Objective: The objective of the study was to assess cerclage to prevent recurrent preterm birth in women with short cervix.

Study Design: Women with prior spontaneous preterm birth less than 34 weeks were screened for short cervix and randomly assigned to cerclage if cervical length was less than 25 mm.

Results: Of 1014 women screened, 302 were randomized; 42% of women not assigned and 32% of those assigned to cerclage delivered less than 35 weeks (%). In planned analyses, birth less than 24 weeks (%). and perinatal mortality (%). were less frequent in the cerclage group. There was a significant interaction between cervical length and cerclage. Birth less than 35 weeks (%). was reduced in the less than 15 mm stratum with a null effect in the 15-24 mm stratum.

Conclusion: In women with a prior spontaneous preterm birth less than 34 weeks and cervical length less than 25 mm, cerclage reduced previable birth and perinatal mortality but did not prevent birth less than 35 weeks, unless cervical length was less than 15 mm.

Key words: cerclage, cervical length, prior preterm birth, vaginal sonography

T
he role of cervical cerclage to prevent preterm birth is controversial.1,2 Originally proposed for use in women with recurrent midtrimester pregnancy loss that was unaccompanied by bleeding, contractions, infection, or ruptured membranes,5 cerclage has sub-sequently been more broadly recommended for women with a history of preterm birth, especially if the gestational age at birth was less than 26 weeks.7,8 Ultrasound studies5,6 showing that the cervix appeared to shorten without contractions in women destined for preterm birth led many to consider cerclage as prophylaxis,7,9 but several randomized trials have not supported this practice.10-12 Althuisius et al13 observed a significant benefit in a small clinical trial of women.
whose history or symptoms suggested cervical insufficiency; preterm birth before 35 weeks of gestation was observed in 44% of the no-cerclage group vs none of the women who were assigned to receive cerclage (P = .002). Larger trials included women with various historic risk factors for spontaneous preterm birth: Rust et al observed rates of preterm birth before 34 weeks of gestation in 35% of cerclage-group women vs 36% of controls. Berghella et al also observed similar rates of preterm birth before 35 weeks of gestation, regardless of group assignment: 45% in the cerclage group vs 47% in controls. Finally, a large multinational trial enrolled unselected, but mostly low-risk women with shortened cervical length of 15 mm or less and found no significant reduction in preterm birth before 33 weeks of gestation in women randomly assigned to treatment with cerclage (22%) vs controls (26%).

More recently a patient-level meta-analysis of these 4 randomized cerclage trials uncovered a relationship between pregnancy history and cerclage: intervention was effective only in singleton pregnancies (there was significant harm observed in women with a multiple gestation), and it was especially beneficial in women who had a prior preterm birth (adjusted odds ratio, 0.6).

Thus, significant controversy remains regarding appropriate candidate selection for cerclage. We hypothesized that cerclage would reduce the rate of preterm birth before 35 weeks’ gestation in women with a prior early spontaneous preterm birth before 34 weeks’ gestation and whose midtrimester cervical length was less than 25 mm.

**Materials and Methods**

This randomized controlled trial was performed by a consortium of 15 US clinical centers between January 2003 and November 2007. Healthy multiparous women carrying a singleton gestation who enrolled for prenatal care were screened to identify those with at least 1 prior spontaneous preterm birth between 17\( \frac{0}{7} \) and 33\( \frac{6}{7} \) weeks’ gestation, confirmed by a review of the patient’s medical records. When efforts to retrieve the records of the prior birth were unsuccessful, we accepted women as eligible if the events surrounding the prior birth included spontaneous causes such as preterm labor or preterm membrane rupture, and the reported birth weight was less than 2 kg.

Exclusion criteria were fetal anomaly, planned history-observed cerclage for a clinical diagnosis of cervical insufficiency, and clinically significant maternal-fetal complications (eg, fetal red cell isoimmunization, treated chronic hypertension, insulin-dependent diabetes) that would increase the risk of an indicated preterm birth and potentially confound the primary study outcome. Women with cerclage in a prior pregnancy were not excluded if review indicated that the cerclage had been placed for an indication other than classically defined cervical insufficiency. Qualifying women were invited to enroll in the ultrasound screening phase of the study.

