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Assessment of UterineAssist™ and Uterine Contour software for automatic uterine biometric measurements and uterine coronal plane obtainment. A validation study.

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Introduction

Ultrasound is currently considered as the first line imaging technique in Gynecological practice. The sonographic assessment of the uterus is essential for diagnosing many conditions related to patients' complaints such as bleeding, pain and infertility[1]. The basic assessment of the uterus and endometrium consist of biometric measurements of these structures[2]. These measurements are performed during real-time examination and might be time consuming.

On the other hand, the advent of 3D ultrasound revolutionized the assessment of the uterus, particularly for the ability of obtaining the so-called coronal plane from a stored 3D volume, particularly interesting for diagnosing uterine Mullerian anomalies[3]. For obtaining such a coronal plane the examiner has to manipulate the 3D volume using different tools and might be also time consuming and it is related to examiner's experience[4].

Artificial intelligence (AI) has emerged as a revolutionary paradigm in medical diagnostics[5]. Artificial intelligence is described as the ability of a computer program to perform processes associated with human intelligence, that can learn and interact[6]. Samsung Healthcare has developed two automated tools for assisting the examiner for both automatic measurement of uterine and endometrial biometry **(UterineAssist™)** and for automatic depiction of the uterine coronal plane **(Uterine Contour).**

The aim of this study was three-fold: 1. To assess whether "UterineAssist™" software can save time for obtaining uterine and endometrial biometry as compared with manual acquisition by expert and non-expert examiners. 2. To assess the agreement of such measurements performed by the "UterineAssist™" software and measurements performed by an expert examiner. 3. To determine the percentage of correct uterine coronal plane obtained by automated "Uterine Contour" tool as compared to a human expert examiner (subjective impression).

Methods

Study design

This is a prospective validation study performed in one single center. A series of 120 non-consecutive premenopausal women, aged 20 to 60 years old were recruited between May 2024 and June 2024 for this study. The study aimed to include Sixty women with a normal uterus according to expert examiner diagnosis and sixty women with pathological uteri.

Ultrasound evaluation

One expert examiner performed a transvaginal ultrasound and used UterineAssist™ for obtaining uterine biometry, namely uterine length, uterine height, uterine width and endometrial thickness (Figure 1). The time spent was recorded in seconds and the measurement obtained were also recorded. Then, the same examiner performed a manual uterine biometry (same measurements as UterineAssist™) (Figure 2) and the time spent and measurements were recorded. Finally, a non-expert examiner performed the second uterine biometry and the time spent was recorded.

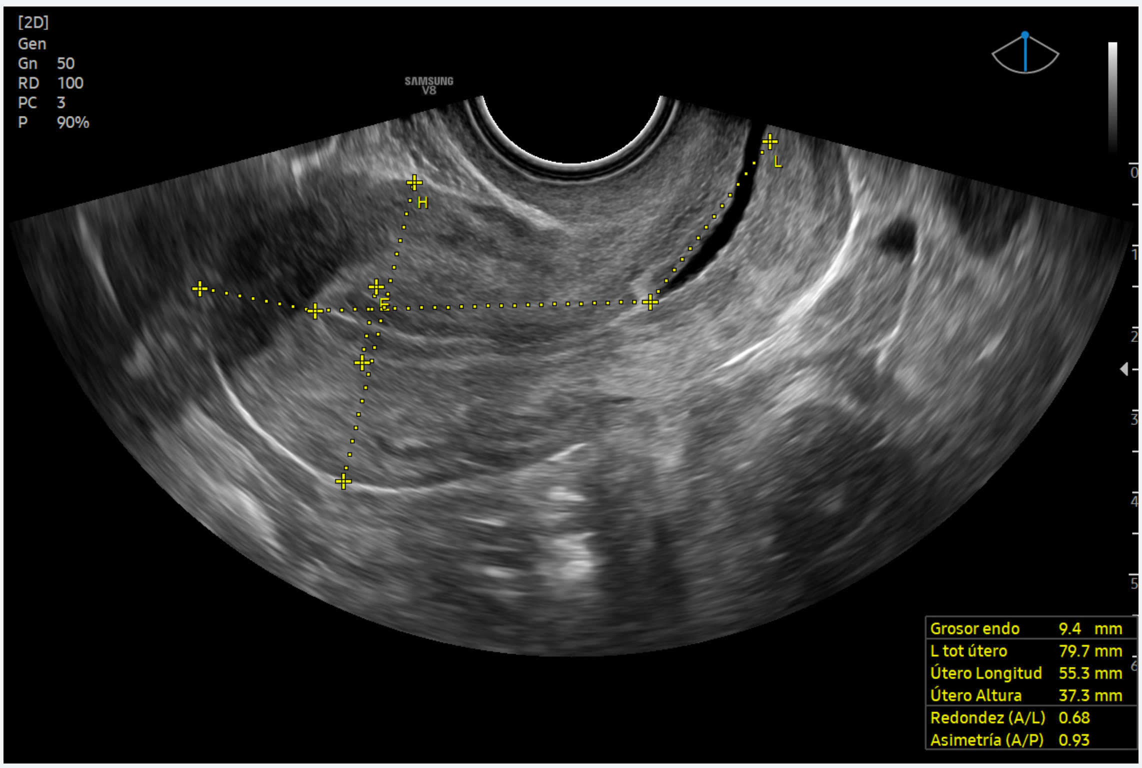

Figure 1A. Uterine measurements obtained by UterineAssist™ (uterine length, uterine height and endometrial thickness)

