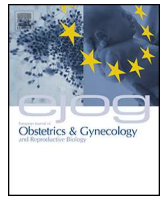




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A multicenter study assessing uterine cavity width in over 400 nulliparous women seeking IUD insertion using 2D and 3D sonography



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ABSTRACT

Background: In the selection of an appropriate IUD little consideration is placed on device size or adequacy of fit. Properly fitting IUDs will likely lead to less adverse effects or patient discomfort resulting in enhanced continuation of use.

Methods: A multicenter study conducted at 7 centers in 410 nulliparous women, to measure the width of the uterine cavity using 2D and 3D ultrasound.

Results: Measurements of maximal fundal cavity width was performed by either 2D or 3D ultrasound by experienced sonographers. The mean width of the uterine cavity in the fundus was 22.2 mm (range 6.0–41.1 mm). There was no statistical difference in the values whether determined by 2D (n = 258) or 3D (n = 152) measurements having a median value of 22.5 mm and 21.6 mm, respectively, 79% of women had a uterine cavity width between 15 mm and 28 mm, 32% < 20 mm and 6.8% < 15 mm, respectively.

Discussion: Uterine cavities in nulliparous women are narrow and rarely wide enough to fit conventional IUDs. Gross discrepancy between the IUD and the uterine cavity leads to side effect (e.g., expulsion, embedment, bleeding, pain) and early discontinuation. Historically, devices too large for the uterine cavity have been routinely inserted which may account for their 5-year continuation rates being only 40 to 50%. Our study suggests that preprocedural 2D or 3D sonography to measure the width of the uterine cavity may result in the selection of a suitable IUD to maximize continuation of use. Measurement of the cavity width is not necessary with a frameless IUD.

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Introduction

Since their inception little consideration has been placed on the differences in uterine cavity size or its shape in any individual women when inserting an IUD despite the advice of experts who stated in 1969 that IUD fit is a critical component in their acceptance [1]. Not until recently and as a consequence of the availability of inexpensive noninvasive visualization techniques, has interest in the compatibility of any given IUD with a woman's

uterine cavity, or how this compatibility relates to patient comfort and continuation of use, been assessed.

The side effect profile of an IUD and user tolerance is basically determined by its physical characteristics and its geometric relationship to the host uterine cavity [2]. Its ability to work locally all but eliminates systemic related side effects. The utilization of safe and well characterized agents such as copper and levonorgestrel and their low dosage are additional factors that limit their overall toxicity. Thus, the tolerability of any device within the uterine cavity remains as the principle determining factor governing the presence or absence of adverse effects. The size and shape of uterine cavities has been compared with the differences in size and shape of our feet. An IUD that is too large for the uterine cavity will be compressed, embedded, or result in

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perforations. Ultimately partial or complete expulsion can occur. Ill-fitting devices can lead to patient discomfort caused by cramping pain and abnormal bleeding which may be exacerbated at the time of her menstruation [3]. The uterus is an active muscle capable of producing significant forces in excess of 70 newtons. If the IUD is ill-fitting it may penetrate the uterine wall or cervix [4]. Shipp et al. found that patients with malpositioned and embedded IUDs were more likely to have pain or bleeding than patients with normally positioned devices [5]. Embedment occurs usually very soon after insertion of a too voluminous IUD. In a study conducted in over 400 parous and nulliparous women, more than 50% of women had apparent embedment of framed T-shape devices as assessed by 3D ultrasound examination only 6 weeks after insertion of the IUD. The authors commented that it is unknown if the embedment represents the presence of a penetrating transverse arm or a true secondary perforation [6]. Conversely, women with a transverse diameter of the uterine cavity in the fundus that is greater than the width of the IUD may have an enhanced risk of expulsion or displacement. This was the case for MLCu375 users with transverse uterine widths ≥ 27 mm and for TCu380A users with cavity widths ≥ 37 mm [7].

