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● *Original Contribution*

COMPARISON STUDY OF LOW-COST ULTRASOUND DEVICES FOR ESTIMATION OF GESTATIONAL AGE IN RESOURCE-LIMITED COUNTRIES

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Abstract—We investigated how accurately low-cost ultrasound devices can estimate gestational age (GA) using both the standard plane and the obstetric sweep protocol (OSP). The OSP can be taught to health care workers without prior knowledge of ultrasound within one day and thus avoid the need to train dedicated sonographers. Three low-cost ultrasound devices were compared with one high-end ultrasound device. GA was estimated with the head circumference (HC), abdominal circumference (AC) and femur length (FL) using both the standard plane and the OSP. The results revealed that the HC, AC and FL can be used to estimate GA using low-cost ultrasound devices in the standard plane within the inter-observer variability presented in the literature. The OSP can be used to estimate GA by measuring the HC and the AC, but not the FL. This study shows that it is feasible to estimate GA in resource-limited countries with low-cost ultrasound devices using the OSP. This makes it possible to estimate GA and assess fetal growth for pregnant women in rural areas of resource-limited countries. (E-mail: Thomas.vandenHeuvel@radboudumc.nl) © 2018 World Federation for Ultrasound in Medicine & Biology. All rights reserved.

Key Words: **Ultrasound, Obstetrics, Prenatal, Resource-limited countries, Obstetric sweep protocol.**

INTRODUCTION

Worldwide, 99% of all maternal deaths occur in resource-limited countries (World Health Organization et al. 2014). Ultrasound can be used to manage obstetric care, but too often remains out of reach for pregnant women in resource-limited countries. There are two main reasons for this. Firstly, ultrasound is too expensive for resource-limited countries. Secondly, a trained sonographer is required to acquire and interpret the ultrasound images. However, there is a severe shortage of well-trained sonographers in resource-limited countries (Carrera 2011; Hofmeyr 2009; LaGrone et al. 2012).

The first problem could be solved with the use of low-cost ultrasound devices. Estimation of gestational age (GA) could be helpful in resource-limited countries (Aliyu et al. 2016; Gladstone et al. 2011; Harris and Marks 2009; Kotlyar and Moore 2008; Shah et al. 2008; Sippel et al. 2011; Stanton and Mwanri 2013; Wanyonyi et al. 2017), but it has never been shown how accurate fetal biometrics can be estimated with low-cost ultrasound systems. In this study we therefore compared three low-cost ultrasound devices to measure the head circumference (HC), abdominal circumference (AC) and femur length (FL) by obtaining the standard planes, as described by Verburg et al. (2008b). The biparietal diameter was not evaluated in this study because guidelines state that HC is more reliable when the head shape is flattened or rounded (American Institute of Ultrasound in Medicine [AIUM] 2013).

The second problem could be solved by using the obstetric sweep protocol (OSP). The OSP was introduced by DeStigter et al. (2011) and consists of six pre-defined free-hand sweeps over the abdomen of the pregnant woman with an ultrasound transducer, as visualized in Figure 1. According to DeStigter et al. (2011), the OSP can be taught, within

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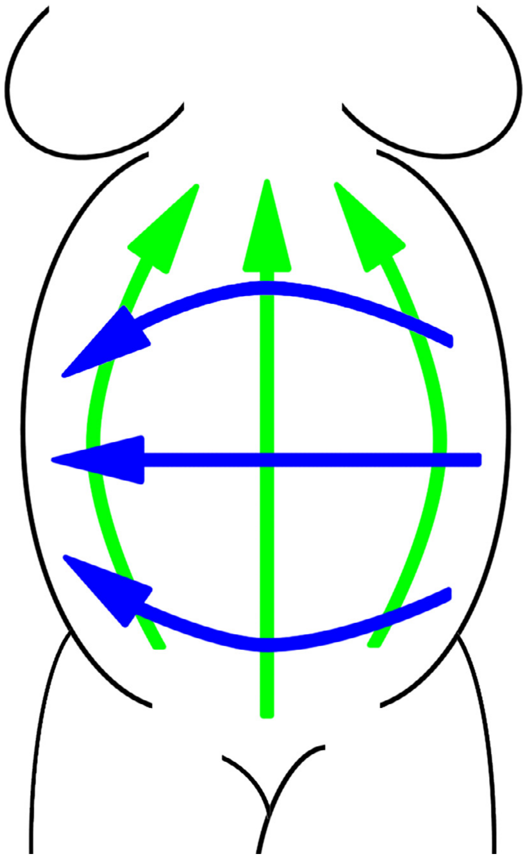

Fig. 1. Visualization of the obstetric sweep protocol, consisting of six pre-defined free-hand sweeps with the ultrasound transducer over the abdomen of the pregnant woman.

a day, to any health care worker without prior knowledge of ultrasound, which makes it a suitable approach for resource-limited countries.

We investigated if it is possible to estimate GA using the OSP. "Correct assessment of GA and fetal growth is essential for optimal obstetric management" (Verburg et al. 2008b). The GA can, for example, be used to estimate due date, to schedule prenatal care and to estimate fetal viability. However, the OSP will most likely not contain the correct standard plane to obtain fetal biometrics. Therefore, we investigated whether it is possible to accurately estimate the HC, AC and FL by manually selecting the frame within the OSP that best resembles the standard plane. If this is possible, computer-aided detection systems could potentially be used to automatically measure these biometrics. Such a system could make ultrasound more widely available in resource-limited countries, because there would be no need for a trained sonographer to acquire and interpret the image to estimate GA and monitor growth of the fetus.

