SONOGRAPHIC CERVICAL LENGTH MEASUREMENT IN PREGNANT WOMEN WITH A CERVICAL PESSARY

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Keywords: Cervical Length, Cervical Pessary, Preterm Birth

ABSTRACT

Objectives: The aims of this study were to describe and assess the feasibility of measuring cervical length (CL) by transvaginal sonography (TVS) and transperineal sonography (TPS) in women with a cervical pessary and compare the measurements with those obtained with a new transvaginal technique.

Methods: Measurement of CL by TPS was attempted immediately before TVS in 48 women with a cervical pessary between 22 and 23 weeks of gestation. TVS consists of two types of measurement: in the first, the probe was placed on the anterior fornix (standard technique), and in the second, the probe was inserted into the pessary to touch the anterior cervical lip (new technique). Two physicians consecutively performed these procedures and compared the measurements obtained. Intraclass correlation coefficients (ICCs) with 95% confidence interval (CI) were used to evaluate interobserver reliability and Bland-Altman analysis was used to assess interobserver agreement.

Results: In total, 258 measurements were analyzed. ICCs on the measurements obtained were 0.58 (95% CI, 0.34 to 0.75) for TPS, 0.65 (95% CI, 0.44 to 0.79) for TVS standard technique and 0.97 (95% CI, 0.95 to 0.98) for TVS new technique. Bland-Altman analysis indicated reasonable agreement between measurements obtained by two physicians for the three methods: TPS (mean difference, -0.99; 95% limits of agreement, -13.23 to 11.25), TVS standard technique (mean difference, -0.23; 95% limits of agreement, -10.90 to 10.44) and TVS new technique (mean difference, -0.01; 95% limits of agreement, -2.57 to 2.55). It is apparent from the images that the external os was not visible in 89% of cases when either the TPS or TVS standard technique was used. However, the external os was visible in 100% of cases when the new TVS method was used.

Conclusions: We propose a new technique for measuring and monitoring cervical length in women with a cervical pessary.

INTRODUCTION

It is well established that a sonographic short cervix is a powerful predictor of spontaneous preterm birth (SPB).[1-12] The interventions that may play a role in treating women with a shortened CL include cerclage[13-22], progesterone[23-26], and the cervical pessary. The use of a cervical pessary has been described as a possible method of preventing SPB in pregnant women when a shortened CL (≤ 25mm) is detected around the 20th week of gestation.[27-29] The cervical pessary is a silicone ring with a smaller diameter fitted around the cervix, and a larger diameter to fit the device against the pelvic floor. This effectively rotates the cervix towards the posterior vaginal wall and corrects the cervical angle (Fig. 1).[28]

Different techniques to measure CL have been described. Using the transabdominal sonographic approach, it is often not possible to obtain an appropriate view of the cervix, particularly if the length is short. A full bladder is also required for visualization, which could yield a falsely long CL.[30-33] Regarding the TPS, Cicero et al. demonstrated that visualization was satisfactory in only 80% of cases compared to the TVS[34]. The TVS has become the standard method to obtain measurements of CL, since it provides the observer with a complete view of the entire endocervical canal in the majority of cases[35,36]. However, in women with a cervical pessary, sonographic visualization of CL is difficult owing to the shadow cast by the silicone on the cervix. (Fig.2).

In view of the inconclusive results using the TVS standard technique, we sought to develop a method to visualize the cervix in patients with a cervical pessary. We found that good visualization of the cervix is enabled by passing through the virtual space between the pessary and posterior vaginal wall and inserting the probe inside the pessary which, if possible, touches on the external cervical os or anterior cervical lip. (Fig.3)

The aims of this study were to describe and assess the feasibility of measuring CL by TVS and TPS in women with a cervical pessary and compare the measurements with those obtained with a new transvaginal-intrapessary measurement technique.

METHODS

Our center offers women attending for routine antenatal care an ultrasound scan at 18-22 weeks which includes transabdominal sonogram of the fetus. At that time, they are offered a TVS of the cervix as a screening test for predicting SPB. Women with a short cervix (≤25mm) were invited to participate in an ongoing randomized controlled trial of the cervical pessary to prevent preterm birth.

