CerviLenz®

CONFIDENT DECISIONS FASTER

CerviLenz® in the Literature

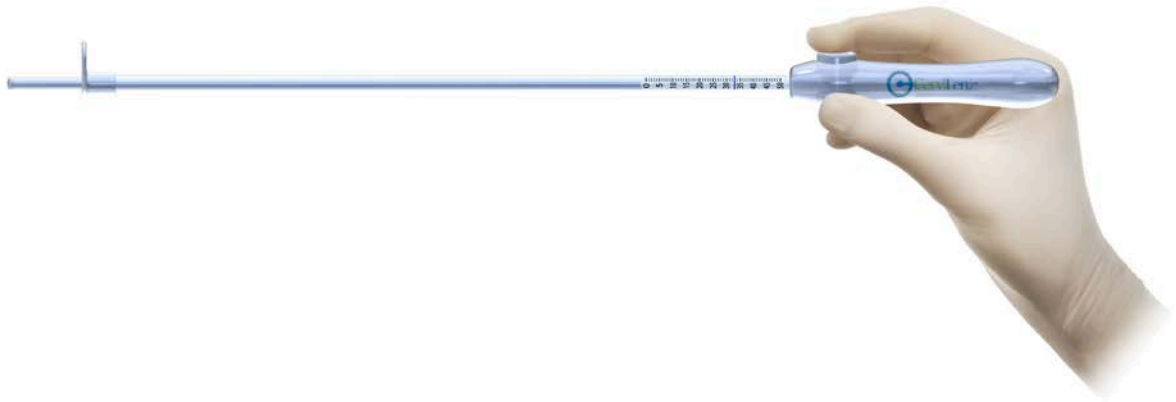
From Research to Clinical Practice

1. Introducing CerviLenz: A New Tool
2. CerviLenz and Transvaginal Ultrasound
3. CerviLenz and Fetal Fibronectin
4. CerviLenz and the Manual Exam
5. Assessing Preterm Birth Risk
6. Triaging Preterm Labor

Using CerviLenz ®

Measure vaginal cervical length objectively

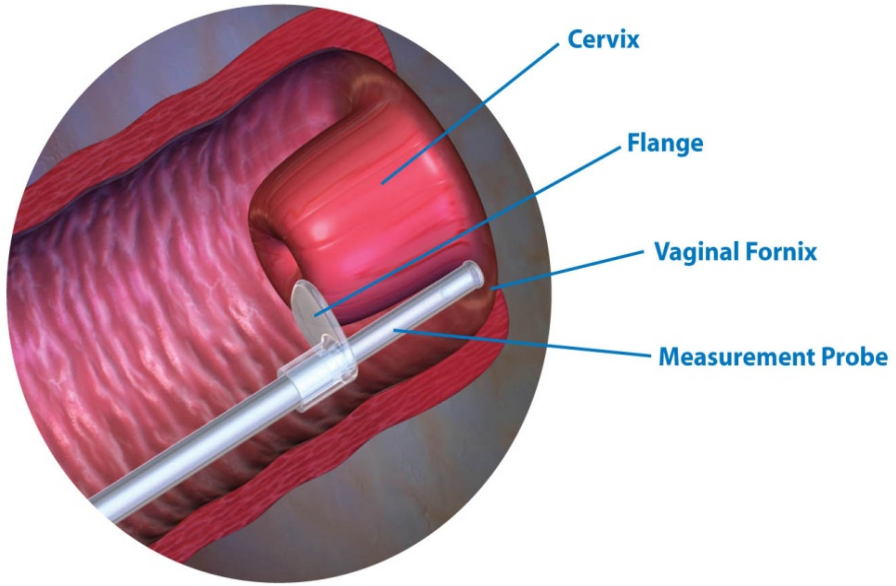
A quick, easy measurement



- Immediate results
- Office, clinic, hospital
- For use by obstetricians, midwives, and nurses
- Used during a speculum exam

Directions for Use

- During the speculum exam, visualize the cervix.
- Insert CerviLenz leading with the measurement probe extended.
- With the measurement probe at 3 or 9 o'clock, advance it along the lateral wall of the cervix until there is slight resistance at the vaginal fornix.
- Advance the flange until it rests gently on the cervix.
- Press the button to lock the measurement probe.
- Remove CerviLenz. Read the scale. Record the CerviLenz measurement.



