POLICY STATEMENT
CerviLenz is a single use device intended to measure vaginal cervical length during pregnancy. The measurement probe has calibrated markings that correspond to vaginal cervical length.

BLOOD BORNE PATHOGEN
EXPOSURE CATEGORY: I (Involves exposure to blood, body fluids, or tissues)

FUNCTION: Care of Clients

EQUIPMENT:
1. CerviLenz
2. Speculum
3. Light
4. Lubrication

POINTS OF EMPHASIS:
Prematurity remains the major cause of perinatal morbidity and mortality. Prematurity constitutes over half of all infant hospital charges. Importantly, prematurity accounts for 75% of perinatal mortality and greater than 50% of long-term morbidity.

The etiology of preterm birth is multifactorial. The major diagnostic classifications include spontaneous preterm labor, premature rupture of membranes, and cervical incompetence. With the exception of indicated preterm delivery, these diagnoses may include a contribution of premature cervical effacement. Of note, spontaneous preterm delivery (including preterm labor and preterm premature rupture of membranes) accounts for 70% of premature neonates.

The profession’s approach to premature labor and premature delivery has experienced a paradigm shift. Whereas early approaches to premature labor addressed tocolytic therapy for symptomatic patients, the focus subsequently shifted to the identification of patients at increased risk of premature labor, and most recently, to the initiation of prophylactic treatments for these identified patients. In part, this shift resulted from studies demonstrating that acute tocolytic treatment of spontaneous PTL may only be effective for 48 hours, after which there is no further benefit.

Despite sophisticated analytic approaches, positive predictive values of risk scoring systems are typically less than 25%, and don’t assess primaparas, who account for the majority of births in the United States. Thus, risk factor scoring systems for predicting a preterm delivery had limited clinical application in general obstetrical practices.

Despite promising reports of the efficacy of progesterone therapy, Petrini et al demonstrated that progesterone treatment in women with a previous preterm birth would have a minimal effect on the overall US preterm birth rate. They reasoned that if 17-hydroxyprogesterone caproate therapy was delivered to all women with a previous spontaneous preterm birth, it would reduce the overall US birth rate by only 0.3%.

A landmark study demonstrated that patients with a shortened cervix, as measured by transvaginal ultrasound (TVU), had a marked increase in the risk of preterm delivery at 24 weeks’ gestation, with relative risks 6-fold among those in the lowest tenth percentile (consistent with a cervical length of 25 mm). The length of the cervix was statistically and inversely correlated with the risk of preterm delivery at less than 35 weeks’ gestation. Cervical length measured by TVU has now been confirmed in numerous studies as a significant predictor of preterm delivery. Relative risks of preterm birth for patients with a short cervical length are significantly greater than that of any other risk factor (including previous preterm delivery) among both primigravidas and multigravidas, as well as symptomatic women and asymptomatic women with singleton pregnancies. Of note, studies of TVU cervical length assessment have demonstrated that cervical length itself is the predictive value, rather than a quantification of
internal os funneling. Funneling did not perform as well as absolute cervical length for the prediction of preterm birth.

Recent studies have demonstrated encouraging outcomes for the prevention of spontaneous preterm birth in patients with shortened cervical length. Prophylactic vaginal progesterone gel administered from approximately 20 weeks’ gestation until term resulted in a significant increase in the gestational age at delivery among patients with a cervical length of less than 28 mm. Not only was there improvement in gestational age, but the progesterone gel resulted in fewer NICU admissions and fewer days hospitalization. In asymptomatic women, with very short cervix, vaginal progesterone resulted in a 44% reduction in the rate of spontaneous delivery before 34 weeks of pregnancy.

The evidence generated by these studies inspired the SGOC to recommend that women with previous preterm labor and/or a short cervix (<15 mm at 22 to 26 weeks’ gestation) are appropriate for prophylactic progesterone therapy. Recently, ACOG indicated that progesterone supplementation for the prevention of recurrent preterm birth should be offered to women with a singleton pregnancy and a prior spontaneous preterm birth, and may be considered for asymptomatic women with an identified very short cervical length.

Opinion leaders have now emphasized the value of routine measurements of cervical length for screening purposes. While it has been stated that cervical length measurements should be a standard part of sonographic examination in the midtrimester, it has also been suggested that up to 5 midtrimester serial cervical length measurements (ie, every 2 weeks from 16 to 24 weeks) may aid in identifying patients at risk for spontaneous preterm birth. The cost of TVU screening however, can add $150 to $200 per scan and follow-up scanning can result in an additional $1,200 scan.

The FDA-approved CerviLenz cervical length measuring device provides a low-cost screening tool to identify patients who may benefit from progesterone therapy.

In Comparison
Digital assessment in an UCLA study were found to underestimate CL, whereas the CerviLenz device permits a visualized and objective CL measure in patients with preterm labor.

The negative predictive value of the CerviLenz measurement was similar, or better than, fFN. This device can rapidly and efficiently be used to identify women who are not at risk for preterm delivery.

Screening Regimen
There is little data to suggest an optimal screening regimen, but the NIH Maternal-Fetal Network trial establishing the predictive value of TVU in high-risk patients screened patients with cervical length assessments every 2 weeks, from 16 to 22 weeks gestation. Additional cervical length assessments may be used for a follow-up of women with borderline cervical lengths or those receiving treatment.

PROCEDURE:
1. Any medical professional trained to do a speculum exam can use CerviLenz.
2. Visualize the cervix. To measure accurately, it is important to clearly visualize the cervix.
3. Insert CerviLenz into the vaginal toward the cervix, leading with the measurement probe extended beyond the flange.
4. Orient the device with the measurement probe at 3 or 9 o’clock, to the right or left of the cervix.
   a. A Southern California study demonstrated that left and right lateral cervical portio length measurements were highly correlated to each other.
5. Do not insert the measurement probe into the cervical os.
6. Advance the measurement probe along the lateral wall of the cervix until there is slight resistance at the vaginal fornix.
7. For accurate measurement:
   a. The probe should slide directly along the cervical wall rather than at the angle or away from the cervix.
   b. The probe should advance only until it is just touching the back of the vagina.
8. Advance the flange until it rests gently on the cervix. For an accurate measurement, the flange should lay flat on the cervix.

9. Lock the measurement probe by pressing the button on the handle.
   a. If unsure that the probe was positioned optimally, another measurement can be taken without removing the device from the vagina. Alternatively, the probe can be removed and inserted again.
   b. Unlock the probe by pressing the button from the opposite side of the handle; reposition the probe and flange for another measurement; re-lock.

10. Remove CerviLenz.

11. Read the scale and record the CerviLenz measurement.

12. Dispose in an appropriate waste container.

13. Remove speculum.

DOCUMENTS:
CerviLenz Informed Consent
CerviLenz Procedure Notes

REFERENCES:


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Penny Lane MSN, CNM                  DATE: 11/10/2012

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DATE: ______________________