All women gave their written informed consent, and the Ethics Committee of our hospital approved the study. We placed cervical pessaries that are CE-certified for the indication of preventing SPB (CE0482 / EN ISO 13485: 2003 annex III of the council directive 93/42 EEC). One size was used: 70 mm x 30 mm x 32 mm cerclage pessaries (lower larger diameter, height and upper smaller diameter) from Dr. Arabin GmbH & Co. We used a Siemens Sonoline G40 ultrasound machine equipped with a 9-4 MHz endo-vaginal transducer. Participants in this trial who attend the Preterm Birth Clinic at our centre undergo a monthly CL follow -up by ultrasound.

In order to validate the new technique, 48 of these patients with a cervical pessary were included in this study. In all cases, cervical length was measured by TPS, TVS (standard technique) and TVS using the new technique (transvaginal-intrapessary technique) between 22 and 23 weeks of gestation. Two experienced specialists carried out the examination and obtained the three proposed measurements in each case. Systematic evaluation showed that the cervix is best visualized when the probe is passed through the virtual space between the pessary and the posterior vaginal wall, and situated inside the pessary, leaning on the external cervical os or the anterior cervical lip (Figure 4). Therefore, it is useful to guide the transducer accordingly first towards the sacrum to reach that space and then towards the symphysis. The first 5 cases of each examiner were excluded from the analysis since they were considered to be part of the learning phase.

Statistical Analysis

Intraclass correlation coefficients (ICCs) and 95% confidence interval (CI) for the ICC[37,38], and the Bland-Altman method for assessing agreement, including calculation of the average discrepancy between measurements (mean difference), the 95% limits of agreement and the SD of mean difference[39], were used to assess interobserver reliability. The Bland-Altman method identifies the boundaries between which measurements are interchangeable, and determines the relationship between the difference in the measurement between observers and the magnitude of the measurement. Data were analyzed using SPSS 16.0 software (SPSS Inc., Chicago, IL, USA).

RESULTS

Mean maternal age (SD) of the 43 participants evaluated was 33.3 (4.67) years. Cervical length was successfully measured transperineally and transvaginally with the standard technique in all cases: 258 measurements were performed and compared. (Table 1)

Although it was possible to locate the cervix, pessary and internal cervical os in all cases, the canal and external os were hidden by the pessary shadow; thus, the measurement was taken from the internal os to the end of the pessary shadow. The new procedure, which permitted complete visualization of the canal with both external and internal os, could not be performed in one of the first five cases (learning period) owing to patient discomfort. In all cases analyzed (43), the external os and cervical canal were visible when the new TVS method was used. Therefore, it is the only technique which provides reliable measurement of the cervix in pregnant women with a cervical pessary.

ICCs of the measurements obtained were 0.58 (95% CI, 0.34 to 0.75) for TPS, 0.65 (95% CI, 0.44 to 0.79) for the TVS standard technique and 0.97 (95% CI, 0.95 to 0.98) for the new technique. (Table 2) There was a trend towards reduced reliability when TPS and the TVS standard technique were performed compared with the new TVS technique. This difference had statistical significance since the new TVS technique did not match the other two intervals.

Bland-Altman analysis indicated reasonable agreement between measurements obtained by two physicians for the three methods: TPS (mean difference, -0.99 (CI -2.9 to 0.89, range: 11.1 to 35.9); 95% limits of agreement, -13.23 to 11.25), TVS standard technique (mean difference, -0.23 (CI -1.89 to 1.40, range: 13.5 to 35.2); 95% limits of agreement, -10.90 to 10.44) and new TVS technique (mean difference, -0.01 (CI -0.40 to 0.38, range: 6.5 to 28.5); 95% limits of agreement, -2.57 to 2.55). Absolute differences between the measurements of the two observers with the three methods were: 42.5 for TPS, 10 for the TVS standard technique and 0.3 for the new TVS technique. (Figure 5)

DISCUSSION

Prospective trials have only recently been started to test the effectiveness of the cervical pessary[40]. We are currently conducting the first randomized controlled trial to test the effectiveness and safety of a cervical pessary to prevent preterm birth in women with a short cervix (≤25 mm). However, placement of a cervical pessary impairs visualization of the sonographic endocervical canal and external os when both TPS and TVS standard techniques are used. Yet, monitoring cervical length in patients treated with a cervical pessary is important, since it permits assessment of the risk for spontaneous preterm labor and birth.