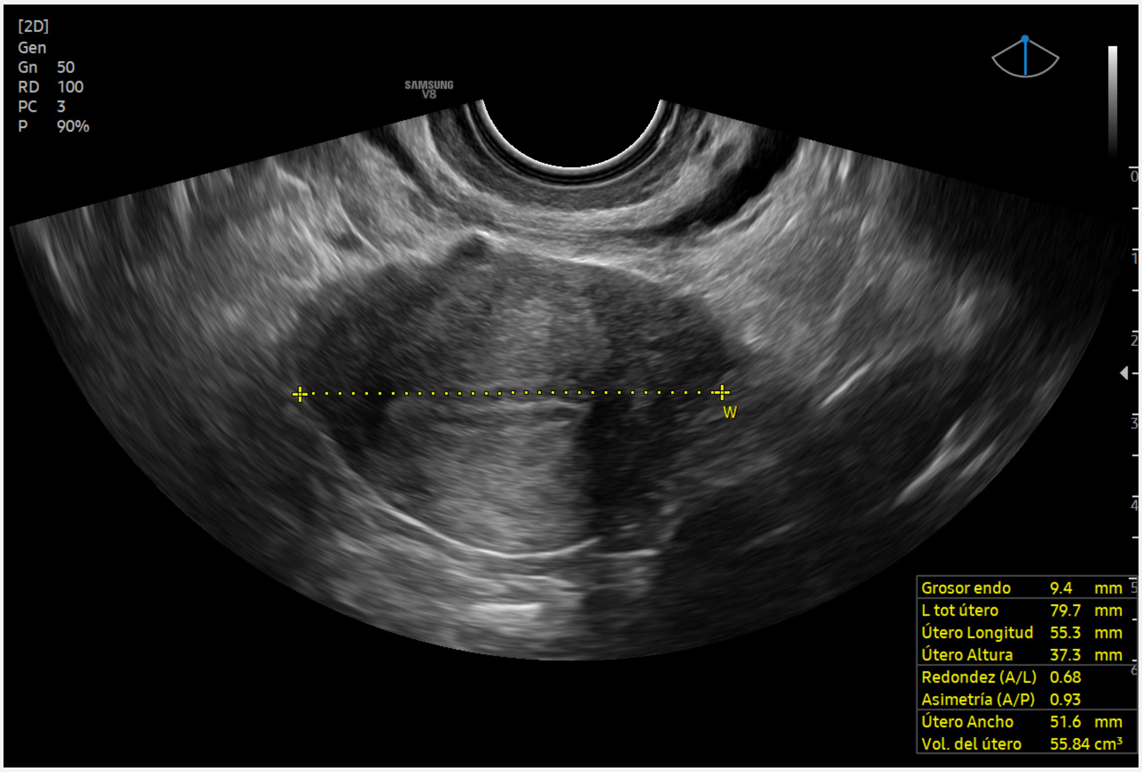

Figure 1B. Uterine measurements obtained by UterineAssist™ (uterine width)

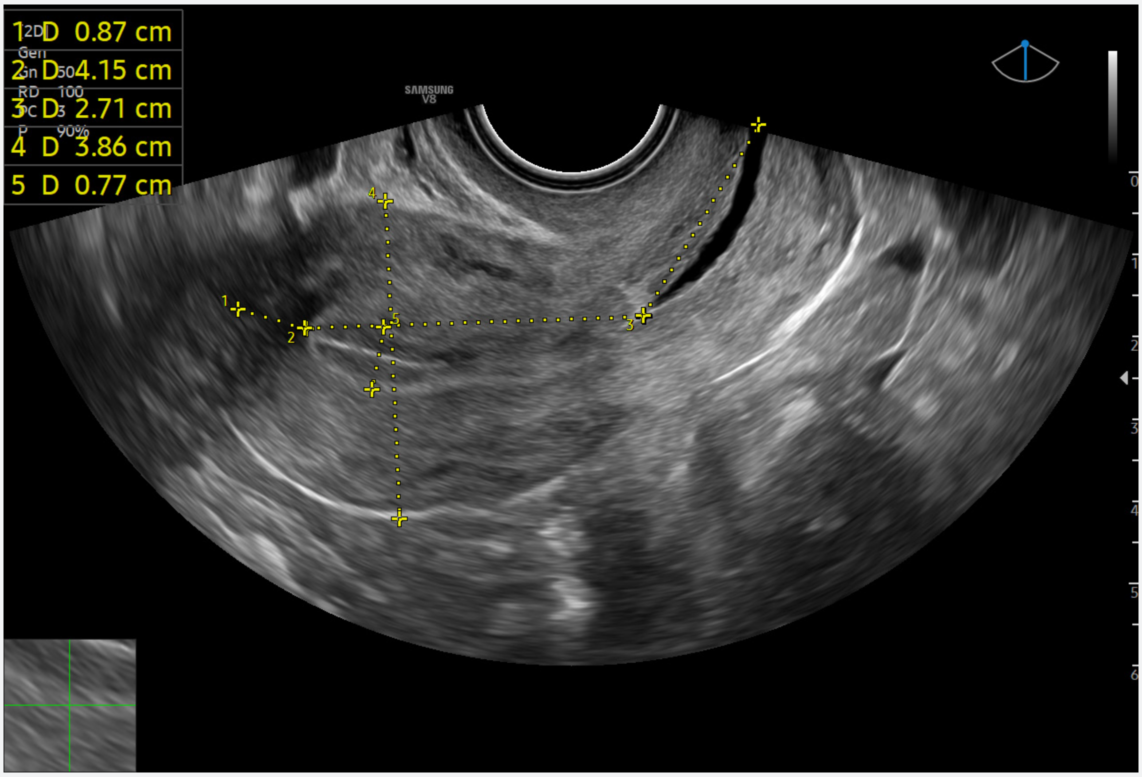

Figure 2A. Uterine measurements obtained by expert examiner (uterine length, uterine height and endometrial thickness)