Many additional IUD trials in young women have produced discouraging results likely as a consequence of using IUDs that did not fit properly. Precisely these young women are most disadvantaged by the occurrence of an unintended pregnancy caused by failure of the IUD [8–13]. There are many clinical and societal advantages for using IUDs that have helped to increase their utilization worldwide. Despite these, the continuation rates of the major IUDs used worldwide (Mirena[®], Bayer Healthcare, Germany and TCu380A/Paragard[®], Teva Pharmaceuticals, USA) for 5 years of use is only 50% and 40%, respectively [14]. Pain, abnormal bleeding, displacement and expulsion prevent many women from having trouble free contraception. Optimization in IUD selection is clearly required. This study of the width of the uterine cavity in a large number of nulliparous women was undertaken to explain the geometric foundation of IUD side effects which may lead to premature discontinuation.

Materials and methods

This non-intervention ultrasound study was conducted by 7 different investigators in Germany, Switzerland and in Belgium. All patients were recruited from a pool of mostly young women either requesting IUD contraception, or who already used an intrauterine contraceptive and are requesting a replacement, or who presented with IUD problems. The 3D volume acquisitions were obtained during transvaginal sonography with an ultrasound system using a 5–9 MHz transducer. The longitudinal view of the uterus was the method as described by Abuhamad et al. [15] Transvaginal 3D ultrasound measurements were done mainly by two investigators (KN, SJ) at any time during the menstrual cycle. The coronal view of the uterus is particularly well-suited to measure the width of the cavity and to demonstrate the relationship between the entire IUD and the uterine cavity [5].

To measure the width of the uterine cavity using 2D ultrasound, the vaginal probe is turned anticlockwise to visualize the uterus at 90° to the sagittal view. The maximum width is measured in this transvers (coronal) plane. Transvaginal ultrasound 2D measurements were preferably done during the second half of the menstrual cycle, or after instillation of gel (Instillagel[®], Farco Pharma, Köln, Germany) in order to visualize the width of the uterine cavity better. The instillation of a uterine gel (3–8 mL is usually sufficient to fill the normal uterine cavity) greatly added in visualization with 2D ultrasound examination. No distention of the width of the endometrial cavity was seen after gel instillation due to its small volume and flow like characteristics. One advantage of 2D ultrasound is that it takes only one minute to measure the width of the cavity in case of good visibility of the endometrium, while 3D ultrasound may take sometimes much longer.

All investigators used fully optimized and calibrated ultrasonographic equipment and measurements were done at any time during the menstrual cycle. The uterine cavity width is the distance between the two internal tubal ostia.

The study intended to determine the variability in the maximal fundal size in a large group of nulliparous women irrespective of

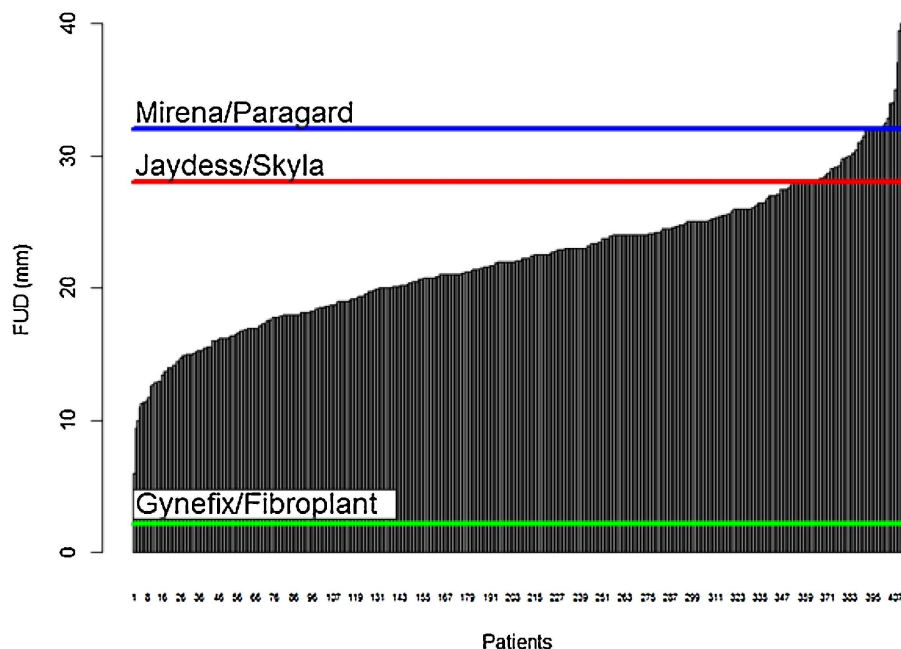


Fig. 1. Collated individual maximal fundal widths by 2D and 3D sonography in 410 nulliparous women seeking IUD insertion or replacement. For comparison the transverse width for Mirena/Paragard (TCu380A), 32 mm, Jaydess/Skyla, 28 mm, and the frameless GyneFix (2.2 mm) and Fibroplant (1.6 mm) are included.