With this new approach, the interobserver differences are minimal, while with the other techniques they are significantly greater owing to the shadow cast by the pessary on the sonographic cervical image, which hinders measurement of the whole cervical canal and only permits measurement from the internal cervical os to the end of the pessary shadow. The difference between the ICCs of the three methods suggests that the most appropriate method of measurement in patients with a cervical pessary is this new model since it provides a better view of the cervix.

The new TVS technique is easy to perform; however, we found that the sonographic examination could be painful in patients who have the pessary firmly applied against the posterior vaginal wall. Nonetheless, owing to patient discomfort, the sonographic examination could not be performed in only one patient.

The results of this study should be viewed within the context of the following limitations. This is the first study comparing CL measurement in pregnant women with a cervical pessary by the two methods published previously: TPS and the TVS standard technique; also, this study included a new method to measure CL in patients with a cervical pessary, the transvaginal-intrapessary technique. The sample size of this study was only 43 patients. More studies are required to independently confirm our results.

In conclusion, we propose a new TVS technique to examine the uterine cervix when women have a pessary. This technique may be helpful in monitoring cervical length during pregnancy in patients carrying this device and may provide insight into the changes in cervical anatomy which result from the use of a pessary.

ACKNOWLEDGMENT
The Institute Carlos III, Fondo de Investigación Sanitaria (FIS), PI 071086, Spain provided funding for this study, and Christine O'Hara for English language correction of the manuscript.

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TABLES AND FIGURES

Table 1.- Sonographic characteristics (CL) of 43 women with a cervical pessary.

	n = 43
TPS physician 1	23.43 mm. (10.4-40.9)
TVS (standard technique) physician 1	24.57 mm. (11.7-42)
TVS (new technique) physician 1	19.00 mm. (6.1-28.6)
TPS physician 2	24.41 mm. (10.2-37)
TVS (standard technique) physician 2	24.8 mm. (13.5-36.9)
TVS (new technique) physician 2	19.01 mm. (7-28.5)

Data are presented as median (range) for non-normally distributed parameters.

CL: cervical length

TPS: transperineal scan

TVS: transvaginal scan

Table 2.- Interobserver reliability of CL measurement with TPS, TVS standard technique and the TVS new technique.

Method	Intraclass correlation coefficient (95% CI)
TPS	0.58 (0.34 to 0.75)
TVS (standard technique)	0.65 (0.44 to 0.79)
TVS (new technique)	0.97 (0.95 to 0.98).

TPS: transperineal scan

TVS: transvaginal scan

Figure 1.- Image of a cervical pessary with a smaller diameter fitted around the cervix and a large diameter to be based on the pelvic floor, thus rotating the cervix to the posterior vaginal wall and correcting the cervical angle.