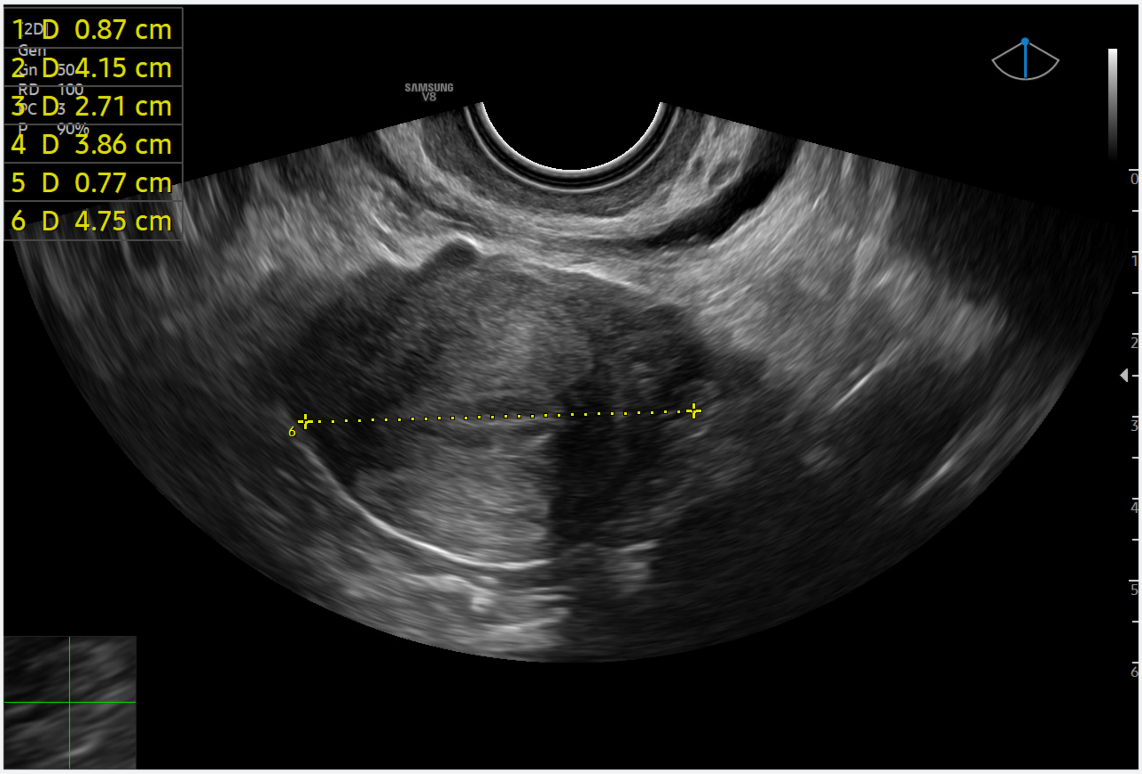

Figure 2B. Uterine measurements obtained by expert examiner (uterine width)

Immediately after this examination was done the expert examiner used Uterine Contour software for obtaining automatically the uterine coronal plane (Figure 3). The 3D box was adjusted to 120° and image quality was set as "EXTREME". After obtaining the coronal plane the image was recorded. Then, the examiner activated regular 3D volume box and acquired an 3D volume of the uterus. This 3D volume was manipulated by the expert examiner until a good coronal plane is obtained by subjective impression.

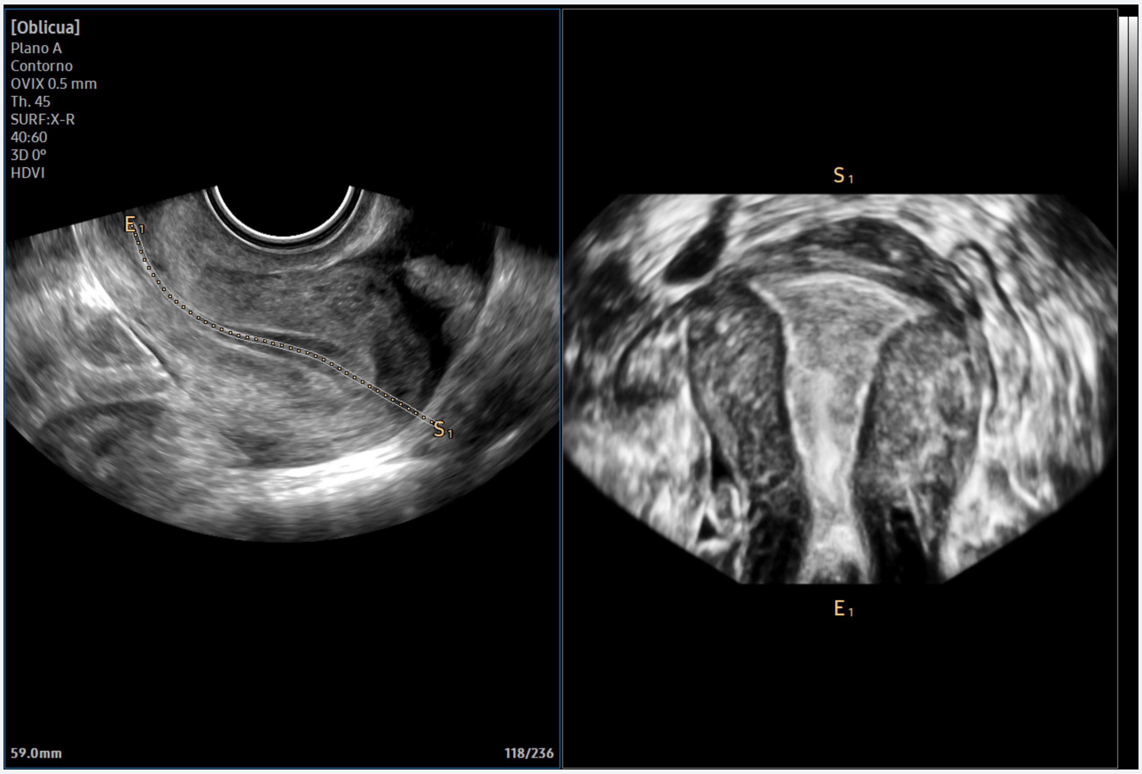

Figure 3. Automatic uterine coronal plane obtained by Uterine Contour

UterineAssist™ and Uterine Contour are two built-in commercially available softwares installed in a high-resolution Samsung V8 ultrasound system, equipped with the endovaginal probe EV2-10A (Samsung Medison, Co., Ltd., Seoul, South Korea).

Statistical analysis

Quantitative variables were expressed in mean, SD and range. Qualitative variables are expressed as number and percentage.

The mean time spent and the uterine measurements obtained by UterineAssist™ and manual expert examiner were compared using Student's t-test. Correlation between measurements obtained by UterineAssist™ and manual expert examiner was assessed by Pearson's correlation coefficient.

Agreement between measurements obtained by UterineAssist™ and manual expert examiner was assessed by the intraclass correlation coefficient. Bland and Altman graphics were plotted to determine the limits of agreement of measurements.

The percentage of cases of "correct" coronal plane automatically obtained by Uterine Contour software and expert examiner criterion was calculated.

A p-value < 0.05 was considered as statistically significant. SPSS v23 software was used for all statistical analysis.

RESULTS

During study period, 120 women were recruited. Sixty-two had normal uteri and fifty-eight had pathological uteri (Table 1).