Gestational age was established by a certain last menstrual period (if available), confirmed by standard sonographic biometric measurements at less than 20 weeks’ gestation. If a certain last menstrual period was not reported, gestational age was defined using the earliest available sonographic biometric information, and a second-trimester fetal anatomic assessment was performed to rule out structural anomalies. The conception date was used for women whose pregnancies were conceived by assisted reproductive techniques. As part of routine obstetric care, women were screened for Neisseria gonorrhoeae and Chlamydia trachomatis, and treatment was prescribed for those who were culture positive.

Fifty-six sonologists underwent a uniform certification process by a single investigator (J.O.) to ensure uniformity in sonographic equipment, measurement technique, completion of study forms, and adherence to protocol. Specifics of this sonographic evaluation based on the technique of Iams have been previously described. Briefly, the cervical length at each visit was measured along a closed endocervical canal, in which minimal degrees of apparent dilation (ie, echolu-
hours of the qualifying scan, and a McDonald procedure with nonabsorbable suture was the cerclage technique of choice. The use of perioperative prophylactic antibiotics and tocolytic medications was not specified in the protocol and left to the discretion of the managing physicians. Postrandomization patient management was similar in both cerclage and no-cerclage groups and included the recommendation for pelvic rest, described as abstinence from any sexual activity involving penetration of the vagina; no use of tampons; and no douching.

Recommended physical activity restrictions consisted of no prolonged standing longer than 4 hours; no heavy physical work involving lifting more than 20 pounds or straining; exercise only in moderation with no-impact aerobics or other activity that involves straining or Valsalva, such as weight training; and avoidance of any activity that brings on symptoms of pelvic pressure or discomfort.

Women were also educated regarding the signs and symptoms of preterm labor and preterm membrane rupture and instructed to report any changes in vaginal discharge, vaginal fluid, bleeding, or abdominal pain to their care providers.

Research nurses at each center maintained weekly contact with participants. Otherwise, management was directed by clinical practice at each center. Women in the no-cerclage group could receive a physical examination–indicated cerclage for acute cervical insufficiency diagnosed on clinical examination, whereas women who had undergone cerclage as their trial intervention could undergo cerclage revision if clinically indicated; postrandomization transvaginal ultrasound information was not utilized for clinical decision making. In the absence of pregnancy complications requiring earlier removal (eg, chorioamnion rupture, labor, hemorrhage), the cerclage suture was removed at 37 weeks’ gestation.

The protocol and consent forms received local institutional review board approval at all centers.

Assessment of outcome and statistical analysis

The primary study outcome was birth at less than 35 weeks’ project gestational age. From a previous report, we estimated that 57% of women in the no-cerclage group would experience a preterm birth before 35 weeks’ gestation. The study was designed to have 80% power to detect a 30% reduction in the rate of preterm birth or to an absolute rate of 40%. Allowing also for a maximum 10% lost-to-follow-up rate, we planned to enroll 300 women in the randomized intervention trial.

Because of previous observations demonstrating a preponderance of midtrimester births in these high-risk women with shortened cervical length, planned secondary outcomes of interest included the rates of birth less than 7 days from randomization; preivable birth (<24 weeks); and perinatal death, defined as either a stillbirth or a postnatal death prior to hospital discharge. We also planned to evaluate preterm birth less than 37 weeks.

Because cervical length as a surrogate for cervical competence is believed to operate on a continuum with a well-documented inverse relationship between shortest midtrimester cervical length and the risk of preterm birth, we had also hypothesized an interaction between cerclage efficacy and cervical length at randomization. Thus, we planned an analysis to assess the interaction between cervical length and treatment, and if found significant at the P = .10 level, associated analyses similar to the primary aims and within cervical length strata (<15 mm vs 15-24 mm) would be performed.

Randomization in predetermined blocks was stratified by each center and qualifying cervical length less than 20 mm vs 20-24 mm. Early in the trial (May 2003), the results of a randomized trial of 17-alpha-hydroxyprogesterone caproate became available. In response to this report, the steering committee and an independent data and safety monitoring board recommended that the use of progesterone for preterm birth prevention be an option for study participants. This was included in the informed consent process, and an additional randomization stratum, reflecting the woman’s stated intent to use progesterone, was added.

