The diagnosis of cervical incompetence, characterized by recurrent painless dilation and spontaneous midtrimester birth, usually of a living fetus. The diagnosis is usually retrospective and made only after poor obstetric outcomes have occurred (or rarely, are in evolution). Because there are few proven objective criteria, and lack of a specific histologic diagnosis other than a rare, gross cervical malformation, a careful history and review of the past obstetric records are crucial to making an accurate diagnosis. Unfortunately, in many instances, the records are incomplete or unavailable, and many women cannot provide a reliable history. Even with excellent records and a complete history, clinicians might disagree on the diagnosis in all but the most classic cases. Confounding factors in the history, medical records, or current physical assessment might be used to either support or refute the diagnosis, based on their perceived importance. The physician managing a patient who experiences a spontaneous midtrimester birth is in the optimal position to assess whether the typical clinical criteria for cervical incompetence were present. Because cervical incompetence is generally a retrospective diagnosis and depends on a history of untoward outcomes, clinicians have sought criteria that might lead to a prospective and more objective diagnosis. In women considered to be “at risk” for cervical incompetence, based on an atypical history or because of other identified “risk factors,” serial examinations may be performed to detect progressive shortening and dilation, leading to a presumptive diagnosis of incompetence, which may be amenable to therapeutic intervention (Table 25-1).
Table 25-1. Diagnostic Criteria for Cervical Incompetence

- Historical Factors:
  - History of painless cervical dilatation with preterm (midtrimester) delivery
  - Painless cervical shortening and dilatation detected by serial digital evaluations, and short cervix detected by sonography in women with a clinical history.

- Index Gestation:
  - Index gestation: Preterm cervical incompetence in the past obstetric events. Thus, finding effective preventive management strategies has been generally unsuccessful and only empirically based.

THE SPONTANEOUS PRETERM BIRTH SYNDROME

Because it is not currently a discrete, well-characterized disease process, spontaneous preterm birth is best characterized as a syndrome comprising several anatomic and related functional components. These include the uterus and its myometrial contractile function (e.g., preterm labor), decidua activation and loss of chorionicallnamic integrity (e.g., preterm rupture of membranes), and finally, diminished cervical competence, either from a primary anatomic defect or from early pathologic cervical ripening (e.g., cervical incompetence). In a particular pregnancy, a single anatomic feature may appear to predominate, even though it is more likely that most cases of spontaneous preterm birth result from the interaction of multiple stimuli and pathways which culminate in the overt clinical syndrome. Nevertheless, the relative importance of these components varies not only among different women but also in successive pregnancies for a particular patient. In many cases, the cervix may simply be an interdependent participant in the spontaneous preterm birth syndrome.

Because the underlying processes (i.e., infection, inflammation, and so on) and their interactions with the anatomic components of the syndrome remain poorly characterized, the specific series of events leading to spontaneous preterm birth cannot be accurately determined, either during pregnancy, when the syndrome is recognized and managed, or by a careful retrospective analysis of the past obstetric events. Thus, finding effective preventive management strategies has been generally unsuccessful and only empirically based.

CERVICAL COMPETENCE AS A BIOLOGIC CONTINUUM

As early as 1962 Danforth and Buckingham suggested that cervical incompetency was not an all or none phenomenon. Rather, it comprised degrees of incompetency, and combinations of factors could cause “cervical failure.” This concept never gained wide acceptance in spite of the obvious heterogeneity observed in clinical practice. Cervical incompetency was generally viewed as dichotomous, possibly because available treatment strategies were similarly devised. These classic investigations demonstrated that the normal cervix is comprised predominantly of connective tissue, unlike the uterine corpus. This fibrous band is the chief mechanical barrier against the loss of the enlarging products of conception. The cervix and mucus glands also play an important immunologic role in preventing organisms from ascending into the normally sterile intrauterine environment.

In a subsequent report, these investigators analyzed cervical biopsies taken from postpartum women and compared them with hysterectomy specimens from nonpregnant patients. Pregnancy was associated with increased water content, a marked decline in collagen and glycoprotein, and increased glycosaminoglycans. The cellular and biochemical changes suggested that cervical dilution in pregnancy is a dynamic process, and this might explain why a woman could have a pregnancy outcome consistent with cervical incompetence in one pregnancy but, then without treatment, have a subsequent term birth. Presumably, the factors inciting the pathologic cervical changes might vary among pregnancies. Women with a more muscular cervix might have an unusual susceptibility or lower threshold for the effects of the factors that precipitated the clinical syndrome of preterm birth.

These earlier observations were enlarged by Leppert and colleagues, who reported an absence of elastic fibers in the cervix of women with clinically well-characterized cervical incompetence on the basis of their reproductive history. Conversely, cervical biopsy specimens from women with normal pregnancies showed normal amounts and orientation of these elastic fibers. Rechberger and colleagues also compared cervical biopsy specimens among nonpregnant controls, women in the midtrimester with clinically defined cervical incompetence and normal postpartum gravidas. Compared with normal postpartum patients, they found increased collagen extractability and collagenolytic activity in women with cervical incompetence, suggesting a high collagen turnover characterized by higher proportions of newly synthesized collagen with lower mechanical strength. It is unknown whether these microstructural and biochemical phenomena were congenital, acquired from previous trauma, or the result of other pregnancy-associated pathology. Collectively, these biochemical and ultrastructural findings support the variable, and often unpredictable, clinical course of women with a history of cervical incompetence.

Although the traditional paradigm has depicted the cervix as either competent or incompetent, recent evidence, including clinical data and interpretative reviews suggest that, as with most other biologic processes, cervical competence is rarely an all or none phenomenon and more likely functions along a continuum of reproductive performance. Although some women have tangible anatomic evidence of poor cervical integrity, most women with a clinical diagnosis of cervical incompetence have ostensibly normal cervical anatomy. In a proposed model of cervical competence as a continuum, a poor obstetric history results from a process of premature cervical ripening, induced by a myriad of underlying factors, including infection, inflammation, local or systemic hormonal effects, or even genetic predisposition. If and when cervical integrity is compromised, other processes may be stimulated, appearing clinically as other components of the spontaneous preterm birth syndrome (i.e., premature membrane rupture, or preterm labor). A decision as to whether diminished cervical competence arises through primary endogenous mechanical deficiencies or exog-
enous factors, would define the optimal therapy. Thus, a more rational concept of cervical incompetence is to view the cervix as an interdependent participant in the multifactorial model of the spontaneous preterm birth syndrome.

TESTS FOR CERVICAL INCOMPETENCE

Because the diagnosis of cervical incompetence has been determined primarily from past reproductive performance and physical examination findings, the obvious limitations associated with the clinical diagnosis have prompted the search for sensitive and specific tests that could be applied in a prospective manner to women deemed at risk for cervical incompetence, thus obviating the need for recurrent pregnancy loss. Such a test might provide a timely diagnosis and the potential for optimal therapeutic intervention.