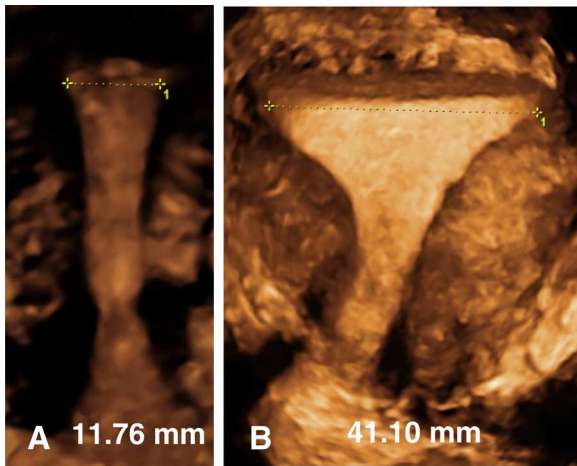


Fig. 2. Uterine cavities vary greatly in nulliparous and parous women. A) 3D ultrasound of a nulliparous woman measuring 11.76 mm in width; B) *ibid.* very wide, normal uterine cavity in a nulliparous woman.

age, body weight or other demographic information. The study also examined the differences in any between the findings based on 2D or 3D ultrasound to determine if either technique held any advantage.

Data analysis

All 2D and 3D coronal images were saved for review. Individual investigators determined the maximal transverse fundal width for their respective patient populations. The findings were collated and all pertinent data included in an Excel spreadsheet. Upon study completion the findings were subjected to statistical analysis by an independent statistician, which was performed using R V.3.3.0 (R Foundation for Statistical Computing, Vienna, Austria). Besides descriptive parameters, data were analyzed with the nonparametric Mann–Whitney *U* test and Kruskal–Wallis test and parametric ANOVA. The significance level was set at $\alpha = 0.05$ [16].

Results

Four hundred and ten (410) nulliparous women participated in this study. The mean age was 26.0 years (25.9) years (SD 6.6 years, range 15–54 years). Fig. 1 illustrates the individual patient data. Maximal uterine cavity widths ranged from a low of 6 mm to a maximum of 41 mm. Fig. 2 illustrates the great disparity in width of uterine cavities in nulliparous women.

The mean maximal fundal width was found to be 22.2 mm (SD 5.2 mm). 32% of uterine cavities were less than 20 mm wide; 6.8% less than 15 mm; and 0.5% less than 10 mm, respectively. Only 10 subjects or 2.4% had uterine widths greater than 32 mm. The interquartile range shows that 50% of uterine cavities in this group are between 18.6 and 25.1 mm wide, respectively. In our group 79% of patients had a uterine cavity width between 15 mm and 28 mm, respectively.

Fig. 3 shows the fundal transverse diameter and range per investigator and the ultrasound method used. Minor differences were seen between the investigators likely as a consequence of sampling variability. ANOVA revealed statistical differences ($P < 0.05$) associated with comparison concerning investigator 4 who contributed 13 subjects to the data set. With the exception of investigator 4, the differences across investigators represented only small deviations relative to the group mean consistent with the nature of the study and the diversity of the investigators. Analysis revealed no differences in the age of the study population across investigators (Fig. 4).

Table 1 shows the results according to the method used, 2D or 3D ultrasound, respectively, and the results in the total group. There was no statistical difference between the measurements made using 2D and 3D ultrasound (Mann–Whitney *U*-test, $P = 0.108$).