Intergroup comparisons were performed using the principle of intent to treat. The primary study outcome and other categorical variables were analyzed with \( \chi^2 \), whereas continuous variables were analyzed using a Student t test or Wilcoxon rank-sum test. Treatment differences in time to birth were assessed by Kaplan-Meier curves and the log-rank test. Multivariable logistic regression and Cox proportional hazard models considered possible confounders for the outcomes of preterm birth less than 35 weeks and time to birth respectively.

A single interim analysis was performed after half the planned sample had been randomized (yielding approximately one third of the planned 300 with pregnancy outcomes) using O’Brien-Fleming boundaries with critical values of \( P = .0064 \) at the interim assessment and \( P = .0498 \) for the final assessment.

Results

Of the 1044 women who were determined to have a qualifying prior preterm birth, 1014 (99%) were consented and underwent their initial sonographic assessment of cervical length. Review of prior pregnancy information indicated that of these 1014, 831 (82%) entered screening after medical record review confirmed a qualifying prior preterm birth. From this cohort, we observed 318 (31%) who experienced cervical length shortening less than 25 mm. Sixteen patients did not consent to randomization, and 302 (95%) were randomly assigned to no-cerclage or cerclage groups. Primary outcome information was available for all 153 in the no-cerclage group and for 148 of 149 in the cerclage group, leaving a total of 301 women in the analysis (Figure 1). Only 1 patient was excluded from randomization because of the diagnosis of acute cervical insufficiency at the randomization visit. Selected baseline characteristics of the study population are shown in Table 1,
FIGURE 1
CONSORT flow diagram

8770 initially screened for eligibility

1044 met initial criteria and consented

1014 women began ultrasound screening

318 observed cervical length shortening <25 mm

302 randomized

149 assigned to cerclage group
138 received assigned treatment
3 cerclage contraindication
8 declined to undergo surgery
1 emergent cerclage revision

153 assigned to no-cerclage group
139 received no cerclage
10 received emergent cerclage
4 received off-protocol cerclage

1 unknown outcome

148 analyzed

153 analyzed

7035 not eligible
691 declined participation

30 exclusions
16 ineligible on further review
14 withdrew from trial

663 cervical length ≥25 mm
33 exclusions
21 lost or unable to contact
9 withdrew from trial
3 became ineligible

16 exclusions
13 declined randomization
2 ineligible at randomization visit
1 withdrew from trial
showing the 2 groups to be well balanced.

Compliance with the intervention was good; a total of 14 women assigned to the no-cerclage group (9.1%) underwent the procedure, 4 solely at the discretion of their managing physicians (off-protocol treatment crossover), whereas 10 were placed for a diagnosis of acute cervical insufficiency (protocol-sanctioned treatment crossover, confirmed by review of the maternal records. Eleven women in the cerclage group (7.4%) did not receive the planned intervention: 8 declined to undergo surgery, whereas 3 procedures were contraindicated because of obstetric complications (intraamniotic infection, fetal death, and cervicitis) and were canceled by the managing physicians.

The primary outcome of preterm birth less than 35 weeks' gestation was observed in 32% of women in the cerclage group vs 42% in the no-cerclage group (odds ratio [OR], 0.67; 95% confidence interval [CI], 0.42–1.07; P = .09). As depicted in Figure 2, the Kaplan-Meier survival analysis, considering the time to death, and cervicitis) and were canceled by the managing physicians.