Most of the earlier reported tests for cervical incompetence were based on the functional anatomy of the interval os in the nonpregnant state and are of historical interest. Attempts at objective assessments include passage of a #8 Hegar dilator into the nonpregnant cervical canal without resistance and traction forces required to dislodge a Foley catheter whose balloon was placed above the internal os and filled with 2 to 3 mm of water. Subjectively effortless passage of the dilator or removal of the Foley balloon with less than 600 g of force would confirm an objective diagnosis.

More recently in 1988 Kiwi and colleagues estimated the elastic properties of the nonpregnant cervix in two cohorts of women: 247 women with a poor obstetric history and 42 controls. Although women in the poor obstetric history group had significantly lower elastance values than the controls, there was significant overlap between the two groups. They reported no subsequent pregnancy outcomes, proposed no clinically useful cutoff for their evaluation, and could only suggest that such objective evaluation might ultimately prove to be clinically useful to accurately select patients for cerclage.

In 1993, Zlatnick and Burmeister reported their experience with a cervical compliance score derived from the results of three other tests: hysterosalpingography, passage of a #8 Hegar dilator, and intrauterine balloon traction performed in 138 nonpregnant women. Their histories included prior delivery less than 34 weeks following clinically diagnosed preterm labor or preterm membrane rupture, with or without antecedent bleeding. A small portion of their cohort had a questionable history of cervical incompetence. Scores could range from 0 to 5, and women with low scores of 2 or less were more likely to have been delivered at 27 to 34 weeks as compared with women with higher scores, who were more likely to have been delivered in the midtrimester at 14 to 26 weeks (P < .01). In subsequent pregnancies, cerclage was recommended in all women with a high score of greater than 2, and most underwent surgery. Surprisingly, in spite of surgical intervention, more women with high scores delivered at 14 to 29 weeks’ gestation (P = .07) casting doubt on the clinical utility of this scoring system.

All such attempts at providing an objective diagnosis of cervical incompetence failed, and none of these tests are in common use today. These reports generally suffered from a failure to evaluate standard test characteristics (i.e., sensitivity, specificity) against some reference standard for the diagnosis or another clinically relevant endpoint. Moreover, none of these tests could reasonably predict pregnancy-associated conditions that would lead to premature ripening and cervical dilation. Finally, because there is no universally applicable standard for the diagnosis of incompetence, and because the results of such tests were never evaluated and linked to a proved effective treatment, their clinical utility was, at best, theoretical. In summary no test for cervical incompetence in the nonpregnant patient has been validated. The clinician is left with performing some form of cervical evaluation in the index pregnancy when the diagnosis of cervical insufficiency is suspected.

CAN SONOGRAPHIC EVALUATION OF THE CERVIX DIAGNOSE INCOMPETENCE?

Over the past 2 decades numerous investigators have suggested that cervical incompetence can be diagnosed by midtrimester sonographic evaluation of the cervix. Various sonographic findings including cervical length, funneling at the internal os, and dynamic response to provocative maneuvers (e.g., fundal pressure) have been used to select women for treatment, generally cerclage (Fig. 25-1). In these earlier reports, the sonographic evaluations were not blinded, leading to uncontrolled interventions and difficulty determining their value. A representative sample of numerous reports linking the findings from cervical sonography to a diagnosis of cervical incompetence is depicted in Table 25-2. Note that the diagnostic criteria are disparate and, in some cases, not described in a quantitative or reproducible manner.

More recently large, blinded observational studies using reproducible methods have been published. These investigators reported the relationship between midtrimester cervical sonographic findings and preterm birth. The National Institutes of Child Health and Human Development (NICHD) Maternal-Fetal Medicine (MFM) Units Network completed a study of 2,915 unselected women with a singleton pregnancy who underwent a blinded cervical sonographic evaluation at 24 weeks’ gestation. The relative risk of spontaneous preterm birth increased inversely proportionally to cervical length. In spite of this highly significant relationship, as a test for predicting spontaneous preterm birth of less than 35 weeks, a cervical length cutoff of less than 26 mm (the population 10th percentile) had low sensitivity (37 percent), and poor positive predictive value (18 percent).

In a subsequent study, the NICHD MFM Units Network examined the utility of cervical ultrasound as a predictor of spontaneous preterm birth of less than 35 weeks in high-risk women, defined as at least one prior spontaneous preterm birth of less than 32 weeks. Women believed to have cervical incompetence (based on a clinical
length shortening. As in the previous study, there was a highly significant inverse relationship between cervical length and spontaneous preterm birth. However, in this high-risk population, at a cervical length cutoff of less than 25 mm, the sensitivity increased to 69 percent and the positive predictive value to 55 percent. A secondary analysis of the data suggested that these high-risk women with shortened cervical length may have a clinically significant component of diminished cervical competence, because there was a preponderance of midtrimester births of less than 27 weeks in this group.27

These reports support the concept that cervical length, as a surrogate function for cervical competence, operates along a continuum of reproductive performance and provides prospective confirmation of an earlier published retrospective analysis. Nevertheless, in spite of the consistent relationship between shortened cervical length and spontaneous preterm birth, the actual identification of an appropriate cervical length action cutoff and confirmation of the potential contribution of related cervical sonographic findings (e.g. funnelling at the internal os), remains problematic. Clearly, cervical sonography performs poorly as a screening test in low-risk women, but it appears to have significant clinical utility in high-risk women, defined as a prior early spontaneous preterm birth. Whether cervical ultrasound has similar predictive values in other populations of at risk women (e.g., diethylstilbestrol [DES], prior cervical surgery, multiple induced abortions, and so on) remains speculative, because it has not been well studied. Although some investigators have included women with these risk factors in their study populations composed primarily of women with previous spontaneous preterm birth, the results could not be subcategorized because of small sample sizes.28 However, in a recent series of 64 women with various uterine anomalies, the authors observed an overall preterm delivery rate of less than 35 weeks of 11 percent and a significant relationship

Table 25-2. Published Reports of the Sonographic Diagnosis of Cervical Incompetence