METHODS

Data acquisition

Four different ultrasound devices were used to acquire the data for this comparison study: (i) the high-end Voluson E10 in combination with the RM6C transducer (General Electric, Zipf, Austria), which can be purchased around $100,000; (ii) the low-cost MicrUs EXT-1H in combination with the C5-2R60S-3 transducer (Telemed Ultrasound Medical Systems, Lithuania); (iii) the low-cost SeeMore USB Probe GP 3.5 MHz (Interson Medical Instruments, Pleasanton, CA, USA) (both the MicrUs and SeeMore are approved by the U.S. Food and Drug Administration (FDA) and are commercially available for between $2000 and $3000); (iv) the custom-developed very low-cost SESAS (Newcastle University, Newcastle upon Tyne, UK), which production costs are around $100 and provides conformance to the FDA Track 1 standards—fetal imaging application—and is described in detail elsewhere (van den Heuvel et al. 2017). All three low-cost ultrasound devices were connected to a laptop using a USB, thus providing a portable solution for rural areas in resource-limited countries.

All 60 participants in this study received a routine ultrasound examination (Salomon et al. 2011) performed by one of three sonographers (D.d.B., D.M. and A.B.), with 27, 14 and 30 years of experience as a sonographer, respectively. The routine ultrasound examinations were performed between December 2016 and March 2017 at the Department of Obstetrics and Gynecology, Radboud University Medical Center, Nijmegen, the Netherlands. During this examination, the standard planes for obtaining the HC, AC and FL measurements were acquired using the Voluson E10 according to the standards of Verburg et al. (2008b). After completion of the examination, the OSP was performed using the Voluson E10. In addition, the three standard planes and the OSP were acquired using one of the three low-cost ultrasound devices. This resulted in three 20-participant groups matched on body mass index of the participant and GA of the fetus. Data were acquired at either 20 or 33 weeks GA, because these are standard time points of routine ultrasound screening for pregnant women in the Netherlands. Only participants with a fetus that did not show any growth abnormalities were included in this study. All ultrasound devices were tested for electrical safety, and the SESAS was also tested on acoustic output power to ensure patient safety. All participants signed an informed consent form approved by the local ethics committee. All data was anonymized according to the tenets of the Declaration of Helsinki.

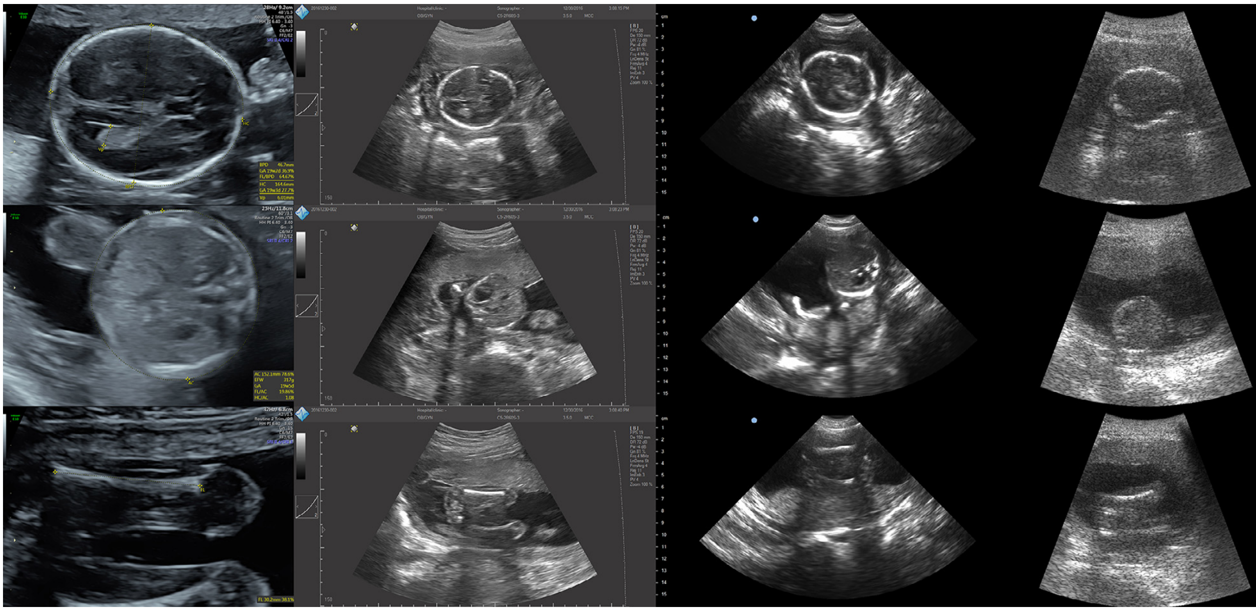

Fig. 2. Example images of the standard plane. From left to right are images obtained using the Voluson, MicrUs, SeeMore and SESAS. From top to bottom are images obtained in the standard plane to measure the head circumference, abdominal circumference and femur length.

Figure 2 shows an example image of the standard plane for obtaining the HC, AC and FL for four different fetuses with a GA around 20 weeks using the four different ultrasound devices. To make the comparison between the different ultrasound devices as fair as possible, a pre-set was defined for each device to minimize the influence of the acquisition protocol on the results. The settings of this pre-set per device can be found in Table 1. Note that not all parameters are the same, because some parameters cannot be changed for the low-cost ultrasound devices. The sonographer was asked to acquire around 100 frames per sweep, but because these sweeps were made in free-hand mode, the number of acquired frames per sweep varied. It was not possible to acquire 100 frames with the SESAS, as this device has a frame rate of only 4 Hz. Instead, the sonographer was asked to acquire the sweep with the SESAS within seven to ten seconds, to limit possible motion of the fetus during acquisition of the OSP. This resulted in 30 to 40 frames per sweep for this device.