Discussion

The use of long-acting reversible contraceptive methods (LARC) are considered of major importance in order to reduce the global “epidemic” of unintended pregnancies, particularly in young women, as they are highly effective and not subject to daily concordance [17]. When viewed in relationship to other

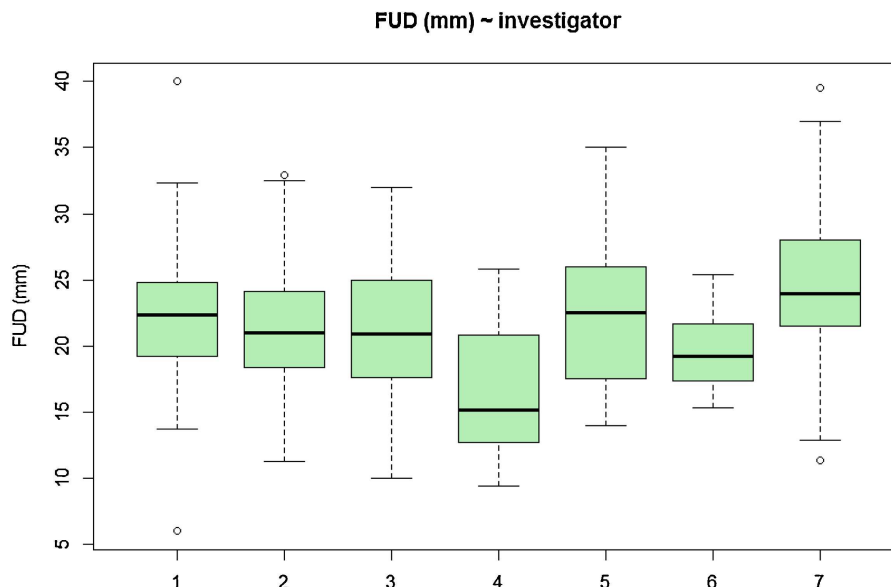


Fig. 3. Standard Box plots of patients maximal fundal uterine width by individual investigators. Investigator 1 and 3 used 3D ultrasound, the others 2D. Investigator 4 measured lower values which is due to the small number of measurements and very narrow uterine cavities of less than 10 mm in 4 young women.

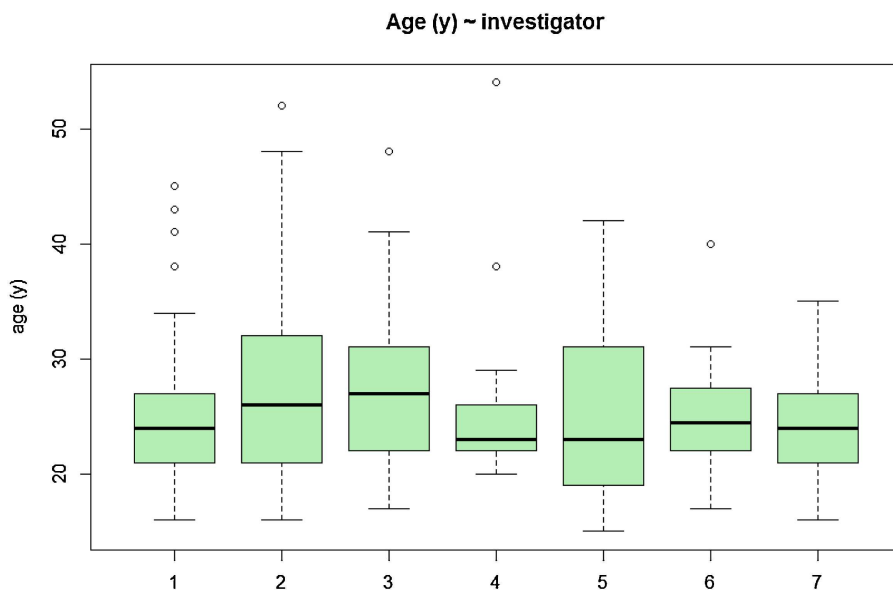


Fig. 4. Standard Box plots of patients age by individual investigators. There were no significant differences in the age of patients across investigators.

contraceptive options, many clinicians and researchers alike view IUDs as the almost near perfect contraceptive system. If true, then why do women using conventional T-shape LNG devices such as Mirena and Levosert/Liletta[®] (Actavis, USA) or the copper IUD TCU380A/Paragard fail to use them for their full effective lifespan beyond simply their desire to conceive? Typical discontinuation rates for medical reasons on average for these devices are 10–15% annually. Medical reasons such as cramping pain and bleeding are the principal reasons that many women discontinue using IUDs. Although still definitively unproven it appears obvious that incompatibility of the IUD itself with the uterine cavity is a significant contributory factor.

