

# Alternative Treatment for a Short Cervix: The Cervical Pessary

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Preterm birth is the leading cause of perinatal morbidity and mortality in the United States. The risk of preterm birth is inversely proportional to the length of the cervix on transvaginal sonography. The traditional treatment for a short cervix has been cerclage and recently there are newer trials using progesterone for this same indication. This manuscript reviews the published data regarding the use of an old method for the treatment of cervical insufficiency, "The Cervical Pessary." A MEDLINE search was performed and articles published since 1959 regarding the use of pessary for cervical insufficiency were identified and reviewed. The pessary may represent an easy and safe intervention in the treatment of a short cervix diagnosed in the midtrimester. Further research is merited to evaluate the role of the cervical pessary as an alternative treatment for a short cervix or for women at high risk for preterm birth.

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Preterm birth is the leading cause of perinatal morbidity and mortality in the United States. Despite efforts to decrease the incidence of this problem over the last few decades, the rate of preterm delivery remains high. In 2007, the Center for Disease Control reported a preterm birth rate, defined as those deliveries at <37 weeks of gestation, of 12.7%.<sup>1</sup> Because of this high incidence, the prevention of preterm delivery is a major area of interest in contemporary obstetrics, as well as a societal necessity. However, the means by which to achieve prevention still remain elusive, and this is an area of research that is frustrating to both women and the clinicians who care for them.<sup>2</sup>

In the landmark study of 1996, Iams et al<sup>3</sup> demonstrated that the risk of preterm delivery is inversely proportional to the length of the cervix on transvaginal sonography between 24- and 28-weeks of gestation, in an unselected US population. Cervical insufficiency (formerly called incompetence) is described as the inability of the uterine cervix to retain an intrauterine pregnancy until term. It is usually characterized as a repetitive, acute, painless second trimester pregnancy

loss, without associated bleeding or uterine contraction. A "short cervix" in the mid trimester, noted whether by ultrasound or digital examination, can be a hallmark finding and often is used as a surrogate marker for diagnosis of cervical insufficiency. This is particularly in those women with a previous history of pregnancy loss or preterm delivery. It has been appealing to clinicians to consider a mechanical method by which to strengthen the cervix, keep it closed, and increase its length in the hope of preventing preterm delivery. Since the introduction of cerclage by Shirodkar<sup>4</sup> and McDonald<sup>5</sup> 5 decades ago, this treatment modality has been submitted to multiple study trials with mixed results. Furthermore, recently the use of progesterone for the treatment of a short cervix is also under intense research evaluation. This article discusses the recent interest in the use of an old treatment for cervical insufficiency, "The Cervical Pessary," because of its simplicity, cost-effectiveness, and safety.<sup>6</sup>

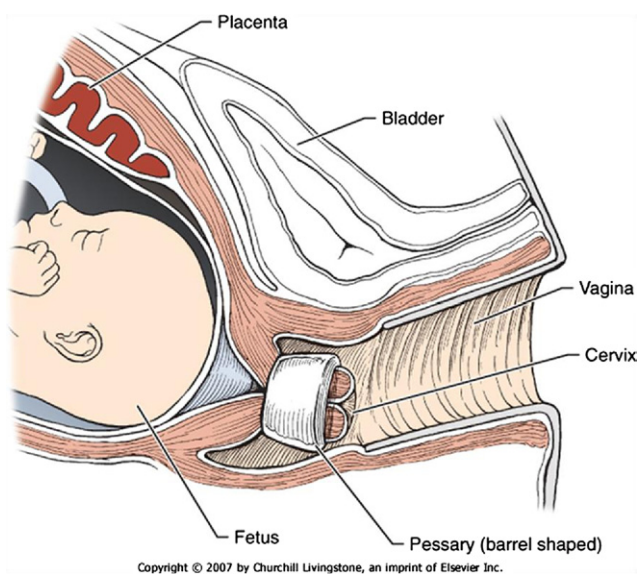
## Pessary for Cervical Insufficiency

The first report on the use of a ring pessary, the Bakelite ring, for the treatment of incompetent cervix, was published in 1959 in the *Lancet* by Cross.<sup>7</sup> A series of 13 patients is described, wherein the Bakelite ring is pushed up and around the cervix, to the level of the internal os. The indications for placement are noted as incompetent cervix (4 patients), his-

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**Figure 1** The cervical pessary. (Reprinted with permission.<sup>20</sup>) (Color version of figure is available online).

tory of cervical lacerations (8 patients), and a didelphys uterus (1 patient). The article describes a history of pregnancy loss after 14 weeks in most patients. With therapy, there were 8 full-term pregnancies, 1 failed pregnancy requiring abortion, 1 case of failed pregnancy that had a cerclage placed, and 3 on-going pregnancies at the time of publication.