Table 1. Pre-set per ultrasound device for the acquisition of the obstetric sweep protocol

	Voluson E10	MicrUs	SeeMore	SESAS
Imaging depth (cm)	15	15	15	15
Focal depth (cm)	8	8.5	7.5	Full depth*
Imaging angle (°)	65	65	90	50
Frame rate (Hz)	33	20	15	4
Center frequency (MHz)	4	3.5	3.5	4.2

* This device uses synthetic aperture focusing (van den Heuvel et al. 2017).

Biometric measurements obtained in the standard plane

Measurements of the HC, AC and FL obtained in the standard plane using the high-end ultrasound device were determined during the routine ultrasound examination and were used as a reference to compare the measurements made with the three low-cost ultrasound devices obtained in the standard plane. The HC, AC and FL measurements obtained in the standard planes using the low-cost ultrasound devices were manually determined by one experienced sonographer (D.d.B.). These measurements were obtained at least one week after the routine ultrasound examination, to avoid a bias toward the measurements obtained using the high-end device. During this process, the sonographer was blinded to the measurement obtained using the high-end device.

Biometric measurements obtained utilizing the OSP

The OSP data will most likely not contain the standard plane normally used to measure the HC, AC and FL. Instead the sonographer selected, from the sweep data, the two frames that best resembled the standard planes to obtain the HC and AC measurement. The HC and AC were manually annotated after these frames were selected. The FL was annotated by selecting the ends of the femur over multiple frames. Annotations were made at least one week after the

Table 2. Maternal age and body mass index of participants and gestational age of the fetus

	All (N = 60)	MicrUs (N = 20)	SeeMore (N = 20)	SESAS (N = 20)
Maternal age (y)	31.1±0.1	31.7±0.2	29.9±0.2	31.7±0.2
Body mass index	23.2±2.5	23.0±2.4	22.8±2.5	23.9±2.6
Gestational age (wk)	23.3±5.3	23.3±5.4	23.3±5.3	23.5±5.4.

HC, AC and FL were obtained in the standard planes, to avoid a bias toward the measurements obtained in the standard planes. During the annotation process, the sonographer was blinded to the measurements obtained in the standard planes obtained using both the high-end and low-cost ultrasound devices.

Estimation of gestational age

The HC, AC and FL can be used to estimate GA. The curve of Verburg et al. (2008b) was used to estimate the GA from each HC, AC and FL measurement. Crown−rump length (CRL), obtained between 8^{+4} weeks and 12^{+6} weeks, was used as the reference GA. Only fetuses with a reference GA <23 weeks were used to compare the GA, because the 95% confidence interval for GA prediction using biometric parameters becomes more than one week after 23 weeks (Butt et al. 2014).

Comparison of results

The biometric measurements obtained using both the standard plane and the OSP were compared with the inter-observer variability presented in the literature to determine whether it is possible to obtain a measurement with an ultrasound device.

The 95% limits of agreement (LoA) for GAs estimated from the HC, AC and FL were compared with the LoA obtained from the curve of Verburg et al. (2008b). When the LoA for the GA fell within the LoA of the curve of Verburg et al. (2008b), we concluded that it was possible to estimate the GA with an ultrasound device. The LoA for the GAs were calculated using the formula of Hayes and Krippendorff (2007). The LoA of the curves of Verburg et al. (2008b) were caused by differences in fetal growth during pregnancy and inter-observer variability of the sonographers. The standard deviation (SD) reported by Verburg et al. (2008b) was used to determine the LoA for the HC, AC and FL. The SD reported by Verburg et al. (2008b) was dependent on GA, so the GA determined from CRL was used to determine the SD for the participants scanned with each ultrasound device.

Statistical analysis

Paired statistical tests were performed to test if the measures (HC, AC and FL) obtained in the standard plane or utilizing the OSP were significantly different ($p < 0.05$) from the measurement obtained in the standard plane using the Voluson E10. A paired *t*-test was used when the data were normally distributed according to the Shapiro−Wilk test. When this was not the case, the Wilcoxon signed rank test was used. The same paired statistical tests were performed to test if the GA estimated from the HC, AC or FL obtained in either the standard plane or utilizing the OSP significantly differed ($p < 0.05$) from the GA estimated from the CRL. The paired statistical tests were also used to test if the results between the low-cost ultrasound devices and the Voluson E10 were significantly different. Unpaired statistical tests were performed to test if the results between the low-cost ultrasound devices significantly differed ($p < 0.05$). An independent *t*-test was used when the data were normally distributed according to the Shapiro−Wilk test. When this was not the case, the Mann−Whitney *U*-test was used.

RESULTS

A total of 60 participants were included in this study. Table 2 lists maternal age and body mass index for the participants and the GA of the fetus. There are no significant differences between the groups. A total of 348 biometric measurements were obtained in the standard planes. The sonographer could measure the HC, AC and FL in the standard plane for all participants using the Voluson, MicrUs and SeeMore. With the use of the SESAS, the sonographer could measure the HC, AC and FL in 19, 17 and 12 participants, respectively. The AC of one fetus was difficult to measure using the Voluson, due of the position of the fetus (GA of 32^{+3} weeks). The AC of this fetus measured using the MircUs resulted in an outlier, which was excluded from the results. A total of 339 measurements were obtained utilizing the OSP. The sonographer could measure the HC in all participants using the MicrUs, SeeMore and SESAS. One HC could not be measured using the Voluson, because the fetus was low-lying and the OSP was acquired too high on the abdomen. The sonographer could measure the AC in all participants using the Voluson and the MicrUs. One AC could not be measured using the SeeMore, as it did not fall completely within the field of view of any of the six sweeps due to the small footprint of the transducer. Three ACs could not be measured using the SESAS, because the number of frames