Nearly 50 years ago, researchers stressed the importance of an optimal interrelationship between the IUD and the uterine cavity as fewer side effects and greater acceptability would thereby be promoted; [1] however, few modern day researchers heeded this advice. Clinical experience has shown that geometric incompatibility between rigid or semi-rigid IUDs and the uterine cavity can lead to patient discomfort, partial or total expulsion, embedment, pain, unintended pregnancy, and abnormal or heavy uterine bleeding, all resulting in early removal of the device (Fig. 5).

Early removal due to cramping pain occurs frequently and more often in nulliparous and adolescent women than in older women. Discontinuation rates after 6–12 months of use of 40–50% are not atypical [18]. Early discontinuation places these young women at risk of unintended pregnancy as many among them move to less effective methods or to no protection at all. More importantly, these women will rarely return to intrauterine contraception. They are also spreading bad publicity about the method. Early discontinuation serves to undermine the clear contraceptive advantages of IUDs with a subpopulation of women failing to consider them as viable options. In addition, the wasted expense of the IUD and the burden of insertion fails to provide the patient and third party payers with maximal economic benefit. Providers of IUDs should realize that the only way to obtain comfort during IUD use, and high user continuation, is by using an IUD that is not substantially wider than the width of the uterine cavity.

The uterine forces at work and the ability of the uterus to undergo multidimensional contractions is quite severe. Devices that are too large for a woman's cavity will result, at a minimum, in discomfort and, at the worst, request for removal or expulsion. The impact of these forces can be seen in Fig. 5D which shows a

completely inverted IUD which illustrates the severity and impact of the forces at work attempting to expel an IUD. Not only is it remarkable that the uterus is capable of rotating an IUD 180°, it is also remarkable that some women can tolerate such a feat.

A growing body of research and clinical evidence is accumulating demonstrating that the uterine cavity for the majority of women is much smaller than many of the IUDs frequently used. A recent 2D ultrasound study conducted in nulliparous women found that about two thirds had a uterine cavity width of less than 24.4 mm. Ultrasound measurement in this group of 165 nulliparous women ranged between 13 and 35 mm [19]. Studies conducted by Kurz in Germany in the 1980s using a measuring instrument inserted in the uterus found a mean fundal transverse diameter in nulliparous women with age between 15 and 39 years of age of between 24 and 25 mm [20]. Our study is in agreement with these previous findings yielding a mean width of 22.2 mm. Surprisingly we found uterine cavities as narrow as 6 mm with 6.8% of the women being below 15 mm. This finding is significant when one realizes that if a device is inserted unknowingly in these women it will be almost 2 cm larger than her cavity itself. Even our mean findings of 22.2 mm demonstrates that over 50% of the women will have maximal uterine widths >1 full cm narrower than the size of Mirena or TCU380A (32 mm). Unfortunately, the optimal IUD size for a specific woman is presently unknown. The muscular nature of the uterus itself may allow for insertion of a larger size device because of its ability to accommodate and is apparently what has been occurring historically in the clinic. Logic suggests that consequences, likely negative, will occur to the patient some of which may result in discontinuation or possibly more drastic

Table 1

Comparison of maximal fundal width (FUD) in nulliparous women as measured by 2D or 3D sonography.