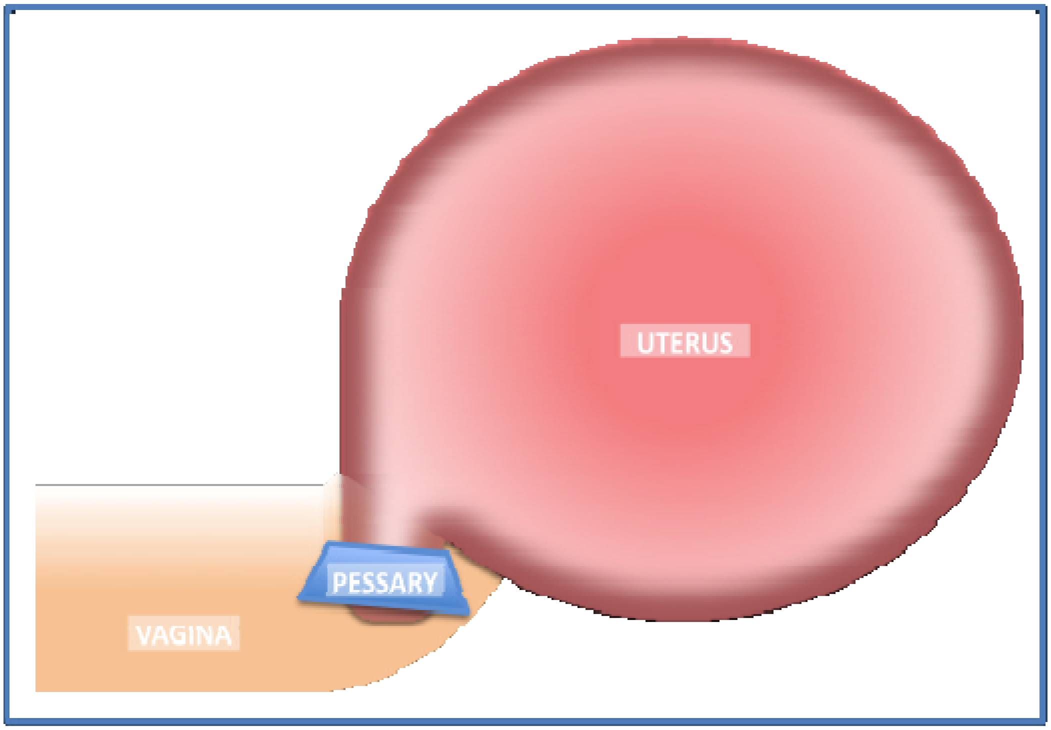


Figure 2.- Ultrasound visualization of cervical length in women using a cervical pessary (standard technique).

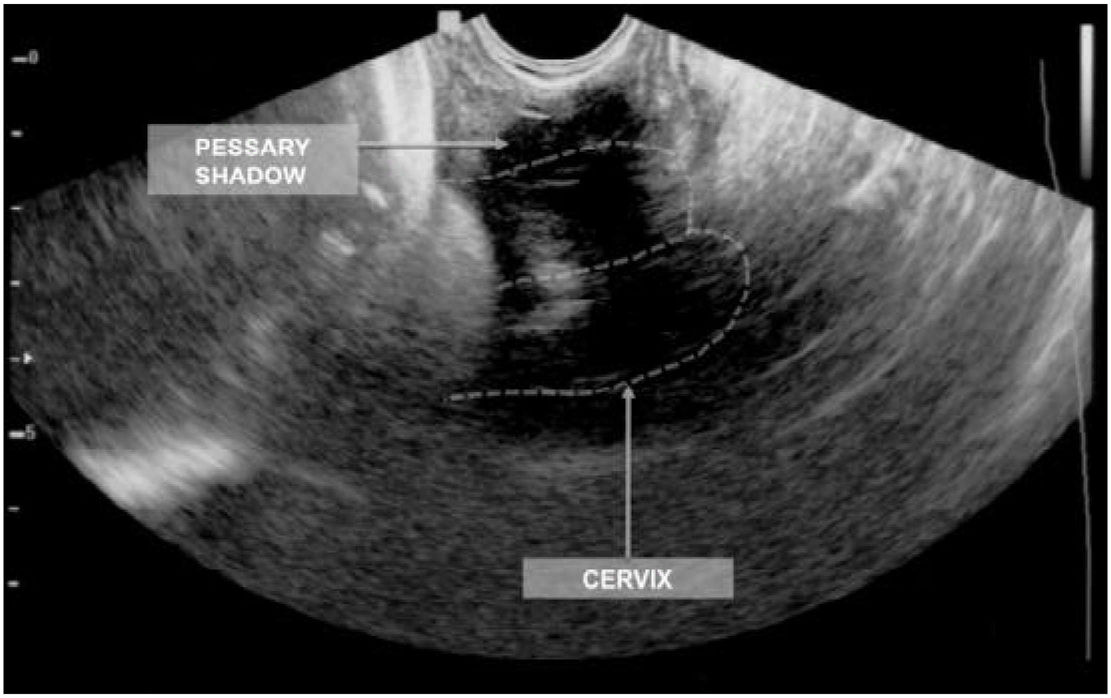


Figure 3.- Ultrasound visualization of cervical length in women using a cervical pessary (new technique).