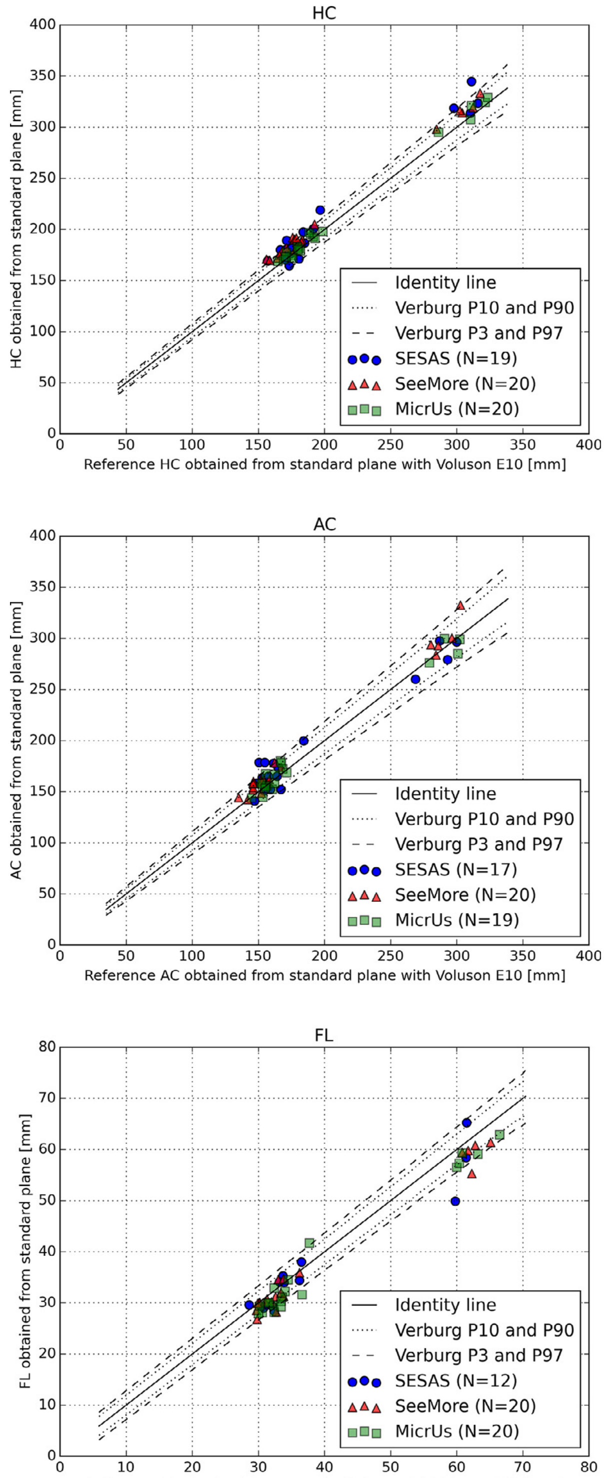

Fig. 3. Scatterplot of measurements obtained using the Voluson in the standard plane compared with measurements obtained using the low-cost ultrasound devices in the standard plane. From top to bottom are measurements of the HC, AC and FL. HC= head circumference; AC= abdominal circumference; FL= femur length.

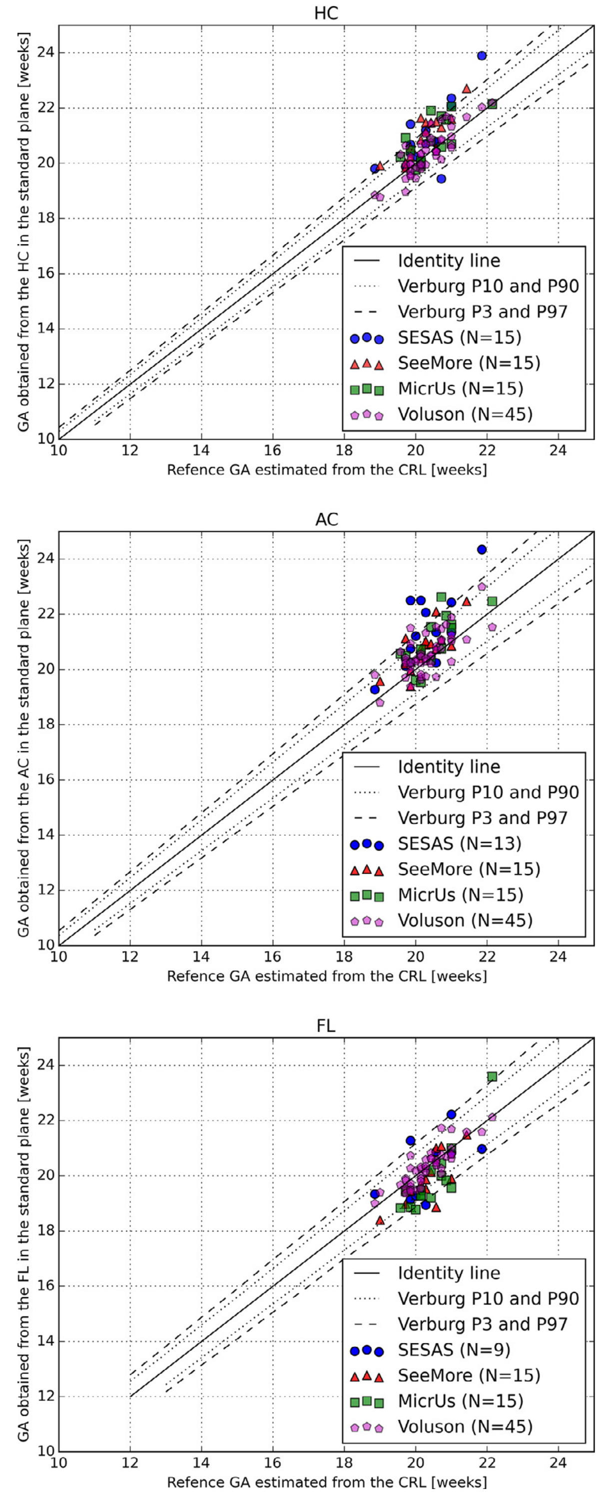

Fig. 4. Scatterplot of GA estimated from the CRL compared to the measurements obtained with the four ultrasound devices in the standard plane. From top to bottom are GA measurements estimated from the HC, AC and FL. GA = gestational age; CRL = crown−rump length; HC = head circumference; AC = abdominal circumference; FL = femur length.