Pessaries currently come in a wide range of shapes and sizes, and are typically used for pelvic organ prolapse. Most practitioners use for prevention of preterm birth, some version of a ring-like pessary, to encompass the cervix and act similar to a cerclage (Fig. 1). The thought behind the mechanism of success of the pessary was proposed by Vitsky<sup>8</sup> in 1961. He described the pregnancy as causing a steady and mounting pressure on the internal os and noted that it is irrelevant whether this is due to trauma or congenital causes. The pattern is the same, and eventually the membranes sacculate into weakness and rupture, and in due time labor with expulsion of the uterine contents ensues. The cervix with its axis directly and centrally aligned into the non-resistant vagina, lends itself to its own dissolution. He suggested that, logically, a device that can alter this colineation so that the force is directed inward would be helpful. He suggested that a pessary might have merit in this situation, as it can change the inclination of the cervical canal and can also compress the cervical canal in the earlier part of pregnancy.

In 1963, Vitsky<sup>9</sup> then published his institution's data regarding the use of a Smith-Hodge pessary as an effective method of therapy. His data included 7 of his patients (5 delivered at >37, 1 at 31 and 1 at 35 weeks of gestation), 7 patients of Dr C Graham (4 delivered at >37, 2 at 34, and 1 at 32 weeks of gestation), 3 patients of Dr W Moore (2 delivered at >37, 1 delivered at 20 weeks of gestation), 3 patients of Dr WH Evans (all of whom delivered at >37 weeks of gestation), and 1 patient of Dr DP Rucker (failed pessary, delivered at 22 weeks). Thus, 21 patients had a pessary

placed for a diagnosis of incompetent cervix or a history of late abortion. Of the 21 patients, 14 (66%) delivered at >37 weeks and 3 (14%) delivered at >34 weeks. Vitsky<sup>10</sup> added to his series in 1968 when he published an article detailing the outcomes of 3 more pregnancies, all of whom had a history of midsecond trimester loss and a diagnosis of incompetent cervix. All 3 patients delivered at term.

After this, the largest US series from this time was published by Oster and Javert<sup>11</sup> in 1966. The authors note that though surgical repair of the cervix between pregnancies using therapeutic cerclage had proven beneficial, it was not without risk. They go further to cite an example of such a situation, and describe a case of maternal death after sepsis from placement of a cerclage in pregnancy.<sup>12</sup> Thus, they describe their findings with the Hodge pessary as an alternative to placement of a cerclage. The study involved 29 patients with a diagnosis of incompetent cervix. This was the first study to clearly explain how an incompetent cervix is diagnosed. They mentioned that the diagnosis was determined by history, visual observation, passage of a 10-mm Hegar's dilator through the nonpregnant cervix without resistance at the internal os or even balloon, or radiographic studies. Before the pessary, this group of patients was described as having delivered 58 nonviable infants, 8 children between 22- and 28 weeks of gestation and 12 children between 29 and 36 weeks of gestation. After the pessary, only 2 nonviable fetuses were delivered, no infants between 22- and 28-weeks of gestation, 6 premature infants <37 weeks of gestation, and 23 term infants. This article was the first to describe the timing of placement as well. The authors noted that the best results were obtained with insertion of the pessary at the end of the first trimester or 14 weeks of gestation. The authors also discuss activity restriction, and state that normal activity was not restricted except for intercourse.

In 1992, Leduc and Wasserstrum<sup>13</sup> published a case report of the use of a Smith-Hodge pessary for a history of cervical incompetence in a patient with Ehlers-Danlos syndrome. The pessary was placed at 14 weeks of gestation. The patient went on to deliver at 33 weeks of gestation, a normal viable male infant.

The aforementioned studies are all retrospective, and there are few prospective studies regarding the use of pessary in the published data. The first, published in 2003 by Arabin et al,<sup>14</sup> described a pilot study designed to determine whether the placement of a specifically designed vaginal pessary might reduce the rate of spontaneous preterm birth in women with a short cervix. This was the first study to thoroughly describe methods of placement, inclusion and exclusion criteria, including a described control group. This was also the first study to note the inclusion of multiple gestations. Between 1997 and 2001, transvaginal ultrasounds were performed on all twin pregnancies as well as all singleton pregnancies with a history of spontaneous preterm birth before 36 weeks, or early symptoms of pressure or contractions. Patients with severe regular contractions, blood loss, or premature rupture of membranes were excluded. Patients with iatrogenic preterm birth were also excluded. Consent for pessary placement was obtained in patients with a cervical length of <15