	FUD (mm)		
	2D	3D	Total
N	258	152	410
Mean	22.5	21.6	22.2
SD	5.1	5.1	5.2
Median	22.1	22.0	22.1
IQR	19.2–25.5	18.0–24.8	18.6–25.1
Range	9.4–39.5	6.0–41.1	6.0–41.1

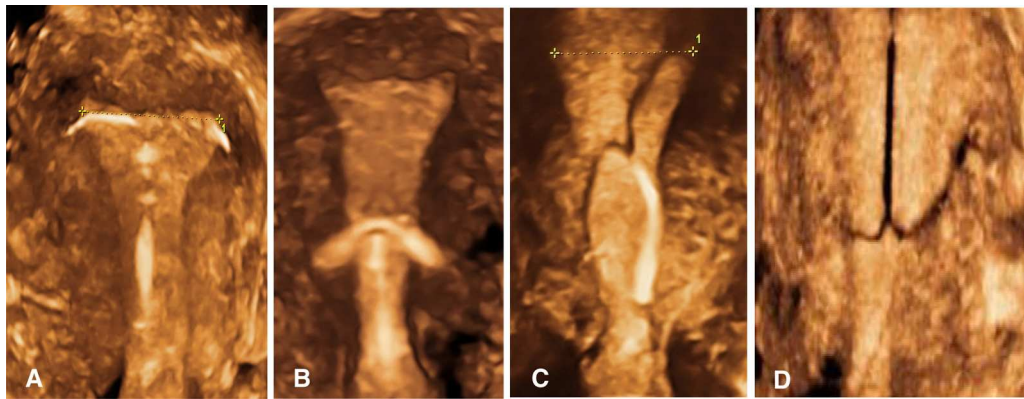


Fig. 5. 3D ultrasound examples of disparity between the IUD and the uterine cavity leading to complaints and early removal. A) 3D showing transverse arms of T-shape IUD embedded in the uterine cornua; B) 3D of embedded T-shape IUD (courtesy of Drs. Benacerraf & Shipp); C) 3D of a T-shaped IUD with transverse arms unfolded causing embedment due to lack of space; D) 3D of inverted IUD with both arms embedded in the myometrium as a consequence of severe uterine contractions (courtesy of Drs. Benacerraf & Shipp).

medical interventions. With respect to conventional framed T-shaped systems the precise IUD which will elicit maximal patient comfort while minimizing the risk of expulsion is unknown. In our study we found only 10 women who had maximal fundal widths greater than 32 mm. A critical, but yet unknown balance is required for T-shaped devices capable of long term comfort and retention.

Fig. 6 shows uteri of nulliparous women with much different IUD cavity widths, examples of uteri from our daily practices. Most nulliparous women (~80%) in our study had a uterine cavity between 15 mm and 28 mm. What is readily apparent from our study using 3D ultrasound, not only is the size of the uterine cavity variable amongst nulliparous women, so is its shape. Few had uterine shapes comparable to those illustrated in medical textbooks and advertisements.

Conventional framed T-shaped IUDs are limited by their requirement that they have transverse arms in order to maintain retention within the uterine cavity. An alternate approach for retention is commercially available frameless IUDs which eliminate the need entirely for any transverse arms and can be inserted in any size or shape uterine cavity. GyneFix[®] (Contrel Research, Belgium) is marketed in several EU countries as a unique copper device capable of a high degree of effectiveness and high patient acceptance [21]. It utilizes free moving multiple copper cylinders around a nonabsorbable suture allowing it to fit different sizes and shapes of the uterus. Its small size, narrow dimensions (2.2 mm) and its flexible nature once inserted allows it to readily adapt to changes in the uterine cavity. A LNG variety of the system,

Fibroplant[®]-LNG, is undergoing final stages of clinical testing. In contrast to conventional T-shaped framed IUDs, frameless IUDs maintain a high rate of continuation over the full lifespan of the IUD. Patient continuation rates for frameless devices appear to be substantially greater than that seen for framed systems with continuation rates being reported of over 90% at 5 years [22,23]. Fig. 7 shows hysteroscopic views of the frameless GyneFix IUD and frameless Fibroplant LNG-IUS in small cavities in comparison with the Mirena IUD inserted in a sufficiently wide uterine cavity. From these pictures, it is clear that the framed Mirena IUD will likely be deformed, expelled or embed if it were inserted in a uterine cavity which is not wide enough. Discrepancy between the size of the IUD and that of the uterine cavity explains the many discontinuations reported in clinical studies in young women [8–13]. In our study several women had maximal fundal widths below 10 mm who had the frameless IUD inserted with no difficulties or modifications to the insertion procedure.