Table 3. Differences between HC, AC and FL measurements obtained with the Voluson in the standard plane and those obtained with the three low-cost ultrasound devices in the standard plane

	Mean±SD (mm)			Mean±SD (%)		
	HC	AC	FL	HC	AC	FL
SESAS	8.5±10.3*,†	4.3±12.3	−1.2±3.4	4.0±4.7*,†	3.0±7.3	−2.6±7.0
SeeMore	10.5±3.7*,†	8.4±6.8*,†	−1.6±1.9*	5.3±2.2*,†	4.7±3.3*,†	−3.7±4.4*
MicrUs	2.4±4.0*	0.6±7.4	−2.2±2.0*	1.1±1.8*	0.6±4.0	−5.5±5.3*

HC = head circumference; AC = abdominal circumference; FL = femur length; SD = standard deviation.
* Significantly different compared with the Voluson in the standard plane.
† Significantly different compared with the MicrUs in the standard plane.

per sweep in combination with the lower signal-to-noise ratio made it impossible to detect the borders of the fetal abdomen. The sonographer could measure the FL in all participants using the SeeMore and Voluson. One FL could not be measured using the MicrUs, as the femur was not visible because of the position of the fetus (GA of 32^{+5} weeks). Fifteen FLs could not be measured using the SESAS, because the number of frames per sweep was too low to be able to detect the femur. A total of 45 participants (15 per low-cost device) had a GA <23 weeks according to the CRL measurement in the first trimester and were therefore included in the GA comparison.

Biometric measurements obtained in the standard plane

Figure 3 shows a scatterplot for the HC, AC and FL measurements obtained in the standard plane. The x-axis shows the reference measurement obtained using Voluson E10 in the standard plane. The y-axis shows the measurements obtained using the three low-cost ultrasound devices in the standard plane. The legend shows how many measurements were obtained using each ultrasound device.

Table 3 lists the differences (mean ± SD) between the measurements obtained in the standard plane using the Voluson E10 and the measurements obtained in the standard plane using the three low-cost devices. The differences were computed in millimeters and as a percentage. All three low-cost devices significantly overestimated HC. The SeeMore also significantly overestimated AC. The SeeMore and MicrUs significantly underestimated FL.

Figure 4 shows a scatterplot of GA estimates based on the HC, AC and FL measurements obtained in the standard plane. The x-axis shows the reference GA estimated from the CRL measurement in the first trimester. The y-axis shows the GA estimated from measurements obtained using all four ultrasound devices in the standard plane. The legend describes how many measurements were obtained using each ultrasound device.

On the left side of Table 4 are the LoA for the GA estimated from the measurements obtained in the standard plane using all four ultrasound devices. On the right side are the LoA for the GA estimated with the Verburg curve for the same groups. The GA estimated from HC using the low-cost ultrasound devices is significantly higher than the GA estimated from CRL. The GA estimated from AC is significantly higher for all four ultrasound devices than the GA estimated from CRL. The GA estimated from FL using the SeeMore and MicrUs are significantly lower compared with the GA estimated from FL using the Voluson E10 and the CRL.

Biometric measurements obtained utilizing the OSP

Figure 5 shows a scatterplot for the HC, AC and FL measurements obtained utilizing the OSP. The

Table 4. Comparison of LoA for GA estimated from HC, AC and FL obtained with ultrasound devices in the standard plane and LoA for GA estimated from CRL measurements, as well as LoA for the Verburg curve for each device

	LoA in the standard plane (d)			LoA of Verburg curve (d)		
	HC	AC	FL	HC	AC	FL
SESAS	−7.4 to 15.8*,‡	−5.9 to 21.8*,†	−15.1 to 14.4	−6.6 to 6.7	−9.3 to 9.4	−8.4 to 8.7
SeeMore	−1.0 to 11.4*,‡	−4.1 to 11.3*,‡	−10.9 to 4.5*,‡	−6.6 to 6.7	−9.3 to 9.4	−8.4 to 8.6
MicrUs	−5.9 to 11.5*	−5.7 to 12.8*	−14.4 to 6.0*,‡	−6.7 to 6.8	−9.4 to 9.5	−8.5 to 8.7
Voluson	−5.4 to 6.7	−6.1 to 9.5*	−5.0 to 4.8	−6.6 to 6.7	−9.4 to 9.4	−8.4 to 8.7

LoA = limits of agreement; GA = gestational age; HC = head circumference; AC = abdominal circumference; FL = femur length; CRL = crown−rump length.
* Significantly different from GA estimated from CRL.
† Significantly different from GA estimated using the MicrUs in the standard plane.
‡ Significantly different from GA estimated using the Voluson in the standard plane.