mm and who were between 22 and 24 weeks of gestation. Before placement of the pessary, evaluation for bacterial vaginosis and fetal fibronectin was performed. A flexible ring-like silicone pessary was inserted into the vagina so that the smaller inner diameter encompassed the cervix. Insertion was facilitated by spreading of an antibiotic cream onto the pessary before placement. A total of 12 singleton pregnancies and 23 twin pregnancies had the pessary placed. A matched-pair analysis was then performed retrospectively, using an already existing database to identify all patients who underwent ultrasound between 18 and 28 weeks of gestation with a cervical length at <10 percentile. For the matched control analysis, 12 singleton and 23 twin pregnancies were identified, accounting for the gestational week at placement and the absolute cervical length. In addition to the primary outcome of preterm birth, information regarding various other clinical characteristics of the patients was obtained. All patients also underwent open-ended questionnaire evaluation about their method of treatment. Among the singleton pregnancies, no significant differences were noted between cases and controls in regard to patient demographics or various risk factors for preterm birth. A total of 50%-53% of the patients had a history of spontaneous preterm birth, with gestational age ranging 21-34 weeks. Only one of the patients in the group with pessary placement had to be admitted to the hospital for preterm labor and given intravenous betamimetics and steroids, as compared with 5 of the singleton pregnancy patients without pessary placement. Regarding their primary outcome, there were no preterm deliveries in any of the 12 patients with singleton pregnancies in whom a pessary was placed, as compared to the 6 of 12 matched controls without a pessary. The study notes 1 complication of a patient who had cervical necrosis, possibly from the pessary, and a resultant shortened cervical length of 25 mm postdelivery.

Our own institution has described a prospective cohort of 18 patients. Ludmir et al<sup>15</sup> identified 18 patients with a history of preterm delivery, with cervical shortening of <22 mm after 20 weeks of gestation on ultrasound. Patients included had either refused a cerclage, or their practitioners felt that cerclage placement was not warranted. All patients were offered pessary therapy. A total of 10 patients had an Arabin (barrel-shaped) pessary placed, and 8 patients were managed with bed rest alone. All patients received betamethasone at 24-34 weeks to enhance fetal lung maturity. The average gestational age at placement of the pessary was 21.4 weeks and the average gestational age at the initiation of bed rest therapy was 22.2 weeks. This was not statistically significantly different. In the pessary group the average gestational age at delivery was  $31.5 \pm 6.8$  weeks and in the bed rest group it was noted to be  $27.5 \pm 3.4$  weeks ( $P = 0.07$ ).

The last and most recent study published was by Archarya et al<sup>16</sup> in 2006. The aim of this study was to evaluate the efficacy and safety of pessary placement in the management of cervical insufficiency. A total of 32 patients who presented to the University Hospital of Northern Norway between 2001 and 2004 were included. A transvaginal cervical length ultrasound was performed every 2-3 weeks after the first routine

anatomy ultrasound, with confirmation of gestational age and exclusion of congenital malformations. All 32 patients were women with progressive shortening of the cervix to <25 mm before 30 weeks of gestation. An additional 6 patients, not included in the 32 patients, were excluded because of the presence of uterine contractions, ruptured membranes, maternal pyrexia, C-reactive protein >5, white blood cell count >15, abnormal vaginal discharge, or vaginal bleeding. An additional patient was excluded secondary to advanced cervical dilation (>3 cm) and a McDonald cerclage was performed, and 1 was excluded as the patient did not agree to the procedure. Thus, a total of 8 patients were excluded. The mean gestational age at pessary placement was 23 weeks (range 17-29) and the mean cervical length was 17 mm (range 5-25). After placement, 2 women were excluded because of iatrogenic-induced preterm deliveries for severe intrauterine growth restriction and HELLP syndrome. In the remaining 29 women, the mean age at delivery was 34 weeks (range 22-42); in 29 patients there were 9 twin gestations and 2 triplet gestations, the rest were singleton gestations. A total of 16 patients (55.2%) delivered at >34 weeks of gestation (Table 1).