<table>
<thead>
<tr>
<th>AUTHOR, YEAR</th>
<th>POPULATION</th>
<th>N</th>
<th>GA</th>
<th>COMMENT</th>
<th>CRITERIA FOR CERVICAL INCOMPETENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varma, '86 (114)</td>
<td>At risk</td>
<td>115</td>
<td>10–32 weeks</td>
<td>40 received cerclage</td>
<td>Not explicitly stated. Cervical canal width &gt;8 mm implied</td>
</tr>
<tr>
<td>Michaels, '86 (115)</td>
<td>At risk</td>
<td>107</td>
<td>N/S</td>
<td>32 received cerclage for sonographic CI</td>
<td>Membrane prolapse &gt;6 mm and short cervix</td>
</tr>
<tr>
<td>Ayers, '88 (15)</td>
<td>Prior MT loss</td>
<td>88</td>
<td>N/S</td>
<td>70 received cerclage</td>
<td>CL &lt;40 mm (~2 standard deviations from the mean)</td>
</tr>
<tr>
<td>Fox, '96 (116)</td>
<td>At risk</td>
<td>19</td>
<td>14–28 weeks</td>
<td>Used sonography to avoid cerclage in women with classic history; 12 of 19 underwent cerclage</td>
<td>&gt;1 cm decrease in CL and/or funneling</td>
</tr>
<tr>
<td>Guzman, '97 (117)</td>
<td>At risk</td>
<td>10</td>
<td>N/S</td>
<td>Examined natural history of fundal pressure response</td>
<td>CL &lt;10 mm or cervix dilated on physical exam</td>
</tr>
<tr>
<td>Guzman, '97 (118)</td>
<td>At risk</td>
<td>89</td>
<td>MT</td>
<td>Transfundal pressure and other provocative maneuvers</td>
<td>Progressive cervical changes to CL &lt;26 mm</td>
</tr>
<tr>
<td>Wong, '97 (119)</td>
<td>High risk</td>
<td>41</td>
<td>17–33</td>
<td>16 had prophylactic cerclage. Postural test evaluated as a provocative maneuver</td>
<td>33% decrease in CL</td>
</tr>
<tr>
<td>Guzman, '98 (120)</td>
<td>At risk</td>
<td>57</td>
<td>MT</td>
<td>Retrospective cohort study. Elective vs. ultrasound indicated</td>
<td>CL &lt;20 mm with or without fundal pressure</td>
</tr>
<tr>
<td>MacDonald, '01 (121)</td>
<td>High risk</td>
<td>106</td>
<td>&lt;24 wk</td>
<td>Serial scans</td>
<td>CL &lt;10 mm with or without fundal pressure</td>
</tr>
</tbody>
</table>

CI, cervical incompetence; CL, cervical length.
between cervical length of less than 25 mm and preterm birth, with summary predictive values similar to other high-risk populations. A recent systematic review summarized the predictive value of vaginal sonography for preterm birth in 46 published series of both asymptomatic and symptomatic gravidas carrying singleton or twin gestations.

Use of cervical ultrasound in twin gestations has also been reported; however, the test characteristics, especially sensitivity and positive predictive value (<40 percent), appear to be generally lower than for women with a prior early spontaneous preterm birth.

**RISK FACTORS FOR CERVICAL INCOMPETENCE**

Based largely on the epidemiologic associations between the clinical diagnosis of cervical incompetence and antecedent historic factors, numerous “risk factors” for cervical incompetence have been recognized. These include prior cervical surgery (i.e., tracheectomy, cone biopsy), in utero DES exposure, prior induced or spontaneous first- and second-trimester abortions, uterine anomalies, multiple gestations or prior spontaneous preterm births that did not meet typical criteria for cervical incompetence. Because DES usage was effectively curtailed in the early 1970s, this congenital risk factor should soon be of only historic interest.

Cervical damage from surgery is diminishing as indications for cone biopsy and more radical surgical procedures are diminishing. More common is the patient who has undergone a loop electrosurgical excision procedure (LEEP), usually for cervical dysplasia. These procedures are plausibly a risk factor for cervical incompetence. Regrettably, it has not been feasible to simultaneously control for the epidemiologic risk factors that are associated with both preterm birth and dysplasia. In 1995, Ferenczy reported 574 women who had undergone conization, laser ablation, or LEEP, and compared these procedures for cone biopsy and more radical surgical procedures with untreated women. Their goal had been to obtain a nominal 7-mm thick specimen and cited a maximum excisional depth of 1.5 cm. In this series, there were no spontaneous preterm births before 37 weeks observed. Data from a similar series of 52 women revealed an incidence of spontaneous preterm birth of less than 10 percent and no midtrimester losses that might suggest a clinical diagnosis of cervical incompetence. A more recent and much larger retrospective cohort study by Sadler et al. examined 652 women treated with laser conization, laser ablation, or LEEP, and compared these with a cohort of 426 untreated patients. The overall adjusted rates of preterm birth before 37 weeks’ gestation were similar; however, the group with the highest tertile of cone height (=1.7 cm) did have more than a threefold increased risk of preterm chorioamnion rupture compared with untreated women. Even considering the effect on preterm membrane rupture, the overall effect on preterm birth was not statistically significant, as the 95-percent confidence interval (CI) included 1.0.

Published data on cone biopsy is similarly reassuring. Weber reported an incidence of preterm birth of only 7 percent in 577 pregnancies of women with a prior cone biopsy. Leiman concluded that the risk of preterm birth was greater only when the maximum cone height was greater than 2 cm or the volume removed was greater than 4 cc. Rao and colleagues performed a matched cohort study of 64 women who had undergone prior laser conization and observed no difference in the incidence of preterm birth compared with their controls (9.4 percent versus 4.7 percent), and statistically similar gestational ages at delivery and birth weights. However, in a secondary analysis, a laser cone height greater than 10 mm was a significant independent risk factor for preterm birth. Other earlier reports have also suggested that larger cone biopsies increased the risk of preterm birth. Nevertheless, the distribution of preterm births in these populations did not confirm a disproportionate incidence of midtrimester loss consistent with cervical incompetence.

Kuoppala and Saarikoski retrospectively reviewed 62 women who had undergone cone biopsy and an equal number of matched control patients. The pregnancy outcomes of 22 who underwent elective cerclage were similar to those managed without cerclage, with fetal salvage rates of 97 percent and 100 percent, respectively. On the basis of their findings and review of seven other published reports, they concluded that prophylactic cerclage was not routinely indicated. Of note, in the largest published randomized trial of cerclage summarized later, women with one or more cone biopsies or cervical amputations had an overall preterm birth rate of 35 percent. However, in this population, there was no benefit from prophylactic cerclage placement.

In summary, most women with prior LEEP or cone biopsy do not appear to have a clinically significant rate of second-trimester loss or preterm birth. However, women in whom a large cone specimen was removed or destroyed (including cervical amputations) or who have undergone multiple prior procedures, probably have an increased risk of spontaneous preterm birth. Whether prophylactic cerclage would be an effective preventive strategy in these at-risk women remains speculative. The available clinical trial data does not suggest a benefit from prophylactic cerclage, and so these women may be followed clinically for evidence of premature cervical changes. Women with a history of prior cervical surgery and spontaneous midtrimester loss, suggesting a clinical diagnosis of incompetence, should be considered for prophylactic cerclage in future pregnancies.