Table 5. Differences between HC, AC and FL measurements obtained with the Voluson in the standard plane and those obtained with the three low-cost ultrasound devices utilizing the obstetric sweep protocol

	Mean±SD (mm)			Mean±SD (%)		
	HC	AC	FL	HC	AC	FL
SESAS	13.7±8.7*,†‡§	8.7±12.6*	−0.8±7.0	7.1±4.9*,†‡§	5.7±7.5*	−3.0±20.5
SeeMore	2.2±9.5	12.7±8.7*,†‡	−1.5±3.8	1.0±4.4	7.4±5.2*,†‡	−3.4±10.3
MicrUs	−2.3±6.6	2.4±7.7	−0.4±5.4	−1.1±3.4	1.6±3.9	1.0±13.3
Voluson	0.4±9.9	3.3±10.1*	0.1±6.3	0.6±4.3	2.0±4.9*	0.8±15.8

OSP = obstetric sweep protocol; HC = head circumference; AC = abdominal circumference; FL = femur length.
* Significantly different compared with the Voluson in the standard plane.
† Significantly different compared with the MicrUs utilizing the OSP.
‡ Significantly different compared with the Voluson utilizing the OSP.
§ Significantly different compared with the SeeMore utilizing the OSP.

x-axis shows the reference measurement obtained using the Voluson in the standard plane. The y-axis shows the measurements obtained using all four ultrasound devices utilizing the OSP. The legend describes how many measurements were obtained using each ultrasound device.

In Table 5 lists the differences (mean ± SD) between measurements obtained in the standard plane using the Voluson E10 and measurements obtained utilizing the OSP using all four ultrasound devices. The differences were computed in millimeters and as percentages. The SESAS significantly overestimated HC compared with the HC obtained in the standard plane using the Voluson E10. The mean difference in HC using the SESAS is significantly higher compared to the mean difference in HC using the other three ultrasound devices. The SESAS, SeeMore and Voluson significantly overestimated AC compared with the AC obtained in the standard plane using the Voluson E10. The mean difference in the AC obtained using the SeeMore is significantly higher compared with the mean difference in AC obtained using the MicrUs and the Voluson E10.

Figure 6 shows a scatterplot of GA estimates obtained from the HC, AC and FL measurements obtained utilizing the OSP. The x-axis shows the reference GA estimated from the CRL measurement in the first trimester. The y-axis shows the GA estimated from measurements obtained using all four ultrasound devices utilizing the OSP. The legend describes how many measurements were obtained using each ultrasound device. On the left side of Table 6 are the LoA for the GA estimated from the measurements obtained utilizing the OSP using all four ultrasound devices. On the right side of Table 6 are the LoA for the GA estimated with the Verburg curve for the same groups. The GA estimated from the HC utilizing the OSP using the SESAS is significantly worse compared with the GA estimated from the CRL and using the other three ultrasound device utilizing the OSP. The GA estimated from the CRL is significantly different from the GA estimated from AC utilizing the OSP for all four ultrasound devices.

Comparison with literature

Table 7 shows a literature overview of interobserver variability for the HC, AC and FL measurements. Some cells are empty, because some articles present the results in millimeters and some in percentages. In

Table 6. Comparison of LoA for GA estimated from HC, AC and FL obtained with ultrasound devices utilizing the OSP and LoA for GA estimated from CRL measurements, as well as LoA for the Verburg curve for each device

	LoA in the standard plane (d)			LoA of Verburg curve (d)		
	HC	AC	FL	HC	AC	FL
SESAS	−0.3 to 17.5*,†‡§	−5.7 to 26.9*,†‡	−48.5 to 44.8	−6.6 to 6.7	−9.3 to 9.4	−8.5 to 8.7
SeeMore	−9.1 to 9.7	−5.9 to 18.5*,‡	−22.8 to 16.9	−6.6 to 6.7	−9.3 to 9.4	−8.4 to 8.6
MicrUs	−10.4 to 11.6	−0.5 to 9.4*	−17.2 to 24.8	−6.7 to 6.8	−9.4 to 9.5	−8.5 to 8.7
Voluson	−7.5 to 11.4*,†	−7.1 to 15.2*	−27.7 to 31.7*	−6.6 to 6.7	−9.4 to 9.4	−8.4 to 8.7

LoA = limits of agreement; CRL = crown−rump length; OSP = obstetric sweep protocol; GA = gestational age; HC = head circumference; AC = abdominal circumference; FL = femur length.
* Significantly different from GA estimated from CRL.
† Significantly different from GA estimated with the MicrUs utilizing the OSP.
‡ Significantly different from GA estimated with the Voluson utilizing the OSP.
§ Significantly different from GA estimated with the SeeMore utilizing the OSP.