Table 1. Distribution of cases according to uterine pathology

		N	%
Group	Normal	62	51.7%
	Myoma	30	25.0%
	Adenomyosis	18	15.0%
	Mullerian anomaly	5	4.2%
	Endometrial cancer	2	1.7%
	Endometrial polyp	1	0.8%
	ACUM	2	1.7%
	Total	120	100.0%

UterineAssist™ validation

Uterine biometry could be performed by UterineAssist™ in 95% of the cases, even in pathological cases (Figure 4). In six cases of large uteri due to large fibroids, the automated software could not yield any measurement.

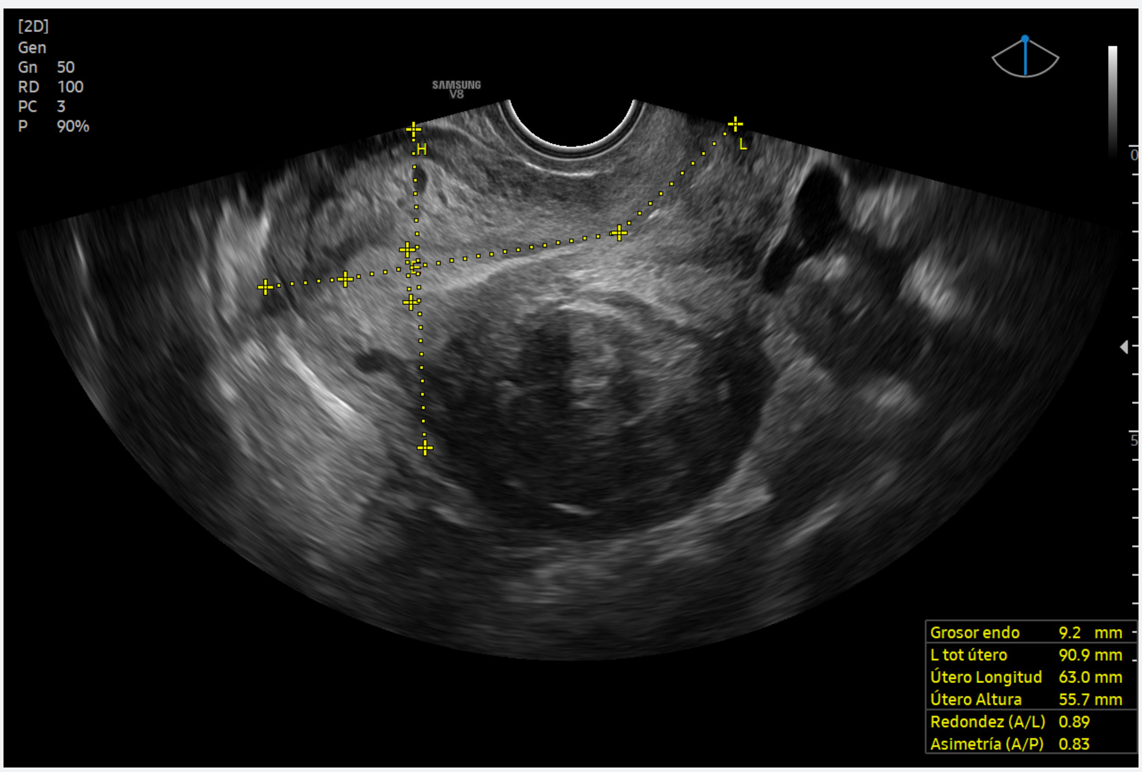

Figure 4. An example of a case where UterineAssist™ provide measurements in a pathological uterus.

UterineAssist™ provided significantly faster biometry than expert examiner and non-expert examiner (Table 2).

Table 2. Median time for obtaining complete uterine and endometrial biometry

Method	Median Time	IQR	Range	P value
Uterine Assist™	16 secs	6	7-62 secs	
Expert examiner	31 secs	7	13-73 secs	< 0.01
Non-expert examiner	40 secs	9	19-98 secs	< 0.01

*IQR: interquartile range

The time spent for UterineAssist™ to perform uterine biometry was similar in cases of normal uteri than pathological uteri (median 17 seconds (IQR:5) versus median 15 seconds (IQR:7)).

There was a significant correlation between measurements obtained by UterineAssist™ and the expert examiner for uterine length ($r2 = 0.800$, $p < 0.001$) (Figure 5), uterine height ($r2 = 0.651$ $p < 0.001$) (Figure 6), uterine width ($r2 = 0.604$, $p < 0.001$) (Figure 7) and endometrial thickness ($r2 = 0.509$, $p < 0.001$) (Figure 8).

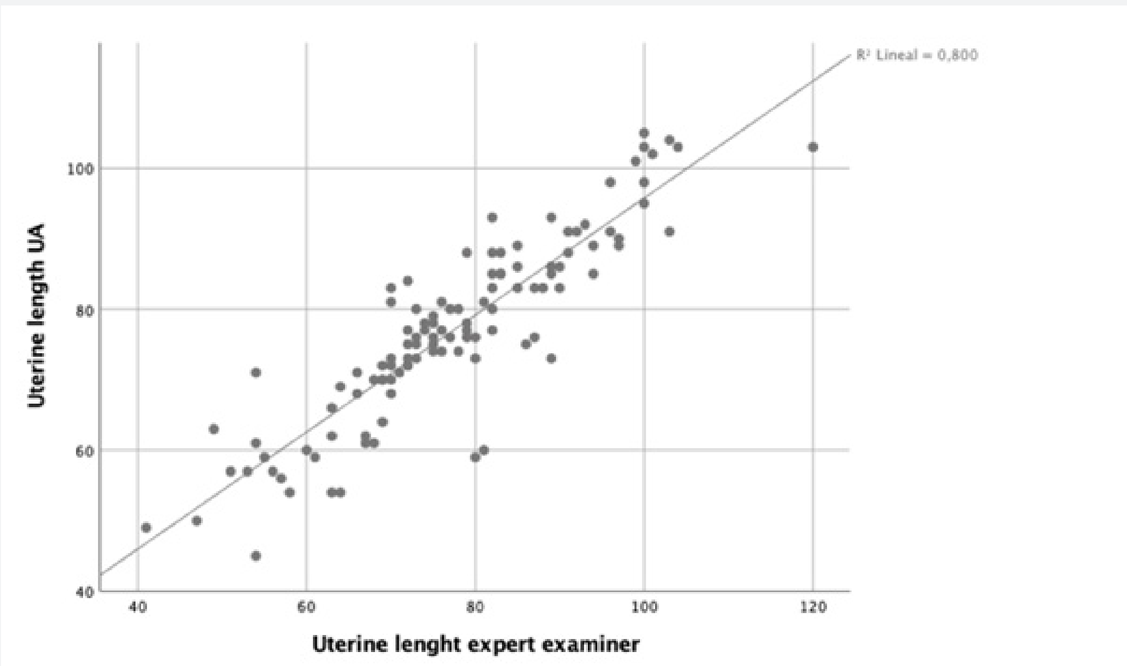

Figure 5. Correlation between UterineAssist™ (UA) and expert examiner uterine length measurement.