**USE OF CERCLAGE FOR RISK FACTORS**

Because of these epidemiologic associates, clinicians have tried to expand the role of cerclage to include women with “risk factors.” To date there have been four randomized clinical trials that included women with various risk factors for spontaneous preterm birth and whose managing physicians did not believe they required a prophylactic cerclage for a typical history of cervical incompetence. Three of these trials were relatively small series and included women based on a scoring system; twin gestation and recurrent spontaneous preterm birth. None of these trials showed a benefit to cerclage but generally
confirmed a higher rate of hospitalizations and medical interventions in the surgical intervention groups.

The largest randomized trial of cerclage was conducted by the Royal College of Obstetrics and Gynaecology between 1981 and 1988. A total of 1,292 women were enrolled in 12 countries because of uncertainty on the part of their managing physicians as to whether a prophylactic cerclage was indicated. As anticipated, these patients comprised a heterogeneous group with at least six distinct risk-factor subgroups identified on the basis of their dominant history or physical examination findings. Although women assigned to cerclage had a statistically significant lower rate of preterm birth less than 33 weeks (13 percent versus 17 percent; P = .03), the investigators estimated that approximately 25 cerclage procedures would be required to prevent one such birth. Moreover, women assigned to cerclage received more tocolytic medications and spent more time in the hospital. Puerperal fever was significantly more common in the cerclage group. Of interest is the finding in a secondary analysis that only the subgroup of women with multiple pregnancies affected, defined as at least three prior spontaneous preterm births including midterm losses, appeared to benefit from cerclage (15 percent versus 32 percent; P = .02). This secondary analysis confirmed the importance of assessing clinical history in considering the diagnosis and treatment of cervical incompetence.

**CERCLAGE FOR CERVICAL SONOGRAPHIC INDICATIONS**

Under the presumption that shortened cervical length (with or without funneling at the internal os) is diagnostic of cervical incompetence, several investigators have studied the effect of sonographically indicated cerclage on reproductive performance. Several investigators published retrospective analyses of uncontrolled use of cerclage in various “at-risk” populations with conflicting results, suggesting that cerclage was either effective or ineffective. In addition to the inherent biases present in these study designs and differences among study populations, small sample size, variable sonographic criteria, type of cerclage, inclusion of ancillary clinical findings, and definition of pregnancy outcome led to an inconclusive analysis.

Currently, four randomized trials of cerclage for sonographic indications have been published (Table 25-3). Althuisius and her colleagues in the Netherlands performed a two-tiered randomized clinical trial of high-risk patients, the majority of whom were believed to have cervical incompetence based on their obstetric history. In the first tier, eligible patients were randomly assigned to receive either prophylactic cerclage or to begin sonographic surveillance. Thirty-five of the patients assigned to the cervical ultrasound group were found to have a shortened cervical length less than 25 mm and underwent a second randomization to either cerclage or no cerclage. Both cerclage and no cerclage groups were instructed to use modified home rest. Of the 19 assigned to cerclage, there were no preterm births before 34 weeks versus a 44 percent preterm birth rate in the no cerclage-home rest group (P = .002). None of the women who maintained a cervical length of at least 25 mm experienced a preterm birth. Rust and colleagues enrolled 138 women who had various risk factors for preterm birth (including 12 percent with multiple gestations) and randomly assigned them to receive a McDonald cerclage or no cerclage after their cervical length shortened to less than 25 mm or they developed funneling less than 25 percent. Preterm birth before 34 weeks was observed in 35 percent of the cerclage group versus 36 percent of the control group. Interestingly, the women who received cerclage for shortened cervical length had outcomes almost identical to women who received the earlier prophylactic cerclage.

In a multinational trial comprising 12 hospitals in six countries, To and colleagues screened 47,123 unselected women at 22 to 24 weeks’ gestation with vaginal ultrasound to identify 470 with a shortened cervical length of at least 15 mm or less. Of these 470, 253 participated in a randomized trial whose primary outcome was the intergroup rates of delivery before 33 weeks’ gestation. Women assigned to the cerclage group (N = 127) underwent a Shirodkar procedure. They had a similar rate of preterm birth as the control population (N = 126), 22 percent versus 26 percent; p = .44. The authors did not specifically comment on the proportion of women in the control group who were delivered in the midtrimester after a presentation consistent with clinically defined cervical

### Table 25-3. Randomized Trials of Cerclage for Sonographically Suspected Cervical Incompetence in Singleton Gestations

<table>
<thead>
<tr>
<th>AUTHOR, YEAR</th>
<th>POPULATION</th>
<th>N</th>
<th>SELECTION CRITERIA</th>
<th>GA</th>
<th>PRIMARY OUTCOME CRITERION</th>
<th>CERCLAGE</th>
<th>NO CERCLAGE</th>
<th>BENEFIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Althuisius (51)</td>
<td>High-risk history consistent with CI</td>
<td>35</td>
<td>CL &lt;25 mm</td>
<td><strong>≤26 weeks</strong></td>
<td>Preterm birth &lt;34 weeks</td>
<td>0%</td>
<td>44%</td>
<td>Yes</td>
</tr>
<tr>
<td>Rust (52)</td>
<td>Unselected, but many had risk factors</td>
<td>113</td>
<td>CL &lt;25 mm or &gt;25% funneling</td>
<td>16–24 weeks</td>
<td>Preterm birth &lt;34 weeks</td>
<td>35%</td>
<td>36%</td>
<td>No</td>
</tr>
<tr>
<td>To (53)</td>
<td>Unselected, low risk</td>
<td>253</td>
<td>CL &gt;15 mm</td>
<td>22–24 weeks</td>
<td>Preterm birth &lt;33 weeks</td>
<td>22%</td>
<td>26%</td>
<td>No</td>
</tr>
<tr>
<td>Berghella (54)</td>
<td>Unselected, but most had risk factors</td>
<td>61</td>
<td>CL &lt;25 mm or &gt;25% funneling</td>
<td>14–23 weeks</td>
<td>Preterm birth &lt;35 weeks</td>
<td>45%</td>
<td>47%</td>
<td>No</td>
</tr>
</tbody>
</table>

CI = cervical incompetence; CL = cervical length; GA = gestational age.
incompetence; however, they observed four stillbirths attributed to birth at 23 to 24 weeks and five neonatal deaths in deliveries at 23 to 26 weeks. In the cerclage group, the respective counts were three and four.

Bergghella and colleagues54 screened women with various risk factors for spontaneous preterm birth (prior preterm birth, curettages, cone biopsy, DES exposure) with vaginal scans every 2 weeks from 14 to 23 weeks’ gestation and randomly assigned 61 with a cervical length less than 25 mm or funneling less than 25 percent to a McDonald cerclage or to a no-cerclage control group. Preterm birth before 35 weeks was observed in 43 percent of the cerclage group and 47 percent of the control group.