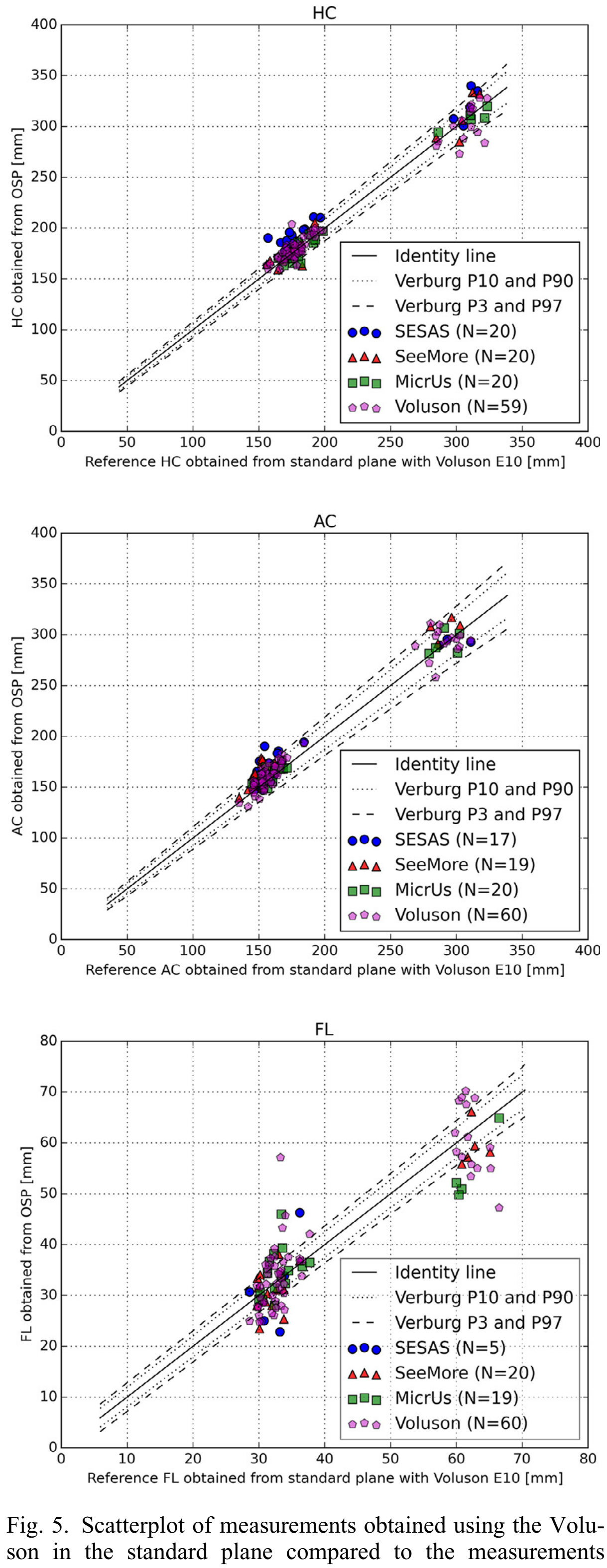

Fig. 5. Scatterplot of measurements obtained using the Voluson in the standard plane compared to the measurements obtained with the four ultrasound devices utilizing the obstetric sweep protocol. From top to bottom are measurements of the HC, AC and FL. HC = head circumference; AC = abdominal circumference; FL = femur length; OSP = obstetric sweep protocol.

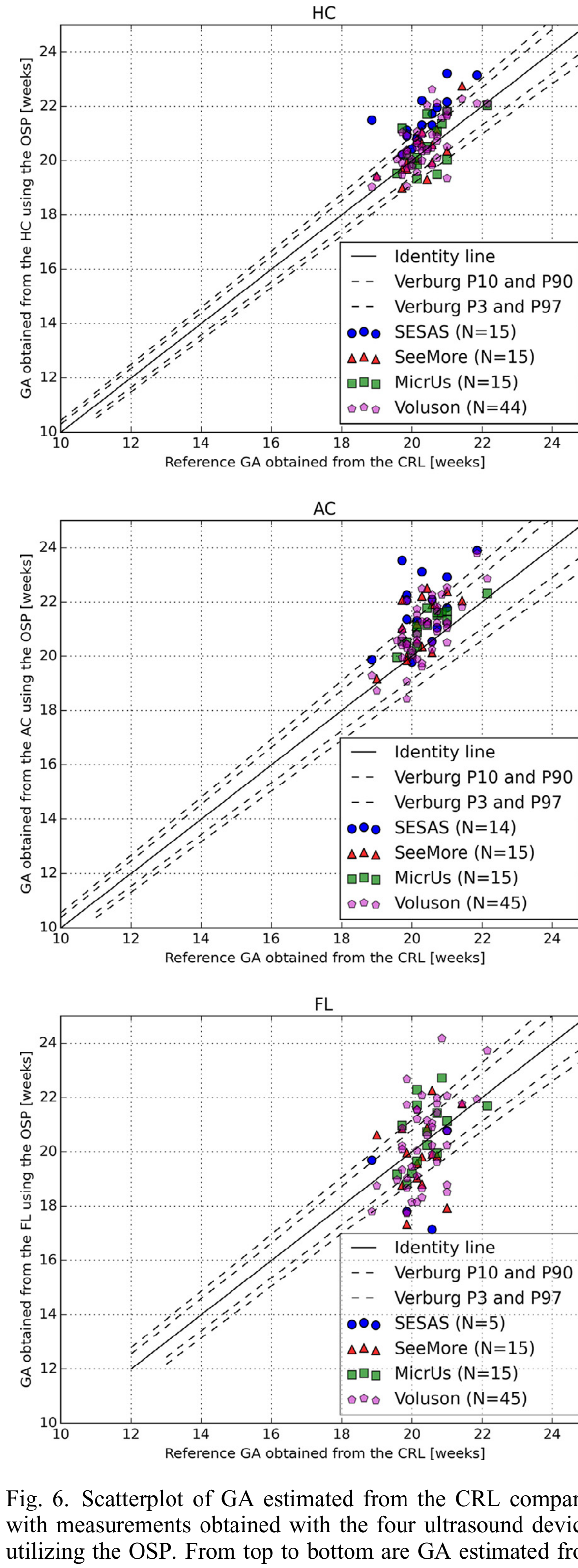

Fig. 6. Scatterplot of GA estimated from the CRL compared with measurements obtained with the four ultrasound devices utilizing the OSP. From top to bottom are GA estimated from the HC, AC and FL. GA = gestational age; CRL = crown–rump length; OSP = obstetric sweep protocol; HC = head circumference; AC = abdominal circumference; FL = femur length.

Table 7. Literature overview of inter-observer variability for HC, AC and FL

	N	Mean±SD (mm)			Mean±SD (%)		
		HC	AC	FL	HC	AC	FL
Sarmandal et al. (1989)	22	−0.1±8.9	−0.6±7.7	−1.3±2.3			
Perni et al. (2004)	122	0.1±5.6	1.0±11.6	0.4±1.9			
Rijken et al. (2009)	90	−1.6±4.8	−0.6±5.7	−0.4±1.4			
Lima et al. (2012)	102		0.0±13.0	0.0±1.1			
Chang et al. (1993)	40	−1.6±5.8	−1.9±7.5	−0.1±1.4	−0.5±1.9	−0.5±2.4	−0.2±2.2
Sarris et al. (2012)	175	0.9±6.1	0.9±10.7	0.0±2.2	0.5±2.5	1.2±2.9	0.0±5.7
Verburg et al. (2008a)	20				1.3±5.4	0.3±5.6	−1.4±5.1
Napolitano et al. (2016)	100				−0.8±2.5		

HC = head circumference; AC = abdominal circumference; FL = femur length; SD = standard deviation.

addition, not all articles contained results for all three biometric measurements.