Objective cervical portio length measurements: consistency and efficacy of screening for a short cervix

Ross MG, Cousins L, Baxter-Jones R, et al.

J Reprod Med 2007

Objective and Design

- Objectives
  - Determine the consistency of CerviLenz cervical portio length measurements at each quadrant of the cervix
  - Assess the ability of CerviLenz measurements to identify patients with short cervix by transvaginal ultrasound
- Inclusion criteria
  - 18 years of age and older
  - 12-34 wks gestational age
  - No active uterine contractions, < 3 cm dilation, intact membranes
  - No cerclage
  - No known placenta previa

Methods

- 189 patients enrolled
- CerviLenz and TVU measurements were performed at the same patient visit
  - Different experienced examiners
  - Blinded to the other measurements
- CerviLenz: measurements at 4 quadrants
- TVU: 3 measurements, technically superior chosen

Results

- Left and right lateral CerviLenz measurements were highly correlated to each other (r=0.95)
- A CerviLenz mean measurement of < 30 mm predicted a short cervix < 30 mm by transvaginal ultrasound
  - Sensitivity of 88%
  - Specificity of 92%
  - Negative predictive value of 99%

Conclusions

- Right and left lateral cervical portio measurements can be easily and objectively obtained with CerviLenz and are nearly equivalent
- Cervical portio length can be consistently obtained with CerviLenz without digital introduction into the cervix or vagina
- A CerviLenz measurement less than 30 mm identifies a patient subpopulation who may benefit from further evaluation and/or intervention, such as TVU cervical length assessment.

Direct cervical measurement using CerviLenz as an indication of sonographic cervical length

Moller M, Newnham JP, Nathan L, et al.

Reprod Sci 2010

Objectives and Methods

- Objectives
  - Assess CerviLenz as a reliable indicator of transvaginal cervical length
  - Assess its suitability as a screening method for cervical shortening in pregnant women both at high and low risk of preterm birth (PTB)
- Methods
  - 75 patients; 261 measurements
    - High risk women: history of spontaneous PTB < 34 weeks or previous cervical surgery; examined at intervals determined by their clinicians
    - Low risk women: all others; examined monthly until 32 weeks
  - CerviLenz measurement and multiple TVS images at each exam
  - Images read independently by two MFM specialists blinded to the CerviLenz measurement; final TVS measure determined by consensus

Results

- Mean CerviLenz measurement: 24mm (±6mm)
- Mean TVS reading was 34mm (±9mm)
- CerviLenz underestimated TVS reading by a mean of 9mm (95%CI 9-10mm p<0.001)
  - Mean difference between CerviLenz and TVS readings decreases with gestational age
  - High risk status did not influence this after accounting for baseline CerviLenz measurements

ga (wks)	12	16	20	24	28	32
Mean difference (mm)	11.9	9.6	7.2	4.9	2.6	0.3
95% CI	16.6, -7.1	-16.1, -3.0	-12.2, -2.3	-11, 1.6	-9.1, 4.0	-7.4, 6.9

Results

- In ROC analysis a CerviLenz measurement ≤ 24.5 mm predicted a TVS reading < 25 mm (AUC=0.867)
  - Sensitivity of 92%
  - Specificity of 56%

CerviLenz assessment of cervical length compared to fetal fibronectin in the prediction of preterm delivery in women with threatened preterm labor

Burwick, R, Zork, N, Lee G, et al.

J Matern Fetal Neonatal Med 2010

Objective and Design

- Objective: to determine whether cervical length measured by the CerviLenz measuring device is an effective screening tool for the prediction of preterm delivery (PTD) compared to fetal fibronectin (fFN)
- Inclusion criteria
  - Patients with threatened preterm labor
  - 24-34 wks gestational age
  - Uterine contractions, < 3 cm dilation, intact membranes
  - Singleton gestation
  - No vaginal bleeding or recent intercourse

Baseline Demographics and Measures

Baseline Measures	N=52
Maternal Age (mean yrs ± SD)	27.9 ± 7.27
Entry Gestational Age (mean wks ± SD)	30.4 ± 2.85
Nulliparous	38.5%
Prior preterm birth	28.9%
Ethnicity	
Hispanic	72.6%
Caucasian	11.8%
African-American	11.8%
Other	3.9%
CerviLenz CL (mean mm ± SD)	33.6 ± 7.1
CerviLenz CL < 30mm	20.9% (9/43)
fFN positive	24.5% (12/49)