Of the four published randomized trials, the findings of Rust and colleagues52 and Bergghella54 seem most applicable to obstetric practice in the United States, and these reports did not support the use of cerclage for sonographic findings commonly cited as “abnormal” in women with various types of risk factors. The multinational trial by To et al. confirmed that shortened cervical length less than 15 mm identified a very high-risk group; however, approximately 1,000 women in a general obstetric population would have to be screened to find one with this risk factor. None of these demonstrated an appreciable benefit from ultrasound-indicated cerclage.

The trial by Althuisius and colleagues50,51 focused on women whom they believed had a clinical diagnosis of cervical incompetence and who would have likely been candidates for prophylactic cerclage in the United States. Nevertheless, their study does suggest a potential role for cervical ultrasound in women with a clinical diagnosis of cervical incompetence, if the intent is to avoid cerclage when the cervical length is maintained at greater than 25 mm. This has also been the conclusion of other investigators.55 In a similar report, Fejgin and colleagues56 presented a case series of 35 women in whom cerclage had been placed in prior pregnancies for questionable indications. Collectively, these women had been managed through 58 pregnancies with cerclage. These investigators followed the cohort through an additional 52 pregnancies managed with clinical examinations and sonography up to 28 weeks’ gestation without elective, prophylactic cerclage. Compared with the pregnancies managed with elective cerclage, fewer perinatal losses were observed in the group managed with serial examinations (0 percent versus 16 percent in the elective cerclage group; P = .01).

A recently published meta-analysis57 of the four randomized trials1–54 described earlier, analyzed patient-level data to determine if certain subgroups of women with midtrimester cervical shortening might benefit from cerclage defined as a reduction in the relative risk of preterm birth before 35 weeks. They observed a marginal benefit from cerclage in women with singleton gestations and particularly those who had experienced a prior spontaneous preterm birth (relative risk 0.61, 95-percent CI 0.4 to 0.9). Paradoxically, they demonstrated a significant detriment in women with multiple gestations (relative risk 2.15, 95-percent CI 1.15 to 4.01), although this has not been confirmed in other series.46,49 Large, multicenter randomized trials in high-risk women defined as one or more prior early spontaneous preterm births, but who lack a clinical history of cervical incompetence, are needed to further define the potential utility of cervical ultrasound screening to select patients for interventions such as cerclage and are currently in progress.58

**PATIENT SELECTION FOR CERCLAGE**

Most of what is known about the management of the incompetent cervix is based on case series that reported surgical correction of the presumed underlying mechanical defect in the cervical stroma. The contemporary mainstay of treatment has been a surgical approach using one of the classic cerclage procedures, although both medical treatments and other mechanical supportive therapies have been used. Like many aspects of clinical medicine, current therapeutic standards are often based more on expert opinion and results of studies using uncontrolled interventions than the findings of randomized clinical trials.58 This is particularly true for cervical incompetence in which, to date, there have been no published placebo-controlled randomized trials of cerclage in women with a typical clinical history.

Branch in 198659 and Cousins in 198060 collectively tabulated over 25 case series of cerclage efficacy published between 1959 and 1981. Branch59 estimated a pre-cerclage survival rate of 10 to 32 percent versus a perinatal survival rate of 75 to 83 percent in the same cohorts of women managed with Shirodkar cerclage. Similarly, case series that used McDonald cerclage reported a pre-cerclage survival range of 7 to 30 percent before and 63–89 percent after cerclage. Cousins60 estimated a “mean” survival before Shirodkar of 22 percent versus 82 percent post therapy and 27 percent and 74 percent, respectively, for investigators who used the McDonald technique. In total, more than 2,000 patients have been reported in these historic cohort comparisons. Interpretation of these series, as noted by Cousins,60 is limited by the fact that (1) diagnostic criteria were not consistent or always reported; (2) definitions of treatment success were inconsistent (but generally recorded as perinatal survival, as opposed to a gestational age-based end point); (3) treatment approaches were not always detailed and might involve multiple combinations of surgery, medication, bed rest, and other uncontrolled therapies; and (4) cases were not subcategorized according to etiology (i.e., anatomic defects versus a presumed functional cause). Nevertheless, based on compelling but potentially biased efficacy data, the surgical management of women with clinically defined cervical incompetence has become standard practice, and it is unlikely that a well-designed intervention trial for classic cervical incompetence will ever be performed if it includes a placebo or no-treatment group. Although interpretation of efficacy based on historic control groups is always problematic, collectively these reports demonstrate that even women with typical histories may have successful pregnancies without cerclage and that cerclage as a treatment is not universally effective. Both of these observations support the multiple etiologies and interactive pathways characteristic of the spontaneous preterm birth syndrome.
Both an analysis of the clinical history and consideration of various coexistent risk factors for cervical incompetence require considerable judgment on the part of the managing physician, because highly specific and practical objective tests to confirm the diagnosis are not available. Unfortunately, clinical assessments are often subject to highly individualized interpretation and, not surprisingly, different clinicians might reasonably disagree over the diagnosis and management in all but the most classic presentations of cervical incompetence. Confounding factors in the history, records, or current physical assessment might be used to either support or refute the diagnosis, based on their perceived importance. The physician managing a patient who experiences a spontaneous midtrimester birth is in the optimal position to assess whether the typical clinical criteria for cervical incompetence were present. Possibly a more specific diagnosis of cervical incompetence can be made by witnessing “incompetence in evolution,” a possible indication for emergent cerclage that is covered later.

Because of its unproven efficacy in randomized clinical trials, and the attendant surgical risks, the recommendation for prophylactic cerclage should be limited to women with recurrent spontaneous preterm birth syndrome, when a careful history and physical examination suggest a dominant cervical component. Unless the physical examination confirms a significant cervical anatomic defect, consistent with disruption of its circumferential integrity, the clinician should assess the history for other components of the preterm birth syndrome: cervical incompetence remains a diagnosis of exclusion. Although a history of preterm labor is generally considered to exclude the diagnosis of incompetence, patients may develop some clinically evident uterine activity once their cervix has spontaneously dilated (Ferguson’s reflex) but generally have a rapid progress in labor.

Women with cervical incompetence often have some premonitory symptoms such as increased pelvic pressure, vaginal discharge, and urinary frequency. These symptoms, although neither specific for cervical incompetence nor uncommon in a normal pregnancy, should not be immediately dismissed, particularly in women with risk factors for spontaneous preterm birth. Thus, the history of rapid, relatively painless labor should perhaps better characterize the diagnosis of cervical incompetence.