Table 1: Baseline characteristics for 301 women randomly assigned to cerclage or to no-cerclage groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No cerclage (n = 153)</th>
<th>Cerclage (n = 148)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race/ethnicity, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black (non-Hispanic)</td>
<td>93 (61)</td>
<td>80 (54)</td>
</tr>
<tr>
<td>White (non-Hispanic)</td>
<td>28 (18)</td>
<td>25 (16.9)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>17 (11)</td>
<td>27 (18.2)</td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Other</td>
<td>15 (9.8)</td>
<td>15 (10.1)</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single/never married</td>
<td>99 (65)</td>
<td>85 (57)</td>
</tr>
<tr>
<td>Married</td>
<td>42 (27)</td>
<td>49 (33)</td>
</tr>
<tr>
<td>Divorced</td>
<td>10 (6.5)</td>
<td>13 (8.8)</td>
</tr>
<tr>
<td>Widowed</td>
<td>1 (0.7)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.7)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Cigarette use, n (%)</td>
<td>10 (6.5)</td>
<td>5 (3.4)</td>
</tr>
<tr>
<td>Any drug abuse, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervicovaginal microbiology, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlamydia</td>
<td>8 (5.2)</td>
<td>6 (4.0)</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>2 (1.3)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>≥1 prior induced abortions, n (%)</td>
<td>25 (16)</td>
<td>25 (17)</td>
</tr>
<tr>
<td>Prior cerclage, n (%)</td>
<td>12 (7.8)</td>
<td>8 (5.4)</td>
</tr>
<tr>
<td>Maternal age, y</td>
<td>26.6 ± 5.1</td>
<td>26.4 ± 5.5</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>29.9 ± 7.5</td>
<td>29.2 ± 7.8</td>
</tr>
<tr>
<td>Number of prior births, n</td>
<td>2 (1.4)</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Years of education, n</td>
<td>11.9 ± 2.4</td>
<td>12.0 ± 2.8</td>
</tr>
<tr>
<td>Gestational age of qualifying birth, wk</td>
<td>24.9 ± 4.7</td>
<td>24.4 ± 4.9</td>
</tr>
<tr>
<td>Weeks of gestation at first vaginal sonogram, wk</td>
<td>17.4 ± 1.4</td>
<td>17.4 ± 1.2</td>
</tr>
<tr>
<td>Cervical length at first vaginal sonogram, mm</td>
<td>29.5 ± 12.9</td>
<td>28.5 ± 12.7</td>
</tr>
<tr>
<td>Weeks of gestation at randomization, wk</td>
<td>19.5 ± 2.0</td>
<td>19.4 ± 1.9</td>
</tr>
<tr>
<td>Cervical length at randomization, mm</td>
<td>19.5 ± 5.3</td>
<td>18.6 ± 6.3</td>
</tr>
<tr>
<td>Total number of vaginal sonograms, n</td>
<td>2 (1, 4)</td>
<td>2 (1, 4)</td>
</tr>
</tbody>
</table>

Plus-minus values are means and 1 SD.

^a^ Race and ethnic group are self-reported; ^b^ Median and interdecile range.


As depicted in Figure 3, the Kaplan-Meier graph and associated log-rank test (P = .024) demonstrated a significant beneficial effect of cerclage in the less than 15 mm stratum. Similarly, a Cox proportional hazards model demonstrated that the women in the less than 15 mm cervical length stratum who were assigned to cerclage had a significantly lower hazard for an earlier birth as compared with the no-cerclage group (hazard ratio, 0.57; 95% CI, 0.34–0.95; P = .03). As observed in the above-mentioned logistic regression analysis, the relationship between cerclage assignment and pregnancy duration in the 15-24 mm stratum in the survival analysis was also null (hazard ratio, 0.84; 95% CI, 0.65–1.09; P = .20).

When the progesterone-use stratum was introduced, only 10 of the eventual 302 women (3.3%) had been randomized. Of the subsequent 292, 117 were randomized within the progesterone
stratum: 56 were assigned to the cerclage group and 61 to no cerclage. Of the 175 who did not plan to use progesterone, 89 were assigned to cerclage and 86 to no cerclage \((P = .62)\). The single woman who was lost to follow-up was randomized both to the cerclage group and with the intent to use progesterone. In a logistic regression model, the effect of the patient’s plan to use progesterone on preterm birth less than 35 weeks was null \((OR, 0.97; 95\% CI, 0.6 –1.6)\). We also included the progesterone strata in a multivariable model with the intervention group and an interaction term. The interaction term was not significant \((P = .94)\). The inclusion of the patient’s plan to use progesterone in the model had no appreciable effect on the relationship between cerclage intervention and birth less than 35 weeks (adjusted OR, 0.67; 95% CI, 0.42–1.1; \(P = .09\)).