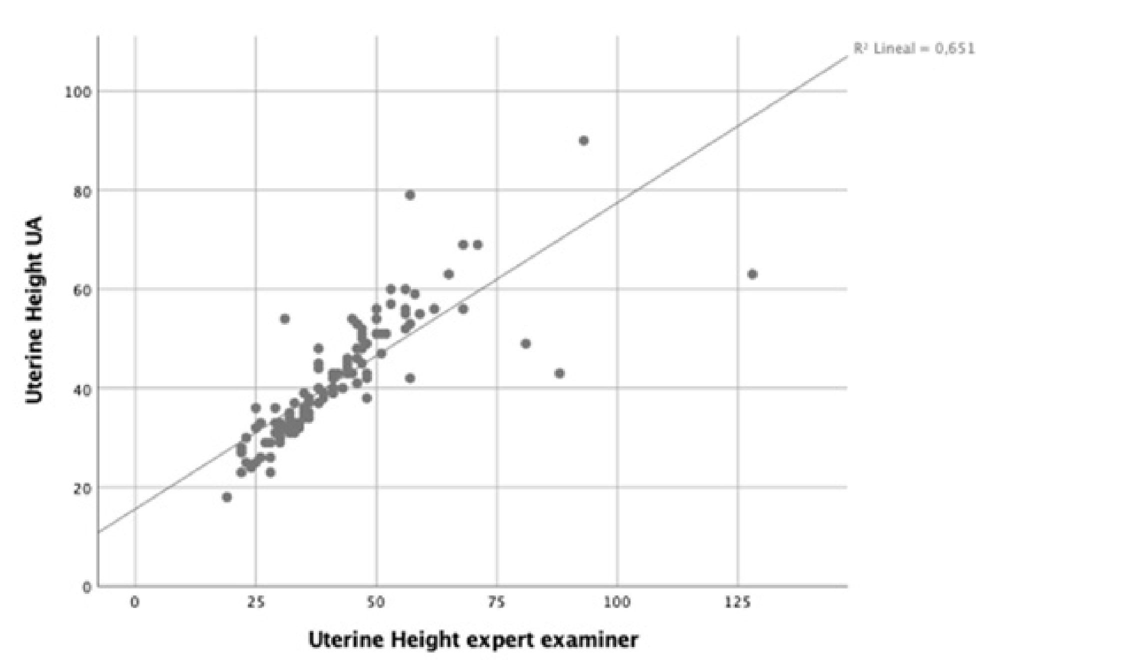

Figure 6. Correlation between UterineAssist™ (UA) and expert examiner uterine height measurement.

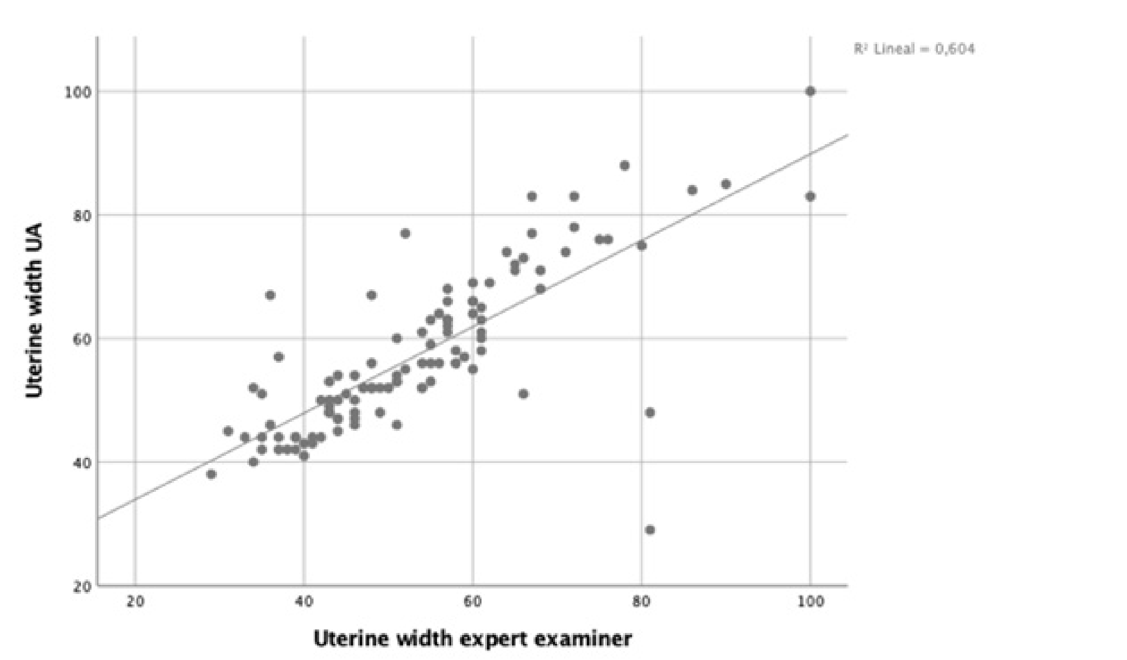

Figure 7. Correlation between UterineAssist™ (UA) and expert examiner uterine width measurement.