Results: Predictive Values

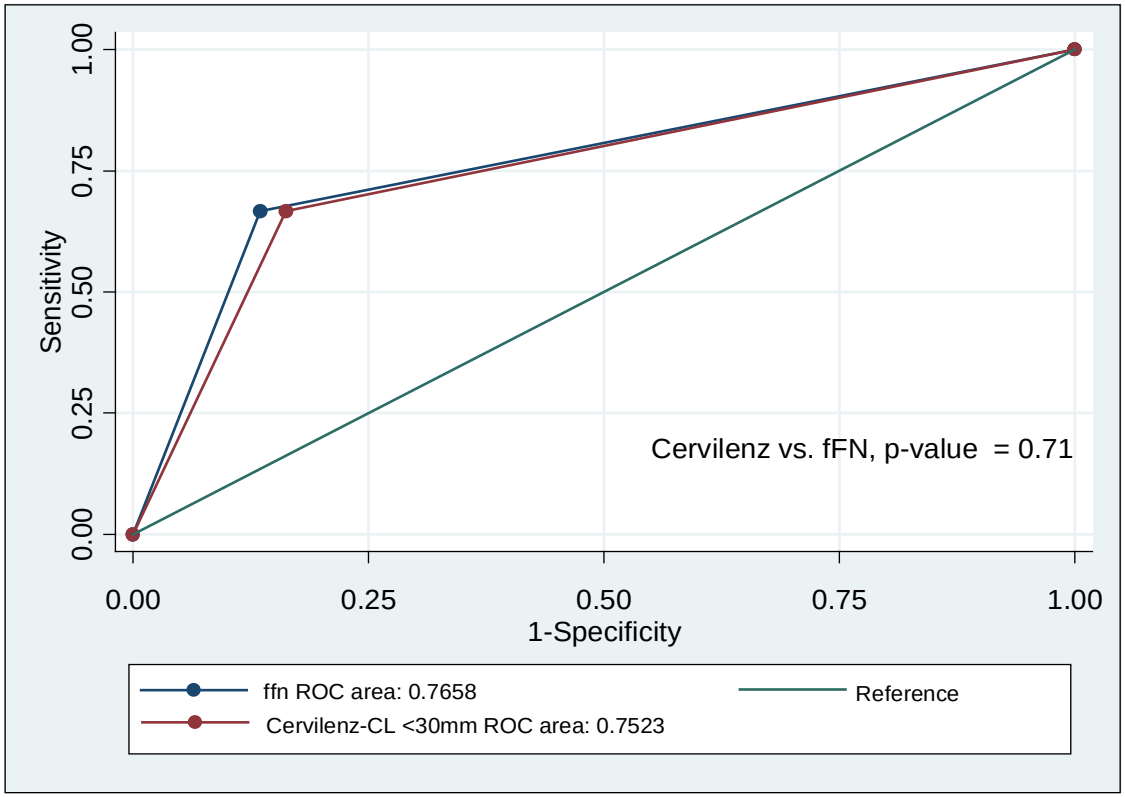
Predictive Values of fFN Testing and CerviLenz-CL < 30 mm

Predictive values	fFN (n=49)	95% CI	CerviLenz CL < 30 mm (n=43)	95% CI
Sensitivity for PTD <7d	**66.7%**	53.5-79.9%	**66.7%**	52.6-80.8%
Specificity for PTD <7d	**78.3%**	66.7-89.8%	**82.5%**	71.1-93.9%
PPV for PTD <7d	**16.7%**	6.2-27.1%	**22.2%**	9.8-34.7%
NPV for PTD <7d	**97.3%**	92.8-100%	**97.1%**	92.0-100%

Measurement of cervical length with CerviLenz is equivalent to fFN in screening symptomatic women for PTD within 7 days or prior to 37 weeks

Results: ROC Curve

fFN compared to CerviLenz-CL < 30 mm in Prediction of PTD < 7 days in Women with Threatened Preterm Labor



