A force-measuring device combined with ultrasound-based elastography for assessment of the uterine cervix

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Abstract

Introduction: In this feasibility study, we hypothesize that the evaluation of cervical biomechanical strength can be improved if cervical length measurement is supplemented with quantitative elastography, which is a technique based on conventional ultrasound elastography combined with a force-measuring device. Our aims were to: (a) develop a force-measuring device; (b) introduce a cervical elastography index (CEI) and a cervical strength index (CSI; defined as cervical length × CEI); (c) evaluate how these indexes assess the cervical softening that takes place during normal pregnancy; and (d) how these indexes predict the cervical dilatation time from 4 to 10 cm.

Material and methods: An electronic force-measuring device was mounted on the handle of the transvaginal probe, allowing for force measurement when conducting elastography. The study group concerned with normal cervical softening included 44 unselected pregnant women. Outcomes were CEI and CSI at different gestational ages. The study group for labor induction included 26 singleton term pregnant women admitted for labor induction. Outcome was defined as cervical dilatation time from 4 to 10 cm. Elastography measured the changes in mean gray value (intensity) during manual compressions. Region of interest was set within the anterior cervical lip.

Results: We found that the mean of all variables regarding cervical softening decreased from early to late pregnancy: ie cervical length from 34 to 29 mm, CEI from 0.17 to 0.11 N, and CSI from 5.9 to 3.1 N mm. Moreover, the cervical dilatation time during labor induction was associated with CEI, although not statistically significantly (area under the ROC curve of 0.67), but not with the Bishop score, the cervical length, or the CSI.

Conclusions: We propose that quantitative elastography based on changes in the intensity of the B-mode ultrasound recording, in combination with a force-measuring device on the handle of the vaginal probe, deserves further investigation as an approach for evaluation of cervical biomechanical strength.
1 | INTRODUCTION

Today, our best tool for assessing the risk of spontaneous preterm birth\(^1-3\) and failed labor induction\(^4,5\) is measurement of the cervical length by transvaginal ultrasound; however, the sensitivities are only 2%–70%, and the positive predictive values are 1%–40%, depending on the outcome measures and the population.\(^3,6-10\) This low performance may be explained by inter-individual differences in the collagen concentration of the cervical connective tissue and by the inter-individual difference in the cervical biomechanical strength. According to this so far unproven hypothesis, women with a congenitally short cervix but with strong connective tissue may erroneously be categorized as patients at risk of preterm birth. In contrast, women with normal cervical length but with weak connective tissue may erroneously be categorized as low-risk patients.

If the above-mentioned hypothesis is true, a combination of cervical length measurement and cervical biomechanical strength assessment may provide a better performance. However, the assessment of cervical strength by biomechanical devices,\(^11,12\) conventional elastography,\(^13\) and shear-wave speed\(^14-16\) have not yet proven their clinical applicability. Therefore, quantitative elastography deserves attention. In contrast to conventional elastography, quantitative elastography refers to a scanning technique by which one obtains an objective assessment of the cervical biomechanical strength. This technique is based on a force-measuring device mounted on the handle of the transvaginal probe.

We invented such a force-measuring device by which we can assess the force applied to the cervix during vaginal ultrasound scanning. Simultaneously, an elastography program determines the deformation of the cervix. That allows us to calculate a cervical elastography index (CEI; force/deformation) which expresses the strength of the cervical tissue within the region of interest (ROI). Furthermore, we merged this CEI with the cervical length measurement in a cervical strength index (CSI; cervical length \(\times\) CEI), which might express the strength of the full cervix.

In this feasibility study, we aimed to evaluate whether the CEI and the CSI express important aspects of cervical physiology. We therefore determined the interobserver variabilities, the associations with gestational age in normal pregnancies, and the associations with the duration of the time for cervical dilatation from 4 to 10 cm after labor induction.

2 | MATERIAL AND METHODS

2.1 | Participants

For the evaluation of the associations between CEI and CSI with gestational age, we included 66 unselected pregnant women with a normal singleton pregnancy and a gestational age within one of the following groups 12\(+0–14+0\), 19\(+0–21+0\), 30\(+0–34+6\), and 35\(+0–40+0\) weeks. For the evaluation of the cervical dilatation time, we included 38 singleton term-pregnant women (gestational age 37\(+0–42+0\) weeks) admitted for labor induction by prostaglandin \((n = 31)\), double balloon catheter \((n = 2)\), or amniotomy \((n = 5)\). The start of the active phase was defined by cervical dilatation of 4 cm, which is in accordance with the national Danish guidelines. A relatively long time for dilatation from 4 to 10 cm was defined as 7 hours. We did not include women with membrane rupture, non-Danish speaking, with an age under 18 years, with uterine contractions, and any connective tissue disease.