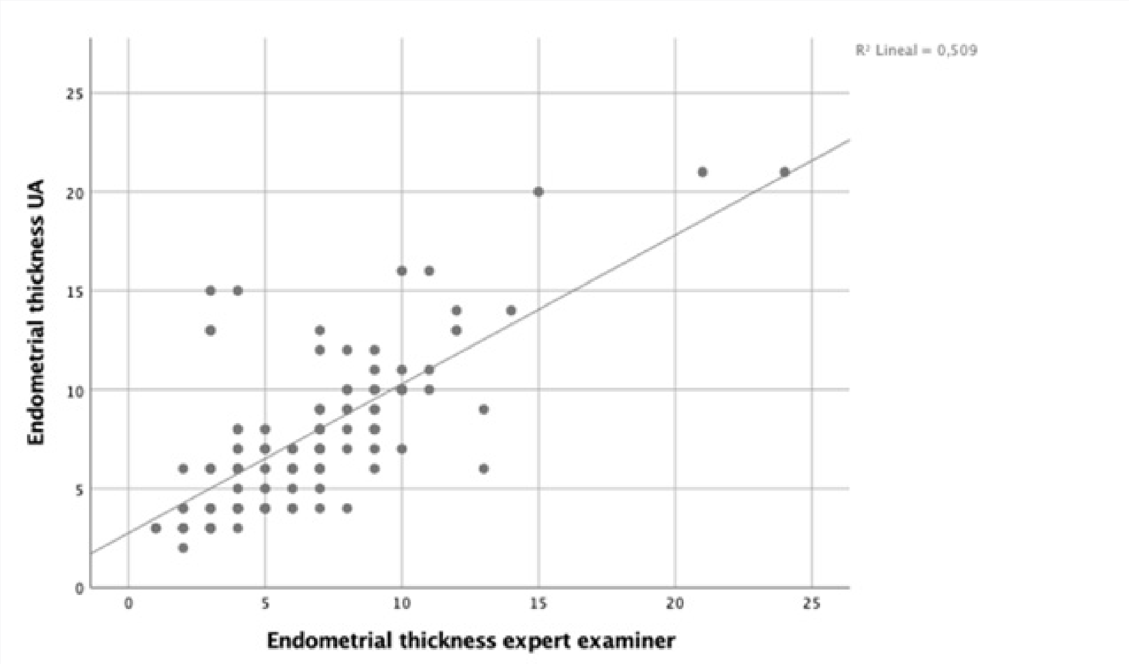

Figure 8. Correlation between UterineAssist^{TM} (UA) and expert examiner endometrial thickness measurement.

Overall, the agreement between measurements performed by UterineAssist^{TM} and the expert examiner was good (Table 3).

Table 3. Overall agreement of measurements between UterineAssist^{TM} and expert examiner in the whole series.

Measurement	ICC	95% CI
Uterine Length	0.945	0.918-0.964
Uterine Width	0.938	0.908-0.954
Uterine Height	0.875	0.812-0.916
Endometrial thickness	0.833	0.751-0.888

*ICC: intra-class correlation coefficient.

This agreement was good for both normal and pathological uteri (Tables 4 and 5).

Table 4. Agreement of measurements in normal uteri

Measurement	ICC	95% CI
Uterine Length	0.952	0.917-0.972
Uterine Width	0.879	0.790-0.930
Uterine Height	0.809	0.669-0.890
Endometrial thickness	0.903	0.832-0.944

*ICC. Intra-class correlation coefficient.

Table 5. Agreement of measurements in pathological uteri

Measurement	ICC	95% CI
Uterine Length	0.932	0.879-0.962
Uterine Width	0.946	0.904-0.970
Uterine Height	0.921	0.854-0.943
Endometrial thickness	0.76	0.563-0.876

*ICC. Intra-class correlation coefficient.

Mean difference for measurements performed by UterineAssist™ and expert examiner are shown in Table 6.

Table 6. Differences in uterine measurements between UterineAssist™ and expert examiner

Measurement	Mean difference	Standard deviation
Uterine Length	-0.69 mm	6.4
Uterine Width	+4.76 mm	6.6
Uterine Height	-0.27 mm	9.8
Endometrial thickness	+1.1 mm	3.0

Bland-Altman plots showed that limits of agreements were good (figures 9 to 12).

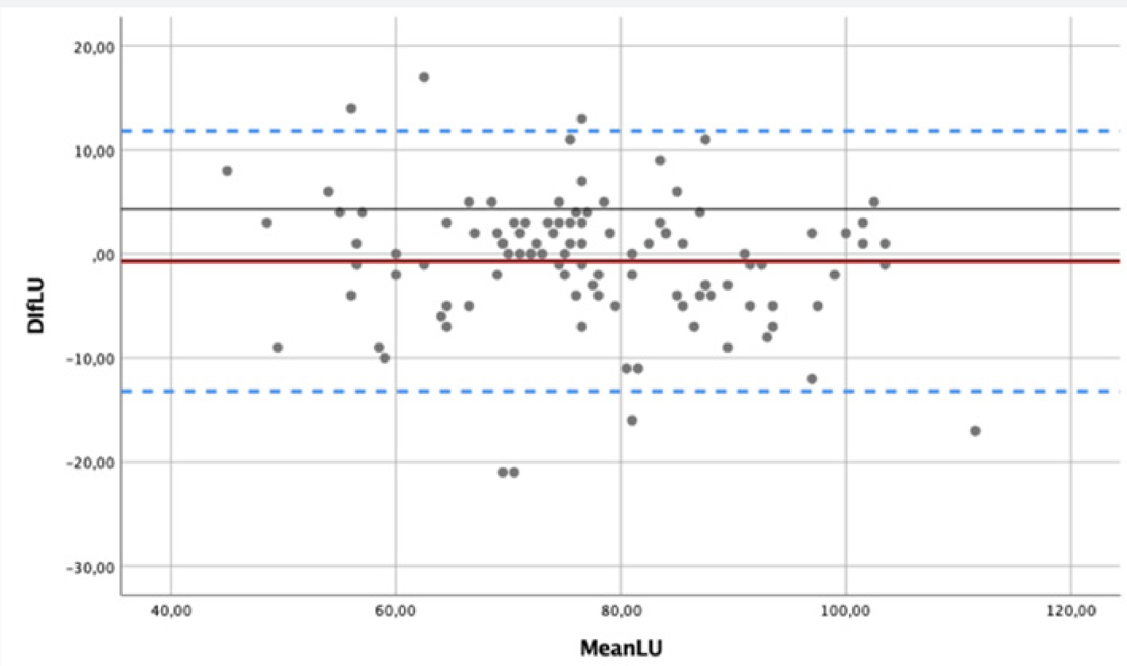

Figure 9. Differences between UterineAssist™ and expert examiner uterine length measurements plotted against their average with 95% limits of agreement.