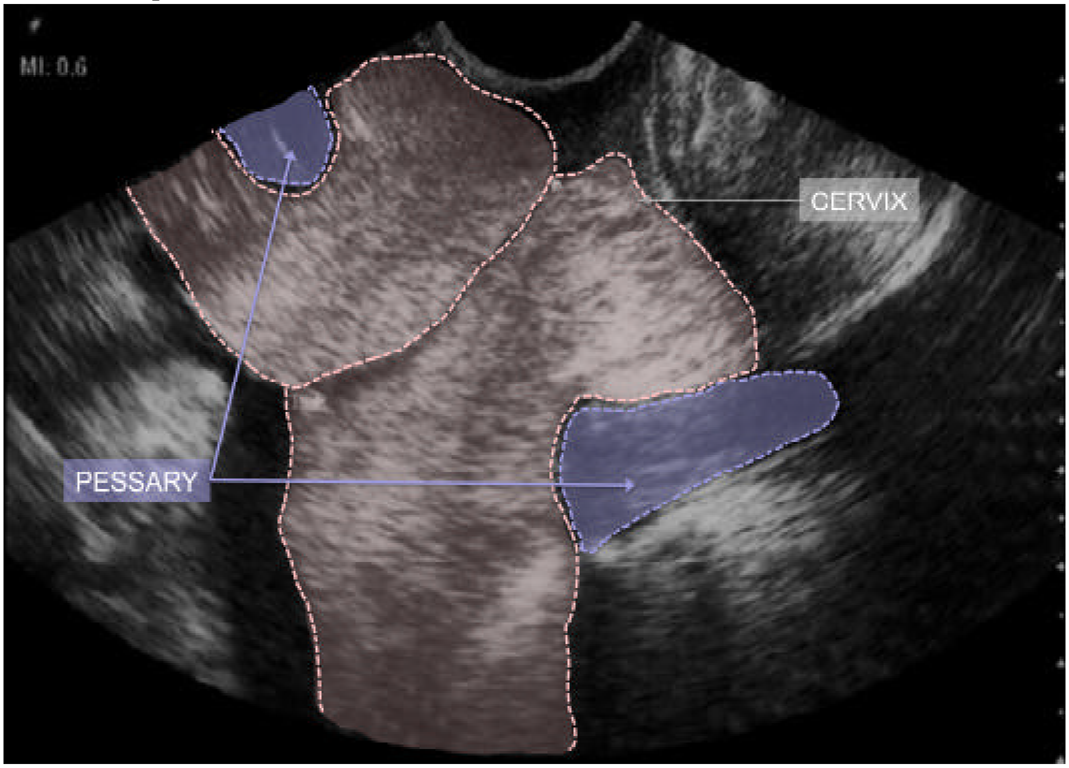


Figure 4.- The three different approaches included in the study and the sonographic images they provide (A: Transperineal measurement, B: Transvaginal measurement with the probe in the anterior fornix –standard approach-; note the pessary shadow in the images below; and C: The new transvaginal measurement approach proposed, with the probe inside the pessary; a complete view of the cervical canal is obtained).