Similarly, a history of midtrimester spontaneous membrane rupture alone can neither confirm nor refute the diagnosis of cervical incompetence, since spontaneous membrane rupture may occur after some pathologic cervical ripening and dilation has exposed the membranes to the genital tract flora. After spontaneous membrane rupture occurs, chorioamnionitis, vaginal bleeding (placental abruption), or labor may ensue, and these events may obscure the underlying etiology. However, if midtrimester membrane rupture occurs in the setting of a closed cervix on physical examination, or if it is followed by a typical course of either spontaneous or induced labor, causes other than cervical incompetence should be emphasized. Conversely, if physical examination after membrane rupture shows marked cervical softening, effacement, and dilation with no antecedent history of painful contractions, the diagnosis of cervical incompetence is supported, particularly if followed by a rapid and relatively painless labor.

A legitimate clinical question arises over the optimal management of a patient who has experienced one spontaneous midtrimester birth, and causes other than cervical incompetence have been excluded by history and physical examination. The observation of a second similar midtrimester birth increases the specificity of the diagnosis and also the likelihood that prophylactic cerclage would be an effective treatment in the next pregnancy. Clearly, if the index midtrimester birth was associated with an identifiable anatomic defect, interval repair or prophylactic cerclage should be encouraged in the next pregnancy. However, in contemporary obstetric practice, such anatomic defects are increasingly uncommon. Although controlled clinical data are lacking, it seems reasonable to follow a patient with this history, using serial clinical evaluations in the second trimester instead of empirically recommending cerclage. Currently, the use of cervical ultrasound to select patients for cerclage is considered investigational, although in selected cases, with worrisome symptoms or pelvic findings, it may be a useful adjunct.

**INCOMPETENCE IN EVOLUTION**

Although the efficacy of cerclage for the treatment of a clinically defined history of cervical incompetence remains unproven in controlled studies, women who present with incompetence in evolution, generally defined as a midtrimester cervical dilation of at least 2 cm and no other predisposing cause (labor, infection, bleeding, ruptured membranes), are often considered for an emergent cerclage. Similar to case series proposing the presumed benefit of prophylactic cerclage, reports describing the outcome of women who present with cervical incompetence in evolution generally have not always included a contemporary control group managed with bed rest or other therapy.

Aarts and colleagues reviewed eight series published between 1980 and 1992 comprising 249 patients who received an emergent midtrimester cerclage and estimated a mean neonatal survival rate of 64 percent (reported range 22 to 100 percent). Noy and colleagues published 35 cases of incompetence in evolution (cervical dilation 2 to 5 cm); The two cohorts included 19 women who received emergent cerclage, and 16 who were managed with bed rest. Neonatal survival was 80 percent in the cerclage cohort versus 75 percent in the bed rest group.

In a prospective, although uncontrolled evaluation of cerclage versus bed rest (cerclage was utilized at the discretion of the attending physician), Olatunbosun and colleagues studied women presenting with more advanced cervical dilation greater than 4 cm. The cerclage group comprised 22 women versus 15 in the bed-rest group. Although neonatal survival was not significantly different (17/22 with cerclage versus 9/15 with bed rest, p = .3) gestational age at birth was a mean 4 weeks older in the cerclage group (33 versus 29 weeks, p = .001). Rates of chorioamnionitis were similar between the two groups.

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Although these reports are not of sufficient scientific quality on which to base firm management recommendations, collectively they demonstrate several important concepts. The earlier the gestational age at presentation and the more advanced the cervical dilation, the greater the risk of poor neonatal outcome. The finding of membrane prolapse into the vagina is also a significant risk factor for poor outcome.64

Recently, Althuisius and colleagues64 published a randomized clinical trial of emergency cerclage plus bed rest versus bed rest alone in 23 women who presented with cervical dilation and membranes prolapsing to or beyond the external os before 27 weeks’ gestation. Both singleton and twin gestations were eligible; however, no information on the amount of cervical dilation was reported, and so it is not known whether the groups were comparable in this important aspect. They observed a longer mean interval from presentation to delivery (54 days versus 20 days; p = .046) in the cerclage group. Neonatal survival was 9/16 with cerclage and 4/14 in the bed rest group. Although the survival differences were not statistically significant, there was significantly lower neonatal composite morbidity (which included death) in the cerclage group (10/16 versus 14/14 in the bed rest alone group; p = .02).

Other reports show that women who present with cervical incompetence in evolution have a higher (nominal 50 percent) incidence of bacterial colonization of their amniotic fluid or other markers of subclinical chorioamnionitis65–67 or proteomic markers of inflammation or bleeding.68 Women with abnormal amniotic fluid markers have a much shorter presentation-to-delivery interval, regardless of whether they receive a cerclage or are managed expectantly with bed rest. Mays and colleagues66 performed amniocentesis in 18 women who presented with this syndrome and analyzed the amniotic fluid for glucose, lactate dehydrogenase (LDH), Gram’s stain, and culture; abnormal results suggested subclinical infection. Of 11 women who underwent cerclage with no evidence of subclinical infection, the neonatal survival was 100 percent, and the mean latent phase duration from presentation to delivery was 93 days. Of the 7 women with abnormal biochemistries in whom cerclage was withheld, no neonatal survivors were observed, and the mean latent phase was 4 days. Recognizing that at least a portion of the 7 women who declined amniocentesis, but who received emergent cerclage, also had subclinical infection, it was predictable that the mean latent phase in this cohort was intermediate (17 days) as compared with the groups with amniotic fluid analyses. These investigators suggested that amniocentesis could aid in selecting candidates for emergent therapeutic cerclage.

In summary, the optimal management of women who present with cervical incompetence in evolution remains indefinite. Although emergent cerclage may benefit some, patient selection remains largely empiric. Although not standard care, the evaluation of amniotic fluid markers of infection and inflammation appears to have important prognostic value, although it is still unclear whether and to what extent the results should direct patient management.