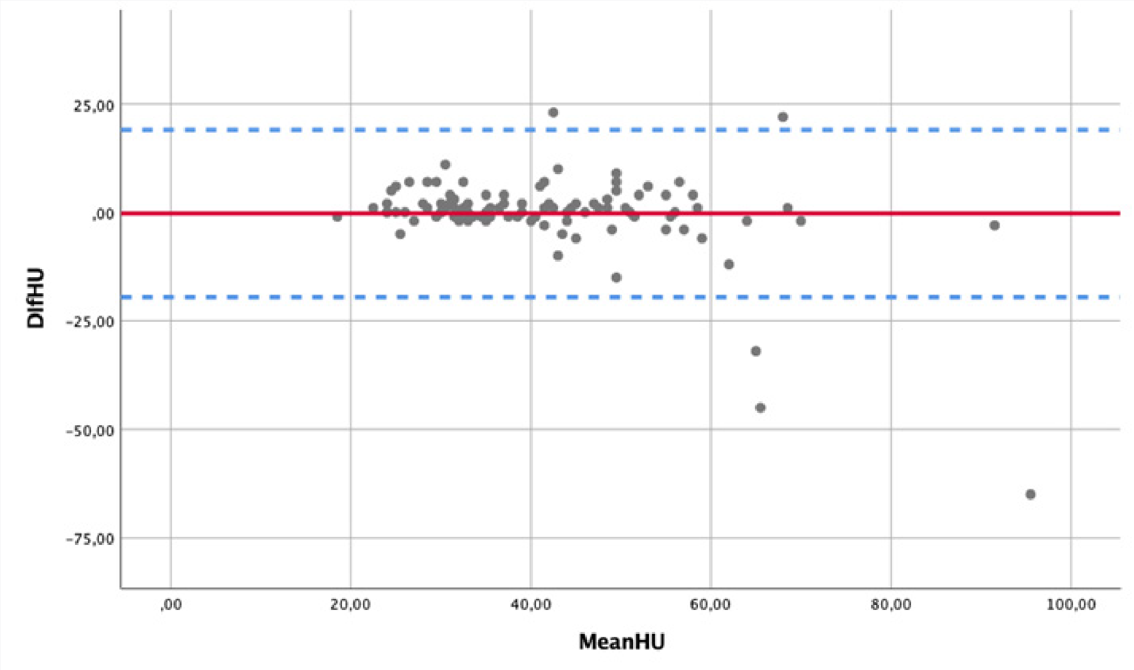

Figure 10. Differences between UterineAssist™ and expert examiner uterine height measurements plotted against their average with 95% limits of agreement.

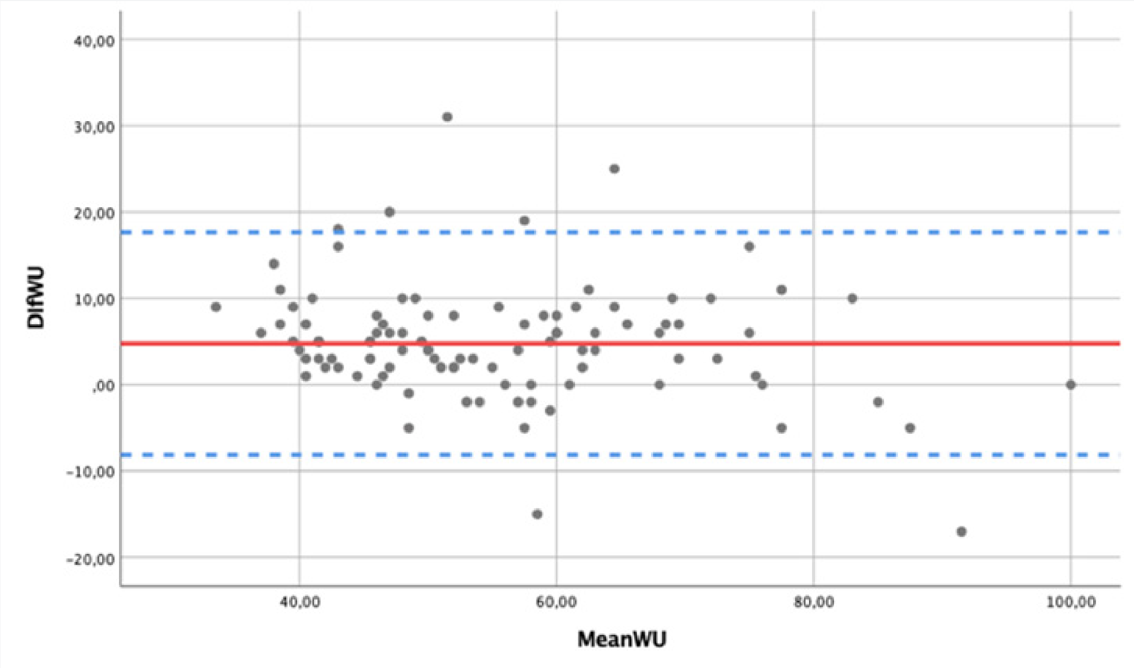

Figure 11. Differences between UterineAssist™ and expert examiner uterine width measurements plotted against their average with 95% limits of agreement.