Secondary perinatal outcomes are depicted in Table 2. Delivery less than 7 days from randomization was very uncommon, affecting only 7 women \((2.3\%)\), and the intergroup distribution was not significantly different \((P = .72)\). However, previable birth less than 24 weeks occurred in 14% of the no-cerclage group vs 6.1% of the cerclage group \((P = .03)\), and preterm birth less than 37 weeks was also less common in the cerclage group \((P = .01)\). Intergroup rates of perinatal death were also significantly different: 8.8% in the cerclage group vs 16% in the no-cerclage group \((P = .046)\).

We also examined the homogeneity of the effect of cerclage on preterm birth outcomes across the participating centers with the Breslow-Day test. There was no significant heterogeneity across sites for birth less than 35 weeks \((P = .06)\), birth less than 37 weeks \((P = .33)\), birth less than 24 weeks \((P = .067)\), or perinatal death \((P = .24)\).

Surgical adverse events associated with cerclage placement were uncommon. Of the women who underwent protocol-directed cerclage \((\text{cerclage group, } n = 138)\), emergent cerclage \((\text{no-cerclage group, } n = 14)\), or a cerclage revision \((\text{cerclage group, } n = 1)\), only 2 experienced a reported complication: 1 experienced chorioamnion rupture during the procedure, and 1 experienced a postoperative hemorrhage. There were 2 reported surgical anesthetic complications: 1 failed spinal and 1 postspinal headache.

**Comment**

We did not observe a statistically significant benefit from cerclage in preventing birth before a gestational age of 35 weeks, the primary outcome for the trial. Whereas somewhat arbitrary, this gestational age endpoint was chosen to avoid cases of near-term birth, which are associated with much lower rates of neonatal morbidity and only rare mortality. Nevertheless, the weight of our findings suggests that cerclage, utilized for shortened cervical length in selected women with a prior early spontaneous preterm birth, can improve pregnancy outcomes with essentially no demonstrable harm.

We believe that the most clinically important finding from this randomized trial is the interaction between cervical length at randomization and cerclage effectiveness. The risk of prematurity is inversely proportional to cervical length measured with endovaginal sonography at various times in gestation, and the midtrimester has been the focus of most of the research in this area. We have demonstrated a biologically predictable, differential benefit of cerclage when the cervical length is very short, less than 15 mm. We chose a priori to examine 15 mm as an alternate cutoff to define shortened cervical length because this has been utilized by other investigators to assess both the predictive value of sonographic cervical length and cerclage effectiveness for shortened cervical length. Still unclear are the factors that incite pathologic cervical shortening in these women. Similarly, the precise mechanism by which cerclage confers a benefit is unknown, but it may support the immunological barrier between the chorioamnion-extraovular space and the vaginal microbiologic flora. Because of the well-known relationship between preterm birth history and

---

**Table 2**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No-Cerclage Group</th>
<th>Cerclage Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery before 7 days</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Birth before 24 weeks</td>
<td>14%</td>
<td>6%</td>
</tr>
<tr>
<td>Birth before 37 weeks</td>
<td>16%</td>
<td>8.8%</td>
</tr>
<tr>
<td>Perinatal death</td>
<td>16%</td>
<td>8.8%</td>
</tr>
<tr>
<td>Surgical complications (2 reported)</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>
subsequent pregnancy outcome,2 we had also considered the possible effect of the gestational age of the prior preterm birth on cerclage efficacy with regard to the trial’s primary outcome; the effect here was null (data not shown). However, based on prerandomization data from this trial, we recently reported the relationship between birth history and cervical length.22 Women with a prior birth less than 24 weeks were significantly more likely to experience cervical shortening (<25 mm) and did so at an earlier gestational age than women whose earliest prior birth occurred at 24-33 6/7 weeks. Thus, we conclude that, whereas birth history affects cervical length in a subsequent pregnancy, once shortening less than 25 mm is observed, this history does not significantly affect the cerclage intervention.

Possible limitations to our trial include the open treatment because blinding may have been possible only with sham surgery. Even then, evidence of the cerclage suture would be readily visible during a pelvic examination. However, because the primary and secondary outcomes were objective, the potential impact from lack of blinding may be minimal. The possibility of missing women who underwent rapid shortening and delivery during the sonographic screening was a concern, but only 1 woman was excluded from the randomized trial because of acute cervical insufficiency.