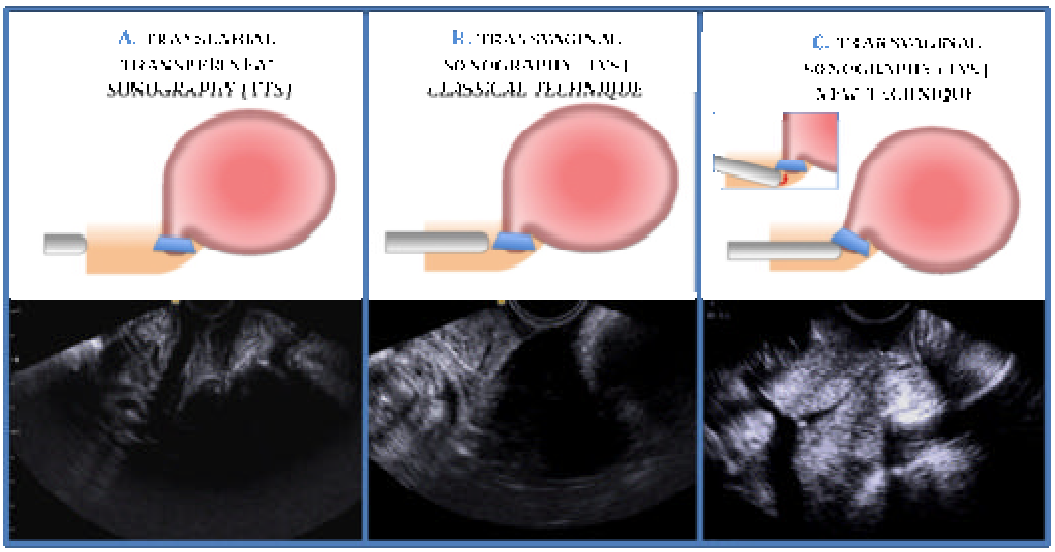
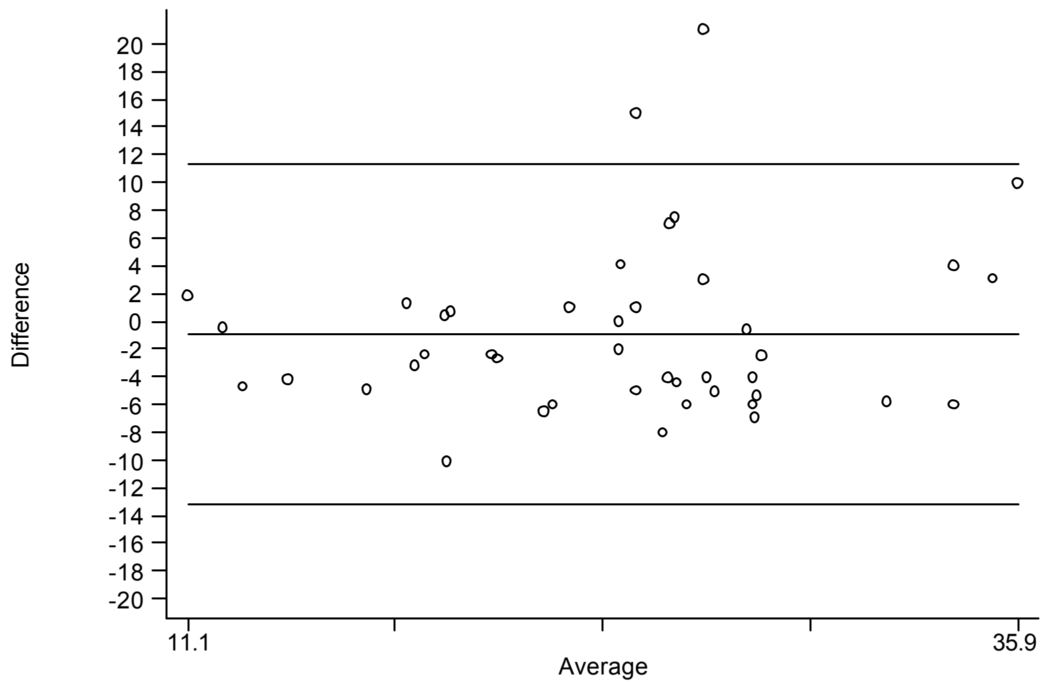


Figure 5.- Bland-Altman plots of interobserver difference in measurement of CL with TPS (a), TVS standard technique (b) and TVS new technique (c).

(a)