CERCLAGE TECHNIQUE

Prophylactic Cerclage

In 1950, Lash and Lash described repair of the cervix in the nonpregnant state involving partial excision of the cervix to remove the area of presumed weakness.69 Unfortunately, this technique had a high incidence of subsequent infertility. In 1953, Shirodkar reported successful management of cervical incompetence with the use of a submucosal band.70 Initially, he used catgut as suture material, and later he used Mersilene placed at the level of the internal cervical os. The procedure required anterior displacement of the bladder in an attempt to place the suture as high as possible at the level of cervical internal os. This type of procedure resulted in a greater number of patients being delivered by cesarean delivery because of the difficulty in removing the suture buried under the cervical surface and may surprise leaving the suture in place postpartum. Several years later, McDonald described a suture technique in the form of a purse string, not requiring cervical dissection, which was easily placed during pregnancy.71 This technique involves taking four or five bites as high as possible in the cervix, trying to avoid injury to the bladder or the rectum, with placement of a knot anteriorly to facilitate removal (Fig. 25-2). Several types of suture material have been used.72 We have been successful in using a Mersilene tape. However, the use of thinner suture material, such as Prolene or other synthetic nonabsorbable sutures like Ethibond, is advocated by others, with the argument that the width of the Mersilene tape places the patient at greater risk for infection.72,73 Currently, there is no evidence that placing two sutures results in better outcomes than placing one.74,75 Preoperative patient preparations, including the use of prophylactic antibiotics or tocolytics, have not been proven to be of benefit. We perform a culture for group B streptococcus and give preoperative penicillin to the patient with a positive culture. Prophylactic cerclage placement is performed after the first trimester, to avoid the risk of spontaneous loss most likely attributable to chromosomal abnormalities.74,75 The choice of anesthesia for cerclage varies.76 Chen et al.77 did not show a difference in outcome between general versus regional anesthesia. In our experience, a short-acting regional anesthetic is sufficient. We advise patients to remain on bed rest for the first 48 hours after cerclage and to avoid intercourse until their follow-up postoperative visit. Decisions regarding physical activity and intercourse are individualized, and based on the status of the cervix as determined by outpatient digital evaluation or sonographic findings (Fig. 25-3).77 The suture is usually removed electively at 37 weeks. However, recent data suggests that removing the cerclage at the time of labor does not result in greater morbidity for the mother.80

In patients with a hypoplastic cervix, such as those exposed to DES in utero, history of a large cervical conization, or a prior history of failed vaginal cerclage, an abdominal cerclage has been recommended.81 This procedure is usually done between 11 and 13 weeks, and requires a laparotomy. A bladder flap is created, and a Mersilene tape is placed at the level of the junction...
between the lower uterine segment and the cervix, lateral to the uterus and medial to the uterine vessels (Fig. 25-4). Greater morbidity including injury to the uterine vessels requires expertise with this procedure. In our experience with more than 60 cases, we have found it helpful to have an assistant provide fundal traction, whereas the surgeon grasps the uterine vessels and retracts them laterally, exposing an avascular space between the artery and the cervix. A right angle clamp is passed anteriorly to posterior through this avascular space, tenting and incising the posterior leaf of the broad ligament and grasping a Mersilene tape that is brought back through the space. The same procedure is repeated on the opposite side, and the tape is tied anteriorly (Figs. 25-5 to 25-8). Novy et al. have reported extensive experience with this procedure, with low morbidity and favorable outcome. Cesarean delivery is necessary, and the suture is left in place. In cases of pregnancy complications requiring midtrimester delivery, we have either performed a posterior colpotomy, cutting the tape and allowing for vaginal delivery, or performed laparotomy and hysterotomy, leaving the suture intact. In most of the reported series of abdominal cerclage including ours, this surgical procedure was performed during gestation. However, recently Groom and colleagues described this procedure as an interval cerclage in the nonpregnant state with subsequent good pregnancy outcome. Advantages of an interval procedure include avoidance of laparotomy in pregnancy and less bleeding morbidity. Disadvantages include inability to become pregnant and the difficulties of pregnancy management if the gestation results in a first trimester miscarriage. Currently, there are no studies

**Figure 25-2.** Placement of sutures for McDonald cerclage. A, We use a double-headed Mersilene band with four bites in the cervix, avoiding the vessels. B, The suture is placed high up in the cervix, close to the cervicovaginal junction, approximately at the level of the internal os.

**Figure 25-3.** Transvaginal sonogram of the cervix after cerclage placement. The internal os is closed, and there is no funneling. Echogenic spots in the cervix correspond to cerclage.
comparing interval versus abdominal cerclage during gestation that enable us to make specific recommendations about timing of the procedure.

To avoid an abdominal procedure in selected patients, we have described the placement of a transvaginal cerclage in cases of a hypoplastic cervix, or when the cervix is flush against the vaginal wall. Under ultrasound guidance, the supravaginal portion of the cervix is dissected away from the bladder and a suture is placed either in a purse-string fashion, or in cross fashion from 12 to 6 o’clock and 3 to 9 o’clock (Fig. 25-9). We have performed this procedure in 22 patients, avoiding an abdominal procedure with successful pregnancy outcome. Fifty percent of patients had a cesarean delivery, and the rest delivered vaginally after the suture was cut through a small posterior colpotomy incision. In the last few years, a laparoscopic abdominal approach to the cervix has been described using the same principles as an abdominal cerclage. The procedure has been described primarily in the nonpregnant state with subsequent good pregnancy outcome. Recently, Cho and colleagues performed laparoscopic abdominal cerclage during pregnancy in 20
Section V  Complicated Pregnancy

Figure 25-6. Abdominal cerclage. Bladder flap has been created and surgeon identifies and palpates uterine vessel.

Figure 25-7. Abdominal cerclage. Surgeon retracts laterally uterine vessel to create an avascular space between uterus and vessel, before passing right angle clamp with Mersilene tape through this space.

Figure 25-8. Abdominal cerclage. Mersilene tape has been placed circumferentially around uterine isthmus and tied anteriorly. Notice ballooning of the lower uterine segment above suture.
patients with minimal morbidity, and successful outcome in 19 of them. There is a need for randomized trials evaluating this new technique in the nonpregnant and pregnant state, compared with a vaginal approach to determine the best approach to patients with a history of failed cerclage.

Therapeutic and Emergent Cerclage

Patients demonstrating cervical change either by digital evaluation or transvaginal sonography may benefit from a therapeutic cerclage. The gestational age limit for cerclage placement is ill defined. Although some clinicians offer this therapeutic modality up to 28 weeks, we do not advocate the use of therapeutic cerclage beyond 24 weeks’ gestation, because of concerns about fetal viability and the potential to cause a preterm delivery while placing the cerclage. Some of these patients have been managed successfully with strict bed rest. If the decision is made to place a cerclage, we treat preoperatively with antibiotics and nonsteroidal anti-inflammatory agents, such as indomethacin. The patient is placed on strict bed rest for the first 72 hours and is advised to refrain from intercourse and strenuous physical activity for the remainder of the pregnancy. We follow these patients with frequent sonographic assessment of the cervix and recommend strict bed rest if the membranes are prolapsing to the level of the suture. Prophylactic tocolytics are not used after the procedure.

In situations in which the cervix has dilated enough to allow visualization of the membranes or the membranes have prolapsed into the vagina, placing an emergent cerclage constitutes a heroic maneuver. These patients are at high risk of having a subclinical infection and subsequent poor outcome, as described previously. To rule out infection, some clinicians advocate amniocentesis before cerclage placement. Several techniques have been described to reduce the prolapsing membranes, including the following: placing the patient in Trendelenburg position; the use of a pediatric Foley catheter to tease the membranes into the endocervical canal, and instilling 1 L of saline into the bladder with upper displacement of the lower uterine segment (Fig. 25-10). The efficacy of antibiotics or tocolytics has not been properly studied, but most series advocate their use. Although clinicians have been reluctant to offer cerclage in patients with protruding membranes, some reports have suggested salvage rate in excess of 70 percent despite advanced cervical dilatation.