Conclusions

- CerviLenz-CL ≥ 30 mm
  - Excellent reassurance against PTD within 7 days (NPV 97.1%)
  - TVU-CL is unnecessary and likely not cost effective; CerviLenz measures the cervical portio length, so TVU-CL would be longer than CerviLenz-CL for the majority of measurements
- CerviLenz-CL < 30 mm
  - Warrants further evaluation, similar to a positive fFN result, given increased risk for delivery within 7 days
  - At a minimum, prolonged observation and serial CerviLenz-CL measurements should be performed to evaluate for active cervical change
  - Alternatively, TVU could be performed
  - In an outpatient setting, the patient should go to the hospital for triage of suspected preterm labor

Blinded comparison of cervical portio length measurements by digital examination vs CerviLenz

Burwick RM, Lee GT, Benedict JL, et al.

Am J Obstet Gynecol 2009

Objective and Methods

- Objective: to compare the accuracy of digital cervical length examinations with CerviLenz measurements, in women presenting with symptoms of preterm labor
- Methods
  - Forty two patients with singleton gestation from 24-34 weeks' gestation and cervical dilation < 3 cm underwent speculum examination and CerviLenz measurement
  - A second examiner, blinded to results, digitally measured cervical length

Results and Conclusions

- Results
  - Digital cervical length was significantly less than CerviLenz: 2.88 vs 3.40 cm ($p<0.001$)
  - Mean absolute difference of 0.89 ± 0.08 cm
  - Difference between digital and CerviLenz measurements exceeded 1 cm in 36% of patients
- Conclusions
  - Digital assessment underestimates cervical length
  - CerviLenz permits a visualized and objective cervical length measurement in patients with preterm labor symptoms

CerviLenz ® in Practice: at the Office, Clinic, or Hospital

What's her CerviLenz measurement?

Assessing Preterm Birth Risk

- Women with a short cervix are at high risk for preterm birth and may need specialized care
- Evaluate for short cervix – during a prenatal visit, a CerviLenz measurement helps you identify patients who may have a short cervix
- Monitor for cervical shortening – at follow-up visits, repeat CerviLenz measurements help you quantify any change in cervical length

Triaging Preterm Labor

- Cervical length is critical for diagnosing preterm labor
- Extensive literature supports a step-wise approach using cervical length as the basis for decisions about further testing and treatment
- Use CerviLenz during the initial assessment of all preterm labor patients – then decide if you need to analyze the fFN specimen or perform a transvaginal ultrasound exam

CerviLenz Guides Patient Management

- A CerviLenz measurement ≥ 30 mm is reassuring and supports managing her expectantly
  - Effectively rules out short cervix by transvaginal ultrasound
  - Represents an extremely low risk for preterm birth within 7 days among women with symptoms of preterm labor (predictive values comparable to fFN)

CerviLenz Guides Patient Management

- A CerviLenz measurement < 30 mm suggests additional assessment or treatment
  - Transvaginal ultrasound
  - fFN analysis
  - Consultation with a Maternal-Fetal Medicine specialist
  - Therapies such as tocolytics or progesterone

Save Time, Save Money, Improve Care

- CerviLenz gives you a new way to measure cervical length quickly and easily
- CerviLenz allows you to use time-consuming, expensive tests more selectively
- CerviLenz helps you identify women who may need high risk care

References

CerviLenz Research

Burwick, R, Zork, N, Lee G, et al. Cervilenz assessment of cervical length compared to fetal fibronectin in the prediction of preterm delivery in women with threatened preterm labor. J Matern Fetal Neonatal Med 2010;0:e1-e5.

Burwick RM, Lee GT, Benedict JL, et al: Blinded comparison of cervical portio length measurements by digital examination vs Cervilenz. Am J Obstet Gynecol 2009;200:e37-e39.

Moller M, Newnham JP, Nathan L, et al: Direct cervical measurement using CerviLenz as an indication of sonographic cervical length. Reprod Sci 2010;17,3 suppl:1A-64A.

Ross MG, Cousins L, Baxter-Jones R, et al: Objective cervical portio length measurements: consistency and efficacy of screening for a short cervix. J Reprod Med 2007;52:385-389.

Other CerviLenz Publications

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Ross, MG. Preventing preterm labor: progesterone and cervical length assessments. The Female Patient 2009;34:38-40.

Ross MG, Beall MH. Prediction of preterm birth: nonsonographic cervical methods. Semin Perinatol 2009;33:312-316.

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