such as the Mersilene tape used by other surgeons. Our study did not aim to compare surgical techniques, and we believe that this comparison is an arduous task, as it involves different sutures, threads, other materials, and surgical instruments.

We think that in these women with a strict past obstetrics suggestive of cervical incompetence, which a McDonald's failure, associated with the presence of favorable local technical conditions, it seems legitimate to recommend the alternative surgical approach presented here. In other anatomic unfavorable conditions, such as extreme short cervix or anatomically damaged by surgery of previous delivery with in situ cerclage stiches, an abdominal cerclage can then be proposed for subsequent pregnancies. Although the absence of a control group does not allow to affirm the superiority of this procedure compared to other techniques of cerclage, the findings presented here are encouraging and can support these recommendations.

# 5. Conclusions

Pre-conceptional cervical-isthmic cerclage by vaginal route here described as Shirodkar-Barini surgery is safe and results in high percentage of live born babies and low prematurity rate on the following pregnancy, in the patients with heavy obstetrics past suggestive of cervical incompetence and previous McDonald's

failure. The procedure is an efficacious and safe when performed by a skilled surgeon.

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