2.2 | Ultrasound equipment and software

Cervical scans were performed with a two-dimensional transvaginal ultrasound probe (IC5-9-D, GE Healthcare, Zipf) at three different Voluson™ E10 Expert scanners (GE Healthcare, Zipf); one with BT18; one with BT17; and one with BT20 software.

The default settings were as follows: gain: 0; dynamic contrast: 6; magnification factor: 1.3; elasto map: 5; persistence filter: 6; line density: 1; window length: 22; window step: 4; filter axial: 2; filter lateral: 7; frame reject: 0; pixel reject: 0; transparency: 195; pulse repetition frequency: 25 Hz; lateral resolutions: 0.5 cm, smoothing filter: average three samples; frame rate: 10 Hz; B-mode image depth: 3 cm and 120° angle; color box depth: 2 cm and 75° angle.
The color box was placed as close as possible to the probe, with the center of the color box at the probe centerline.

2.3 | Force-measuring device

Custom-built, force-measuring shells were mounted on the handle of the transvaginal probe (Figure 1A), and are described in Appendix S1. The force was determined along the probe centerline by a button load cell (0–20 N, OMEGA™) (Figure 1B). The force was sampled at 80 Hz with an HX711 (Elextra.dk) connected to an Arduino Nano (RS Components, DK) that transferred the force and time to a computer.

2.4 | Scans

The certified operators (CRT or MSSJ) measured the length of the cervical canal in accordance with the Fetal Medicine Foundation guideline17 and conducted two or three elastography scans of six to ten compression-decompression cycles at ≈1 Hz.

All elastography scans were saved as AVI (audio video interleave) movies and separated into individual images using VirtualDub v.1.10.4. The image sequences were imported to imageJ.18 We defined the anatomical area of interest as the homogeneous area within the middle third of the anterior cervical lip. The depicted ROI was placed at the B-mode image within 30° from the probe centerline within the anatomical area of interest, but surrounded by a small buffer zone in order to ensure that areas outside the anatomical area of interest were not included in the ROI during the compression-decompression cycles (Figure 2A).

2.5 | Data processing

The fundamental principal behind quantitative elastography is to quantify the elastic modulus (stiffness) of the cervical tissue, which is defined as the force needed to induce a certain deformation, i.e. the proportionality constant between stress and strain.19,20 It is proposed that the measured force is proportional to the stress, and the change in intensity of the ultrasound image is proportional to the strain. It can be argued that acoustic impedance is dependent on the tissue density and compressibility.21–23 This implies that the more deformed the tissue is, the higher the echo intensity measured, and this intensity is converted into a numerical value (often 8-bit gray scale) for the ultrasound images/movies recorded (aka brightness mode or B-Mode images). Hence, quantitative elastography is the proportionality constant from the change in the intensity of the B-mode image recorded as the change in the applied probe force. The obtained data can be applied for calculating the cervical elastography index (CEI; N) (see below) expressing the biomechanical strength and a cervical strength index (CSI; N mm), which was this CEI multiplied by the cervical length.

The ROI intensity (I) was calculated by imageJ as the mean gray value (0–255) for each image. Image time was computed based on the time stamp in the images. The intensity and force data were processed in a Python script (Python 3.8) (see Appendix S1 for script). After importing the intensity and force data sets, the force data were calibrated and expressed in Newtons (N). The first three taps, which in all scans were shorter and faster, were used for aligning the intensity and force times by time shifting the force data and thereby obtaining alignment of the peak apexes (Figure 2B). If the initial taps were corrupted or missing, up to eight taps were included in the time adjustment. A baseline correction was performed for both the intensity and the force data by subtracting the baseline calculated by linear regression, thereby placing the noisy base of the peaks below zero. Subsequently, the CEI was calculated as the slope of the positive intensity vs the corresponding force data by linear regression, i.e. only including the peaks in the CEI (Figure 2B). All intensity and force data were evaluated by two authors (CRT and MH). Data sets were found to be unsuited for further analysis if time shifting was not possible or the data were without peaks. Hence, CEIs were only based on the data sets, which passed this evaluation.