Finally, 2 randomized trials conducted in Europe are ongoing. The Maternal-Infantil Vall d'Hebron Hospital, in Spain, has recently concluded the "PECEP" study (prevention of preterm birth using cervical pessary in pregnant women with short cervix). This is a multi-institutional randomized controlled phase IV trial conducted in Spain. The study included all patients found to have a cervical length of <25 mm at 18-22 weeks of gestational age, regardless of history of preterm birth. A total of 109 patients were randomized to the Arabin pessary arm (silicon ring pessary), and 112 patients did not receive any intervention. Although the results of this study have not been published, it seems that the group treated with the cervical pessary will demonstrate a decreased rate of preterm delivery (Elena Carreras, personal communication).<sup>17</sup>

The second trial, titled "A Randomized Study of Pessary versus Standard management in Women with an Increased Change of premature Birth," is underway at multiple institutions across the world. The primary site is noted to be King's College Hospital in the United Kingdom. The study is under the primary direction of Dr Kypros Nicolaides. The aim of the study is to determine the effect of pessary placement on the incidence of spontaneous delivery between randomization and 34 weeks in asymptomatic women with singleton and twin pregnancies, found at routine mid-trimester screening to have a cervix of <25 mm in length. This is a phase III open-label trial.<sup>18</sup>

## Guidelines for Pessary Placement

The following describes basic guidelines to be considered when offering placement of a pessary for prevention of spontaneous preterm birth.

**Table 1** Summary Table of Reports of Treatment With Cervical Pessary in Women With Presumed Cervical Insufficiency

Author, Year	Before Pessary (Untreated Pregnancies)			Postpessary (Treated Pregnancies)		Pessary Type
	No. Patients	Total No. Pregnancies in All Patients	No. Full Term (>37 wk Gestation) Deliveries	No. Pregnancies	No. Full-Term (>37 wk Gestation) Deliveries	
Cross, 1959 <sup>7</sup>	13	40	8	13	8	Bakelite
Vitsky, 1963 <sup>9</sup>	21	83	19	21	14 (3 at >34 wk)	Smith-Hodge
Oster and Javert, 1966 <sup>11</sup>	29	94	16	35	23	Hodge
Leduc and Wasserstrum, 1992 <sup>13</sup>	1	1	0	1	0	Smith-Hodge
Arabin et al, 2003 <sup>14</sup>	12	6 patients with history of prior preterm birth		12	12	Arabin
Ludmir et al, 2002 <sup>15</sup>	18	All patients with history of prior preterm birth		10	3	Arabin
Archarya et al, 2006 <sup>16</sup>	32	12 patients with history of prior preterm birth		29	16 (>34 wk)	Arabin
Carreras, 2010 <sup>17</sup>	221		Results anticipated June 2010			Arabin

1. Identify the population with a history of spontaneous preterm birth or cervical length shortening at <25 mm on transvaginal ultrasound.
2. Ensure that the patient does not have an infection or has signs or symptoms of active preterm labor.
3. Counsel and inform the patient that there is yet not strong evidence that a cervical pessary can prevent spontaneous preterm birth.
4. Perform a sterile speculum examination to inspect the cervix and identify an appropriate pessary size. In our practice, we use an Arabin-type pessary (barrel-shaped). This type of pessary is easily available through various manufacturers in the United States.
5. Place the pessary carefully into the vagina and fit it high and tight around the cervix. The pessary should be fit, similar to one used for prolapse. A speculum examination can be performed to ensure that the cerclage pessary is fitted around the cervix. The smaller inner diameter of the pessary should encompass the cervix, keeping it closed and preventing membranes from herniating through the cervical os. Different sizes are available (Fig. 1).
6. Observe the patient for a short period to ensure there is no discomfort, vaginal bleeding, or uterine activity and that the patient is able to void.
7. Be mindful that the pessary should be removed in cases of premature rupture of membranes, blood loss, increasing contractions, or pain.
8. The pessary can be carefully removed around 37 weeks of gestation or if the patient is uncomfortable or symptomatic.

## Conclusions

Conventional cervical cerclage can be associated with complications and is not without risk.<sup>19</sup> The cervical pessary may offer a safe and easy alternative to cerclage for the treatment of cervical insufficiency and prevention of preterm birth. Several types of pessaries have been used and shown to be effective in various observational trials. Cerclage pessary is a relatively noninvasive, operator-independent, cost-effective outpatient procedure. Although this modality has been described for 50 years and is in use in Europe, its use has been limited in the United States. The optimal time and cervical length, and type of pessary with greatest benefit remain to be elucidated. As Vitsky<sup>10</sup> stated in 1968, "The pessary may someday find wider acceptance in the treatment of the incompetent cervix. Unfortunately, there are no true controls, but neither are they existent for those who perform cerclage. The efficacy of the pessary is obscured by its simplicity. The rewards of its use are found only in patients' happiness and physicians' sense of accomplishment." Thus, we are eagerly awaiting the results of the current on-going randomized trials.

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