The recent introduction of Jaydess/Skyla with a transverse arm length of 28 mm is positioned for shorter term use (3 years) in younger women. Its physical characteristics are nearly identical to Mirena, only marginally smaller. Although data is still being acquired the patient continuation rates for Jaydess over its 3 year lifespan is ~70–75%, a value consistent with the annual discontinuation rate of 10–15% seen with larger devices [24]. Discontinuation rates of ~17% have been reported in one study over a 12 month period in 304 adolescent girls [25]. Even the more recently introduced intrauterine ball device which relies on the use

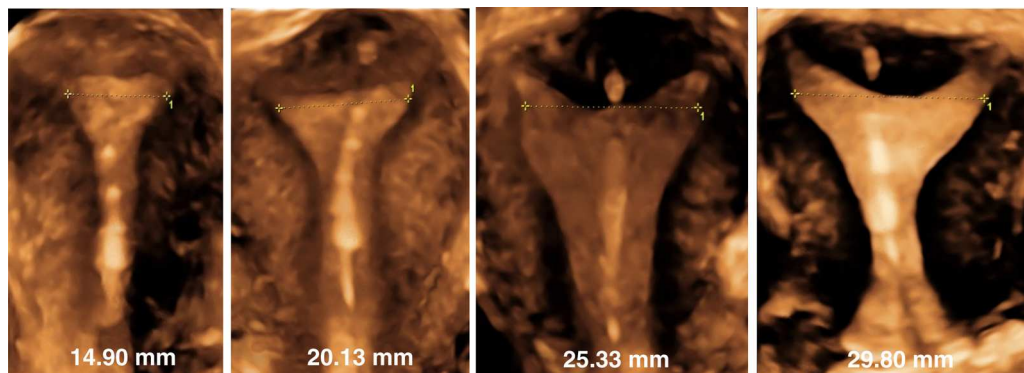


Fig. 6. 3D ultrasound images of uterine cavities of nulliparous women with different sizes and shapes, varying in cavity width from 15 to 30 mm, which is the width of the uterine cavity in ~80% of women. All contain the frameless IUD.

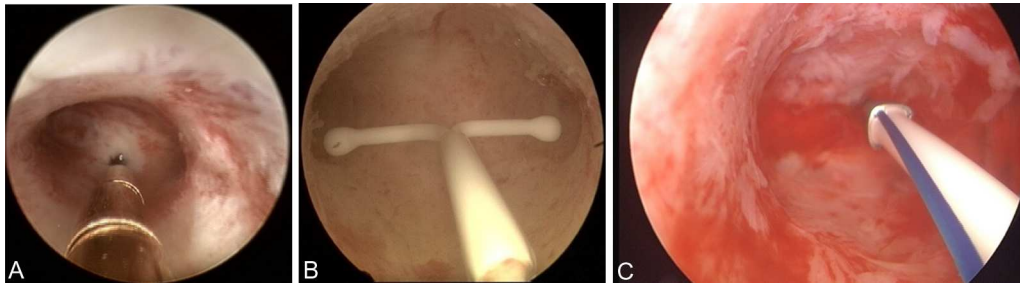


Fig. 7. (A) Hysteroscopic view of the frameless GyneFix[®] copper IUD inserted in a narrow uterus. (B) Hysteroscopic view of the Mirena[®] IUD inserted in a sufficiently large uterine cavity; (C) Hysteroscopic view of the frameless Fibroplant[®] LNG-IUS in situ.

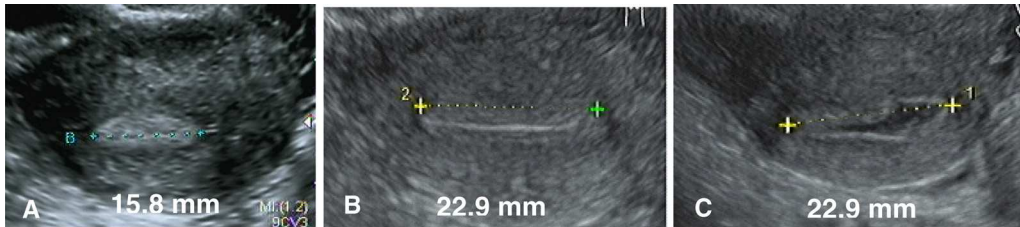


Fig. 8. (A) 2D transverse ultrasound with cavity width of 15.8 mm taken in second half of the cycle; (B) 2D transverse ultrasound taken in the first half of the cycle measuring a cavity width of 22.9 mm; (C) *ibid.* same patient following instillation with gel, showing more clearly the boundaries of the uterine cavity.