Another possible limitation was our decision to cap the upper gestational age cutoff for screening and randomization at 22 6/7 weeks of gestation, potentially limiting the generalizability of results beyond this gestational age. Although somewhat arbitrary, we were concerned about the possibility of cerclage-associated complications at the threshold of viability and the possibility of an interaction with other common postviability treatments for women threatened preterm birth. We recognize that other investigators have extended this temporal window to include more of the midtrimester.10 To the extent that some of our high-risk patients may have continued to experience pathologic cervical shortening after completion of ultrasound screening (as evidenced by the 10 women who later presented with acute cervical insufficiency and underwent physical examination-induced cerclage) and who may also have benefitted from earlier cerclage placement, our findings may have underestimated the utility of the intervention in this population.

The finding of no interaction between cerclage and progesterone and the complete lack of effect of progesterone on preterm birth in this trial was surprising. We purposefully added the progesterone stratum after a large randomized trial reported a reduced rate of recurrent preterm birth in women treated with 17-alpha-hydroxy progesterone caproate.20 Nevertheless, in spite of that demonstrated benefit, only 39% of our participants stated their intent to use progester-

---

**TABLE 2**

Secondary perinatal outcomes for 301 women randomly assigned to cerclage or no-cerclage groups

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No cerclage (n = 153)</th>
<th>Cerclage (n = 148)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth &lt;7 d from randomization, n (%)</td>
<td>3 (2.0)</td>
<td>4 (2.7)</td>
<td>.72</td>
</tr>
<tr>
<td>Preterm birth &lt;24 wks, n (%)</td>
<td>21 (14)</td>
<td>9 (6.1)</td>
<td>.03</td>
</tr>
<tr>
<td>Preterm birth &lt;37 wks, n (%)</td>
<td>91 (60)</td>
<td>66 (45)</td>
<td>.01</td>
</tr>
<tr>
<td>Perinatal death, n (%)</td>
<td>25 (16)</td>
<td>13 (8.8)</td>
<td>.046</td>
</tr>
</tbody>
</table>

*One neonate in the cerclage group was lost to follow-up.*

one for preterm birth prevention. However, because 17-alpha-hydroxyprogesterone caproate has to be extemporaneously compounded and is variably covered by third-party payers, we could not control the precise form of progesterone locally available to participants or the gestational age at the initiation of treatment. Moreover, the stratum was based on only a subject’s intended use of progesterone at the time of randomization, not an intention to treat by the managing physicians.

We emphasize that this screening and treatment regimen was limited to a highly selected population of women with a prior spontaneous preterm birth of a nonanomalous singleton at less than 34 weeks of gestation, primarily confirmed by history and review of maternal records. We have demonstrated that women with a prior early spontaneous preterm birth represent a population that can benefit from endovaginal sonographic cervical assessment. We recommend that women with this history be considered for serial cervical length measurement at 2 week intervals, beginning as early as 16 weeks of gestation.

Our screening schedule included weekly assessment if the cervical length was within 5 mm of our action point for randomization (25-29 mm). Nevertheless, our findings may not be prescriptive regarding the optimal cervical length cutoff for cerclage for the indication of shortened cervical length in these women at risk for recurrent preterm birth.

In planned secondary analyses we demonstrated improved obstetric outcomes in the form of lower rates of perinatal mortality using the trial’s entry cervical length cutoff of 25 mm. However, we also recognize that the beneficial effect of cerclage for pregnancy prolongation varies, depending on the degree of cervical length shortening prior to 23 weeks of gestation and is significantly more pronounced in women with very shortened cervical length less than 15 mm.

ACKNOWLEDGMENTS
Data safety and monitoring committee included: Dr. Andrew Satin (Chair), Dr. Cora McPherson, Dr. Alessandro Ghidini, Dr. Roger Soll, and Heidi Maloni. We also acknowledge George Howard, DiPth, Rachel Copper, RN, MSN, and Robin Steele for their many contributions to the trial.

REFERENCES