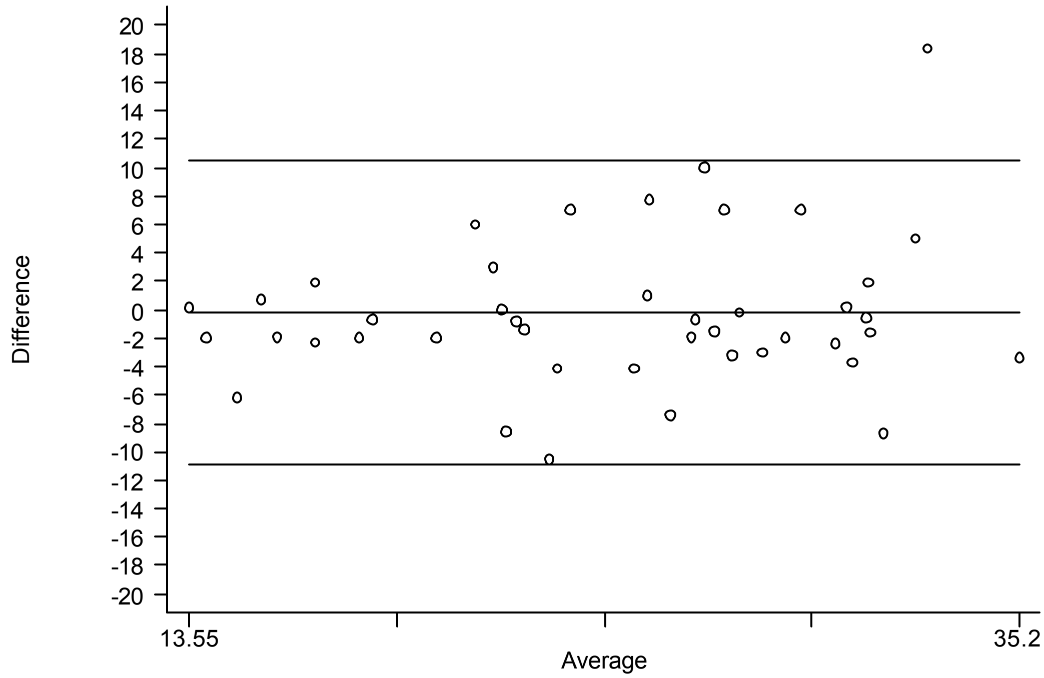


CL: cervical length

TPS: transperineal scan

TVS: transvaginal scan

(b)

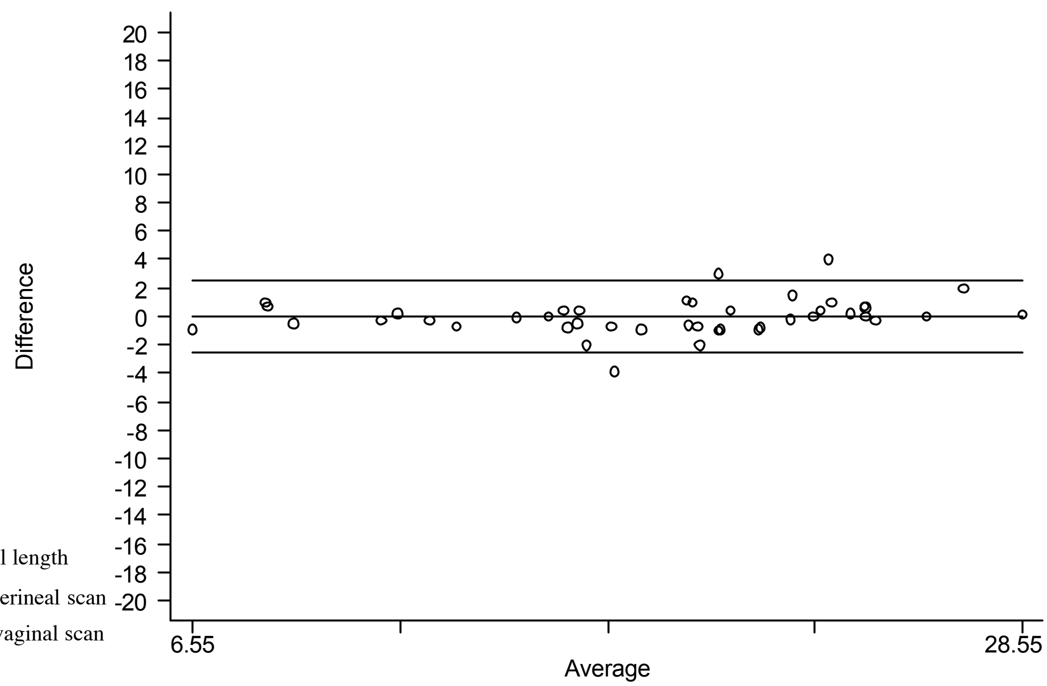


CL: cervical length

TPS: transperineal scan

TVS: transvaginal scan

(c)



CL: cervical length

TPS: transperineal scan

TVS: transvaginal scan