of a memory wire to maintaining shape may provide an option, but recent data suggests that expulsion and request for removal for this device are approaching 50% of participants [26].

The strength of the present study is that the 2D and 3D measurements were performed by competent sonographers with a great deal of experience in either 2D or 3D sonography and the use of adequate equipment by all investigators. 3D ultrasound is generally recognized as the gold standard for the evaluation of the uterine cavity. The high number of women evaluated and its multicenter design, as well as the general agreement between the 3D and 2D measurements are strong points.

The ability to conduct sonographic measurements in most gynecological practices and clinics affords the clinician an opportunity to assess the suitability of the uterine cavity prior to as well as immediately post insertion and with minimal inconvenience. Our study suggests that either 2D or 3D ultrasounds are suitable. The boundaries of the uterine cavity can be accurately visualized premenstrual with 2D ultrasound although instillation of gel may be necessary in the first half of the menstrual cycle. Instillation with Instillagel (Farco Pharma, Germany) allows mostly good visibility and clear definition of the uterine cavity boundaries (Fig. 8).

3D ultrasonography has added advantages in its ability to fully visualize the entire cavity and IUD simultaneously. It affords the gynecologists the ability to routinely check placement not only at placement but follow-up visits. As utilization of sonography occurs, and physicians become more aware of the importance of uterine cavity with respect to IUD selection, more information on suitable limits with respect to IUD size and shape can be generated.

There are some minimal discrepancies between our measurements of the mean uterine cavity width with those found in previous studies using 2D ultrasound or a measuring instrument (Cavimeter[®]) [19,20]. However, there is little doubt that the maximal uterine fundal width of most women is much less than first believed. The overall uniformity of our data across independent centers serves to further substantiate the findings.

3D ultrasound is the best methods to visualize and evaluate the suitability of IUD in the presence of acquired or congenital anomalies of the uterus. With respect to uterine suitability, uterine

anomalies such as uterus arcuatus or a partial septate uterus may reduce the available space in the uterus for conventional IUDs further. These mullerian anomalies are probably more frequent than the incidence of 5% mentioned in the literature [27,28]. A uterine cavity width in the superior range should be suspected of uterus arcuatus or subseptus. It should be noted that bimanual examination is not useful to assess the size of the uterine cavity as there is no relationship between the size of the body of the uterus and the size of the uterine cavity [29].

Summary statement

Conventional IUDs are generally too large for uterine cavities of nulliparous women. The use of appropriate intrauterine devices that take into account the geometric relationship of the device to the host uterine cavity will likely result in high rates of continuation due to greater patient comfort leading to fewer unintended pregnancies and induced abortions. At least 2D, preferable 3D equipment, as well as highly trained health care providers, should be available at all sites providing intrauterine contraception as the assessment of a patient's uterine cavity size is essential in the selection of an appropriate IUD. When selecting a framed IUD, consideration to uterine compatibility should be made. It is evident that measurement of the cavity width is not necessary with the frameless IUD. Routine and repeat ultrasound confirmation of IUD placement, whether 2D or 3D, should be made in an effort to maximize patient comfort.

Conflict of interest

Kilian Nolte, MD Sohela Jandi, MD Ansgar Pett, MD, Thomas Hasskamp, MD, Sabine Linden, MD, Maarten van Santen, MD, PhD, Olivier Julien, MD: nil. Dirk Wildemeersch, MD, PhD has conducted research in the field of non-hormonal and hormonal, framed and frameless intrauterine devices, including in nulliparous and adolescent women, since more than 20 years and is the inventor of the GyneFix[®] IUD. He did not receive any financial compensation of any kind.

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