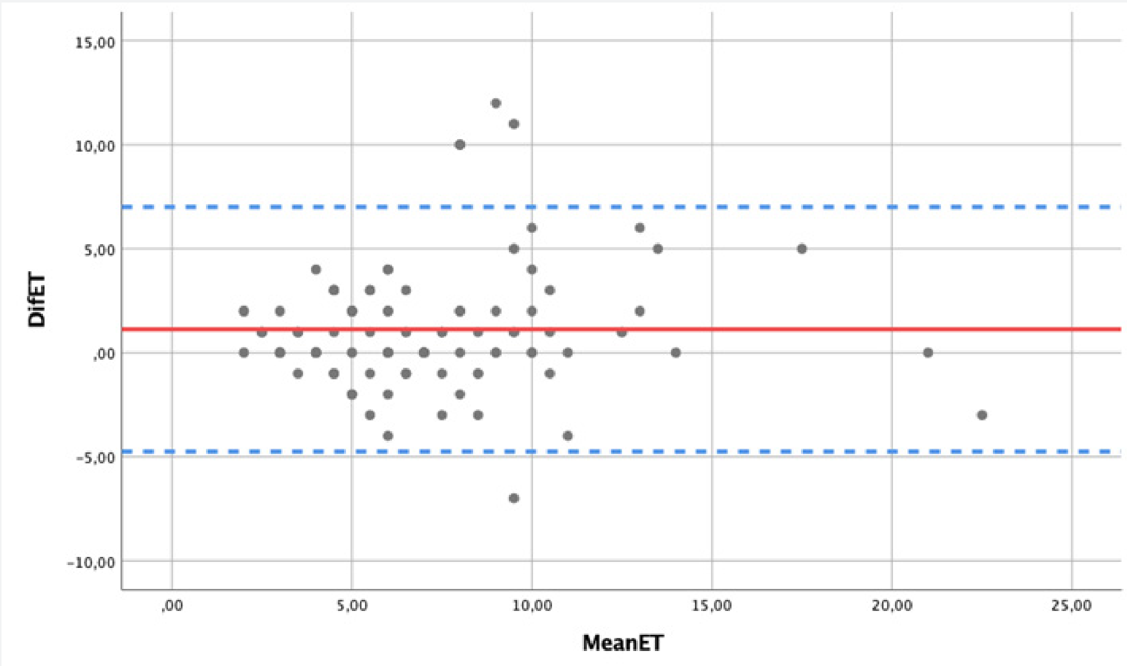

Figure 12. Differences between UterineAssist™ and expert examiner endometrial thickness measurements plotted against their average with 95% limits of agreement.

Uterine Contour validation

For Uterine Contour validation a simple analysis was performed. According to the expert examiner criterion, this automated tool provided a correct uterine coronal plane in 84% of the cases, even in pathological uterus (Figure 13). Those cases where Uterine Contour tool did not provide a good coronal plane were cases of uteri with adenomyosis or very thin endometrium.

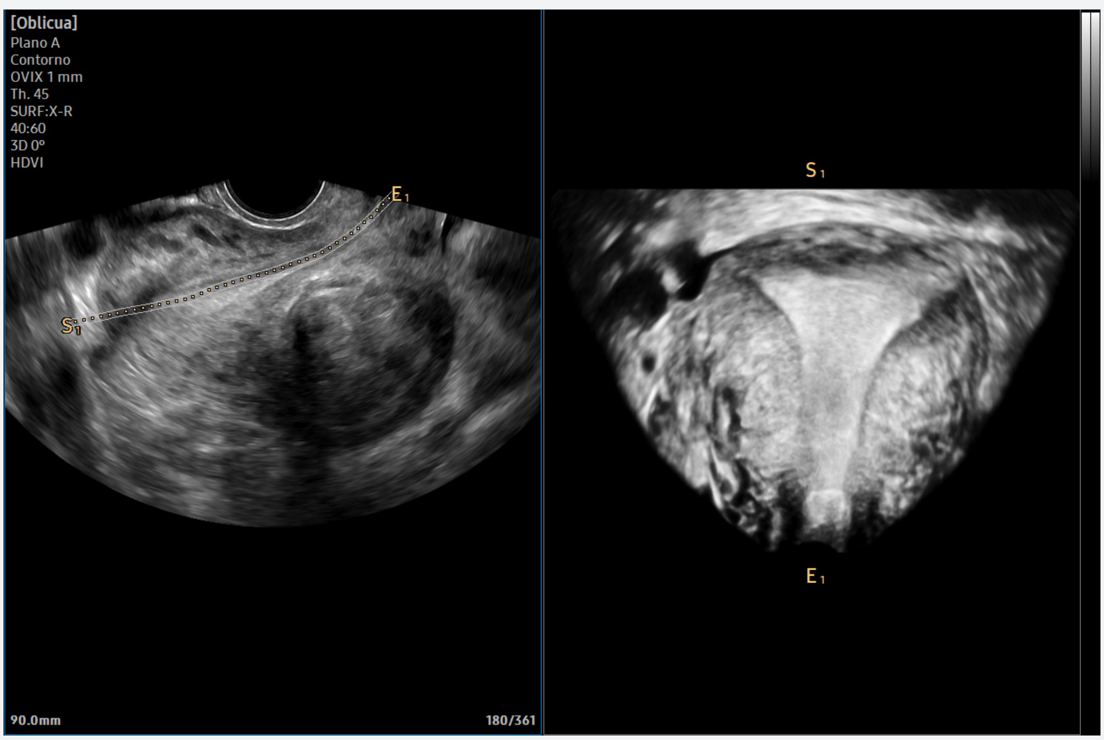

Figure 13. Example of a case where Uterine Contour did provide a good uterine coronal plane for assessing uterine cavity in a pathological uterus.

Discussion

In this study we have validated two automated tools for sonographic assessment of the uterus. We have observed that the use of UterineAssist™ save time, which can be important in current medical practice and potentially it could improve the workflow in ultrasound laboratories, particularly where non-expert examiners work. UterineAssist™ is able to provide automatic measurements in cases of normal uteri and most pathological uteri. But, it should be borne in mind that in some cases of uteri with pathology (large uterus with fibroids) AI may be difficult to apply.

The measurements obtained by this automated tool are reliable. This is particularly true for uterine length and height, as well as for endometrial thickness. For this latter measurement the mean difference observed between automatic measurement and manual expert measurement is about 1mm, well within the inter-observer variability noted in several studies[7,8]. Therefore, the measurement should be considered as reliable.

We have observed that UterineAssist™ tends to overestimate the width of the uterus as compared with manual expert measuring (about 4mm larger). This finding should be considered when using this tool.

On the other hand, the use of Uterine Contour yielded a good view of the coronal plane of the uterine cavity in 84% of the cases, as interpreted by the expert examiner. Although we did not assess the time saved using this tool as compared to expert examiner, the automatization clearly saves time. Therefore, this tool can be also very helpful in most cases of uterine assessment.

We could conclude that UterineAssist™ is a reliable tool for automatic uterine measurements and saves time. However, the measurements may not be reliable in some pathological cases, so expert confirmation is necessary. Uterine Contour might be a good tool for automatic assessment of uterine cavity morphology. Therefore, UterineAssist™ and Uterine Contour automated tools can be reliably used in routine gynecological ultrasound for uterine assessment.

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