The mean of three CEIs per woman was reported. However, if one CEI measurement differed by 15% or more from the mean

FIGURE 1  (A) The transvaginal probe with the force-measuring device mounted on the handle. (B) Transvaginal probe handle (red) with the silicone spacers, allowing small movements of the handle and thereby measurements of the force by the load cell. The inner shell (yellow) contains the electronics and serves as an extension of the probe-handle, whereas an outer handle (gray) is mounted for protection as well as to ensure proper sanitation
2.6 | Statistical analyses

For the four gestational age groups, the means and the 95% confidence intervals (CI) were calculated and compared using linear regression with robust variance estimation to account for unequal variances. In addition, a test for trend was performed without dividing the gestational age into groups.

Receiver operating characteristic (ROC) curves were applied, showing the sensitivity against 1–specificity for different choices of cut-off. The overall ability to discriminate between women with a cervical dilatation time longer than 7 hours was measured by the area under the ROC curve. Statistical significance was defined as a two-tailed $p$-value less than 0.05. Statistical analyses were conducted using STATA/IC 16.0 (Stata Corp.).

The measurement variations were analyzed by the limits of agreement, which present 95% of the difference in measurements and an estimate of the standard deviation of the intra-individual measurement variation ($SD_m$). The intra-individual measurement variation between the two operators was compared using the Pitman test. The assumptions of the limits of agreement were assessed using a Bland-Altman plot. In addition, intraclass correlation coefficients were calculated. The mixed-effects linear regression model was used to estimate the intra-observer reliability for the two observers after assuming the same standard deviation in the groups compared.

2.7 | Ethical approval

The study was conducted according to the Declaration of Helsinki II and approved by the Danish Regional Committee on Health

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**TABLE 1** Cervical length (CL), cervical elastography index (CEI) and cervical strength index (CSI) dependence on gestational age (GA)

| GA (weeks) | n  | CL (mm)       | CEI (N)          | CSI (N mm)        |
|------------|----|---------------|------------------|-------------------|
| $12^{+0} - 14^{+0}$ | 9  | 33.8 (30.7–36.8) | 0.17 (0.15–0.20) | 5.9 (4.8–7.0) |
| $19^{+0} - 21^{+0}$ | 10 | 35.5 (33.0–37.9) | 0.15 (0.11–0.18) | 5.2 (4.1–6.3) |
| $30^{+0} - 34^{+6}$ | 10 | 34.0 (29.8–38.1) | 0.12 (0.08–0.16) | 3.9 (2.6–5.1) |
| $35^{+0} - 40^{+0}$ | 15 | 28.8 (23.8–33.8) | 0.11 (0.08–0.14) | 3.1 (2.2–4.0) |

$p$ value: 0.055 0.001 <0.001

Note: Values are given as mean with 95% confidence interval. Statistical analysis: Test for trend.

$n$, number of pregnant women.

(100% – [CEI/mean] 100% ± 15%), then the CEI was excluded. The mean of the remaining two scans was then calculated, and if the CEs differed by 15% or more from this mean, both scans were excluded, i.e. the woman was excluded from the study.

To assess the interobserver reliability for the CEI, two operators (CRT and MSSJ) independently performed the scans and placed the ROI within these scans. For intra-observer reliability, the ROI placement and the data processing were repeated after 4–6 weeks to avoid recall bias.
Research Ethics (1-10-72-138-16) on August 21, 2017 and the Danish Data Protection Agency (2012-58-006) on May 18, 2017. All participants gave written informed consent. Data were collected and managed using REDCap.24

3 RESULTS

During the compressions and the decompressions of the uterine cervix, we observed a linear correlation between the change in the force applied to the cervix and the change in the intensity of the B-mode picture (Figure 2A). Based on linear regression, we could therefore calculate the CEI (Figure 2B).

We included 66 pregnant women with different gestational ages but had to exclude 15 because the quality of the elastography scans was not satisfactory and seven because the CEIs differed by 15% or more from the mean. This resulted in a study population of 44, including 27 (61%) nulliparous women. Table 1 and Figure 3 show that the cervical length decreased slightly (15%) with advancing gestational age, whereas the CEI decreased more (35%) and the CSI (cervical length multiplied by CEI) even more (47%).

The results of the intra- and interobserver testing are presented in Table 2. There was no difference in the intra-individual measurement variation between the two observers (p = 0.137). Conversely, the interobserver results showed significant difference in the mean of the CEI: 0.069 (95% CI 0.018–0.121) (p = 0.013), contributing to the mediocre interobserver intraclass correlation coefficients.