DISCUSSION

We have shown the feasibility of measuring the HC, AC and FL with low-cost ultrasound devices using both standard planes and the OSP. The results indicate that the HC, AC and FL measurements obtained in the standard planes with the low-cost ultrasound devices are similar to the inter-observer variability presented in the literature. The results also indicate that it is possible to measure HC and AC utilizing the OSP to estimate GA.

Biometric measurements obtained in the standard plane

The HC was overestimated using all three low-cost devices in the standard plane. This could be caused by the lower image quality, which made it more difficult to determine the correct standard plane and accurately delineate the HC. The difference between the MicrUs and the reference was only 2.4 mm (1.1%), which is significantly better compared with the HC measured with the SESAS and SeeMore and falls within the inter-observer variability outlined in Table 7. Due to this overestimation, the upper limit of the LoA for GA estimated using the low-cost devices was increased, whereas the LoA interval remained close to the 13.3 days of the Verburg curve.

The AC measured using the MicrUs and SeeMore show similar results compared to the inter-observer variability presented in the literature, which indicates that it is possible to measure AC with these low-cost devices. The LoA intervals of the GA were 15.4 and 18.5 days for the SeeMore and MicrUs, which are smaller compared with the LoA interval of the Verburg curve, but the GA estimated from the AC was significantly higher compared to the GA estimated from the CRL for all four devices. Since the AC was also overestimated with the Voluson E10, we conclude that the average AC of fetuses in this study population was larger than the population average. The AC could not be measured in three of the twenty participants using the SESAS, and the LoA interval for the estimated GA for the remaining participants was 27.7 days, which is larger than the LoA interval of the Verburg curve.

It was not possible to measure the FL in the standard plane using the SESAS in eight of the twenty participants. This was caused by the low frame rate of the SESAS, which made it very difficult to image the femur of a moving fetus. The GA estimated from the FL using the SeeMore and MicrUs were significantly lower compared with the GA estimated from the FL using the Voluson E10. This indicates that these two low-cost devices underestimate FL and therefore underestimate GA. The results show that the LoA interval therefore increases, but this increase is only three days compared to the LoA interval of the Verburg curve. Therefore, we conclude that FL can be measured using the SeeMore and MicrUs.

Biometric measurements obtained utilizing the OSP

It is possible to measure the HC using the SeeMore, MicrUs and Voluson E10 utilizing the OSP, because the difference between the HC measured utilizing the OSP and the HC measured using the Voluson E10 in the standard plane is close to the inter-observer variability presented in the literature. The LoA interval for the HC obtained uttilzing the OSP was 22.0 days, which is nine days longer than the 13.3 days of the Verburg curve.

The AC obtained utilizing the OSP is significantly higher compared to the AC measured using the Voluson E10 in the standard plane. The OSP will most likely not contain the standard plane and will therefore result in an oblique section of the abdomen. This results in a larger AC compared to the standard plane, but the AC measured with the Voluson E10 and MicrUs utilizing the OSP still fall within inter-observer variability. The LoA interval for the AC obtained utilizing the OSP was 24.4 days, which is six days longer compared to the 18.8 days of the Verburg curve.

The SESAS could not be used to accurately measure the HC and AC utilizing the OSP. This was caused by the limited number of frames within the OSP data of the SESAS in combination with the lower contrast sensitivity, which made it more difficult to select the correct frame to obtain an accurate measurement.

The results indicate that it was not possible to accurately measure the FL utilizing the OSP. The OSP will most likely not contain the standard plane used to measure the FL. A random cross section through the femur bone will differ substantially from the FL measured in the standard plane and will therefore not give an accurate estimate of the FL.

Study limitations

The GA in the acquired data ranged from 18^{+6} to 33^{+0} weeks, so the feasibility of measuring HC and AC utilizing the OSP in the first trimester could not be investigated. Data from the first trimester would be required for this, but it should be noted that most women in resource-limited countries will not receive an ultrasound examination in the first trimester of their pregnancy.

Clinical implications

The results indicate that the OSP can be used to measure the HC and AC for estimation of GA with the use of low-cost ultrasound devices. In this work, a well-trained sonographer was still required to interpret the OSP data and manually obtain the biometric measurements. In the future, computer-aided detection systems could be used to automatically measure these biometrics. This would obviate the need for a well-trained sonographer to both obtain and interpret the data for estimation of GA and monitoring fetal growth.

CONCLUSIONS

We show that it is possible to accurately estimate GA with low-cost ultrasound devices using both the standard plane and the OSP. The results indicate that a trained sonographer was able to determine the standard plane and measure the HC, AC and FL to estimate GA using the SeeMore and MicrUs within the inter-observer variability presented in the literature. The SESAS can be used to measure the HC and AC to estimate GA, but showed a larger standard deviation. This study also shows that the OSP can be used to accurately estimate GA by measuring the HC and AC, but not the FL. Since the OSP can be taught to health care workers without prior knowledge of ultrasound within one day, it is feasible to estimate GA and assess fetal growth with low-cost ultrasound devices without training dedicated sonographers. In the future, computer-aided detection systems could be used to automatically measure these biometrics. This would obviate the need for a well-trained sonographer to both obtain and interpret the data for estimation of GA and monitoring of fetal growth.

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