Risks of Cerclage

Cervical lacerations at the time of delivery are one of the most common complications from a cerclage, occurring in 1 to 13 percent of patients. Three percent of patients require cesarean delivery because of the inability of the cervix to dilate secondary to cervical scarring and dystocia. Although the risk of infection is minimal with a prophylactic cerclage, the risk increases significantly in cases of advanced dilatation with exposure of membranes to the birth canal. Cervical cerclage displacement occurs in a small number of patients. We have not performed revision of the cerclage during the index pregnancy, although small series have reported successful surgical treatment of a failed cerclage. When the clinician is faced with premature rupture of membranes distant from term in a patient with cerclage, the decision to remove or leave the suture is controversial. Our own data suggests...
that with suture retention, there is an increased period of latency, at the expense of an increased risk for neonatal sepsis and mortality. These data have been challenged by reports from Jenkins and colleagues suggesting an increased latency period (244 versus 119 hours) without an increase in neonatal morbidity, in cases of retained cerclage, and by McElrath et al., who did not find differences in latency or neonatal outcome in patients when the suture was left in situ after rupture of the membranes. Decisions to remove the suture at the time of ruptured membranes should be individualized until more information becomes available. Finally, even though cerclage placement is considered a benign procedure, a maternal death secondary to sepsis in a patient with retained cer-

Figure 25-10. Emergent cerclage for bulging membranes at 23 weeks. A, Cervix dilated 3 cm with membranes protruding through the external cervical os into the vagina. B, Patient placed in Trendelenburg position, and bladder filled with saline. Stay silk sutures placed on anterior and posterior lip for traction while reducing membranes. McDonald cerclage placed distal to reduced membranes.
clage has been reported. The liberal use of this surgical procedure should be carefully balanced against potential harm, in particular for patients in whom the indications for cerclage are not clear.

**Alternative Treatments to Cervical Cerclage**

Nonsurgical interventions have been advocated for patients with presumed cervical incompetence. The rationale for the recommendation for bed rest alone, or in conjunction with cerclage, relies in the theoretical concept of putting less pressure on the cervix while in the recumbent position. The validity of this concept has not been scientifically proven and to date there are no proper studies evaluating this intervention alone versus cerclage, in a randomized prospective fashion. The efficacy of pharmacologic agents such as indomethacin, progesterone, antibiotics, and others remains to be elucidated. Recently the MFM Units Network reported their results, comparing weekly injections of 17-hydroxyprogesterone caproate for the prevention of preterm birth in women with history of prior spontaneous preterm delivery. Patients receiving the progestational agent had a 33 percent reduction in preterm birth compared with those receiving placebo. At this point, it is unclear how this information applies to patients with a history of cervical insufficiency, and further investigation is necessary.

Since the description by Vitsky in 1961 of the use of a vaginal pessary instead of cerclage for patients with cervical incompetence, several studies mainly in Europe suggest the same outcome for patients managed with this noninvasive modality compared with a surgical intervention. Recently Arabin et al. studied the use of a vaginal pessary in patients with a sonographically detected short cervix (Fig. 25-11). Patients managed with a pessary gained 99 days compared to 67 days for patients managed with bed rest alone. We have reported our initial experience using the same type of vaginal pessary studied by Arabin in patients with sonographic cervical shortening and a prior history of preterm delivery. When compared with bed rest alone, patients with pessaries gained significantly greater gestational age (10.0 ± 41 weeks versus 5.1 ± 3.6 weeks p = 0.03). Further prospective, randomized trials comparing pessary, cerclage, and bed rest are necessary before conclusions regarding the efficacy of any of these interventions can be established.

**SUMMARY**

Cervical incompetence is rarely a distinct and well-defined clinical entity but only one piece of a larger and more complex spontaneous preterm birth syndrome. The original paradigm of obstetric and gynecologic trauma as a common antecedent of cervical incompetence has been replaced by the recognition of functional, as opposed to anatomic, deficits as the more prevalent etiology. Cervical competence functions along a continuum, influenced by both endogenous and exogenous factors that interact through various pathways with other recognized components of the preterm birth syndrome: uterine contractions and decidual/membrane activation. Thus, the convenient term, cervical incompetence, may actually represent an oversimplified, incomplete version of the broader, though poorly understood, pathophysiologic process. Consequently, the continued use of traditional therapies, unsubstantiated by results of clinical trials, must be questioned. Effective, evidence-based management guidelines will stem from a more complete understanding of the preterm birth syndrome. This will improve patient selection and permit specifically tailored treatment regimens, confirmed by the results of well-designed intervention trials.
Cervical incompetence remains a clinical diagnosis, because a clinically useful, objective test coupled with an effective therapy, has not been identified. At present, cervical ultrasound represents a powerful research instrument that can be used to screen selected high-risk populations, identify patients who may have a treatable component of cervical insufficiency, and recommend effective interventions. Surgical intervention in the form of prophylactic cerclage, sonographically indicated cerclage, emergent cerclage, and abdominal/laparoscopic cerclage may be reasonable in a few selected patients. Alternative treatments such as bed rest and a vaginal pessary require further investigation.

KEY POINTS

- Cervical incompetence or insufficiency is primarily a clinical diagnosis characterized by recurrent painless dilatation and spontaneous midtrimester loss.
- Cervical incompetence is rarely a distinct and well-defined clinical entity, but only one piece of the larger and more complex preterm birth syndrome.
- Current evidence suggests that cervical competence functions along a continuum, influenced by both endogenous and exogenous factors, such as uterine contractions and decidua/membrane actuation.
- There is no objective diagnostic test for cervical incompetence.
- Cervical ultrasound performs poorly as a screening test in low-risk women, but it may be helpful in selected high-risk populations who may have a treatable component of cervical insufficiency.
- Prophylactic cerclage for patients with a classic history of cervical insufficiency remains a reasonable approach.
- Serial ultrasound evaluations of the cervix in patients at risk for cervical insufficiency may be an acceptable alternative approach to prophylactic cerclage.
- The benefit of cerclage for a sonographic short cervix in a high-risk population remains controversial.
- When a short cervix is found on ultrasound, cerclage does not improve outcome in women at risk for preterm delivery.
- Emergent cerclage may be beneficial in reducing preterm birth in a subgroup of patients without markers of infection.
- There is a need for randomized studies to evaluate alternative treatments for cervical insufficiency such as bed rest, pharmacologic therapy, and vaginal pessary.

REFERENCES


Section V Complicated Pregnancy

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