Among the 38 women admitted for labor induction, we excluded four because the quality of the elastography scans was not satisfactory: six because the CEIs differed by 15% or more from the mean, and two because of acute cesarean section before active labor. This resulted in a study population of 26 including 17 (65%) nulliparous women. ROC curves for CEI, CSI, Bishop Score, and cervical length demonstrated statistically insignificant associations for the time of cervical dilatation from 4 to 10 cm being longer than 7 hours. The areas under the ROC curves were 0.67 for the CEI (95% CI 0.41–0.92); 0.62 for the CSI (95% CI 0.36–0.88), and only 0.56 for the Bishop score (95% CI 0.23–0.90) and 0.35 for the cervical length (95% CI 0.07–0.64). These results did not change after restricting the analysis to nulliparous women (results not shown).

4 DISCUSSION

This study demonstrates that a quantitative CEI (force divided by deformation) can be based on changes in the intensity of the B-mode scan combined with simultaneous assessments by a force-measuring device. With increasing gestational age, this CEI decreases much more than the cervical length. However, the CSI (CEI multiplied by the cervical length) decreases the most.

A strength of this study is the use of a well-described elastography algorithm, which we developed because the ultrasound machine’s algorithm was unavailable. A limitation to this study is the high number of scans excludes (31%–33%) because the data were not suitable for further analysis. In some cases, this was due to fetal movements affecting the position of the cervix, which caused displacement of the ROI. In other cases, the CEIs differed by 15% or more from the mean. According to our protocol, we obtained only two or three scans per woman. As these scans are not associated with significant discomfort for the woman, the number of scans can easily be increased to six or more within 1–2 min. This will allow us to exclude the suboptimal scans, thereby reducing the fraction of excluded patients and improve the interobserver reliability. In addition, the development of a force-measuring device that performs standardized compression itself may be considered. Further improvements may include simplification of the data processing, because it takes 10 minutes to analyze one scan. Another limitation is the design. Women being examined longitudinally through the pregnancy is preferred compared with the cross-sectional design used in this study.

It is well established that the softening of the uterine cervix starts in early pregnancy and proceeds towards term.25 This so-called ripening process has been associated with a 55% decrease in the cervical collagen concentration from gestational week 10 to term.26 This is a decrease that corresponds well with the 35% decrease in the CEI and the 47% decrease in the CSI described in this study. Most probably, the cervical shortening does not occur until the stress applied by
the growing fetus and the myometrial contractions exceeds the biomechanical strength of the cervix. Therefore, the cervical length only changes moderately during the first two trimesters. According to this hypothesis, women at risk of preterm birth may experience preterm cervical softening before the preterm cervical shortening; as a result, the CSI may be a valuable biomarker. Another group of women at risk of preterm birth has a congenital low collagen concentration in the cervix, ie the collagen concentration is low also in the non-pregnant state. These women may also be identified by the CSI. In accordance with this the cervical sliding sign is found to be associated independently with an increased risk of preterm labor in women with preterm uterine contractions. The cervical sliding sign is defined as the sliding of the anterior cervical lip on the posterior one when applying gentle pressure with the transvaginal probe.

In cervical biopsies taken immediately after spontaneous vaginal delivery, the collagen concentration is strongly associated (R² = 0.93) with the time for cervical dilatation from 2 to 10 cm, especially in nulliparous women. Furthermore, a study of labor induction using quantitative elastography based on reference material placed between the ultrasound probe and the cervix reported a statistically significant area under the ROC curve of 0.71 using cervical dilatation time above 5½ hours as the outcome, which is equivalent to our finding concerning the CEI.

5 | CONCLUSION

This study demonstrates that quantitative elastography of the uterine cervix can be based on changes in the intensity of the B-mode scan and simultaneous recordings from a force-measuring device. The derived variables CEI and CSI might be superior to the cervical length only measurements for the evaluation of the cervical softening taking place during normal pregnancy. Hence, they constitute a potential supplement for the evaluation of risk for preterm birth.

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CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTIONS

The idea for the study came from NU, PS, and MH. CRT, AKL, TØM, MSSJ, PB, NU, PS, and MH contributed to developing the method for the data processing. CRT and MSSJ conducted the scans and performed the statistical analysis. CRT wrote the first draft of the paper and edited the following versions. CRT, MSSJ, AKL, TØM, PS, PB, MH, and NU discussed the design, edited the manuscript, and agreed on the final version.

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SUPPORTING INFORMATION
Additional supporting information may be found in the online version of the article at the publisher’s website.

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