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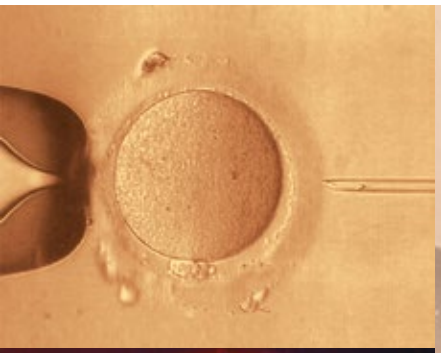

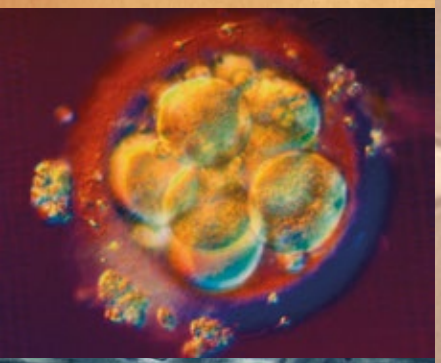

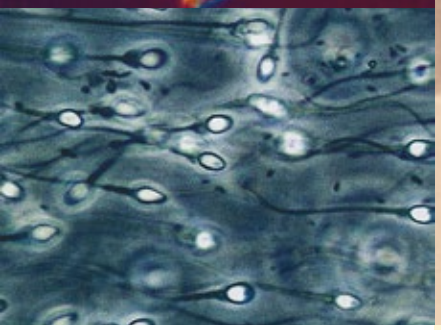

Geometric Foundations of Intrauterine Device Complications and Implications for IUD Users – Importance of the IUD Size to maximize Tolerability and Prevent Early Discontinuation

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Geometric Foundations of Intrauterine Device Complications and Implications for IUD Users – Importance of the IUD Size to maximize Tolerability and Prevent Early Discontinuation

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Intrauterine devices (IUD) are long-acting reversible contraceptive methods that are independent from daily attention. Unlike methods that need daily motivation, IUDs are "forgettable" methods that are also highly effective. They are, therefore, advocated by all major organizations to prevent unintended pregnancy. However, current IUD use often leads to early discontinuation, even within 3 or 6 months following insertion. It is known for many years that IUDs perform best, leading to high continuation of use, if attention is given to geometric factors such as size and shape of the host uterine cavity prior to inserting an IUD. Continuation of use, for the full claimed duration of action, will usually remain low if the relationship between IUD and uterine cavity is out of proportion **J Reproduktionsmed Endokrinol_Online 2015; 12 (4): 255–9.**

Key words: IUD, IUS, geometric factors, side effects, adverse events, continuation of use

Background

The intrauterine contraceptive device (IUCD/IUD) occupies a prominent role in reducing unintended pregnancy rates. It has higher continuation of use than oral contraceptives, implants and depot medroxyprogesterone acetate [1]. The IUD is also an excellent candidate for use immediately following induced first-trimester abortion, resulting in significantly fewer repeat abortions [2]. In addition, copper IUDs are more effective than emergency contraceptive pills, providing long-term protection simultaneously [3] and they are more cost-effective than any other available contraceptive method [4].

In many ways, IUDs are the near ideal form of contraception and are strategically important for preventing unintended pregnancies and family planning. Their ability to reduce or eliminate unintended pregnancy is governed by women or couples continuing to use the method. The IUD-cavity relationship and the tolerability of the device is paramount to achieving this aim. One aspect of IUD use often overlooked by physicians is uterine compatibility. Given the design similarities of commercially available IUDs, patient individualization with respect to size and uterine fit has not been easily achieved. Various factors contribute to patient selection and use of IUDs. This article will review the concept of uterine compatibility as it relates to IUD design.

Size and Shape of the Uterine Cavity

Almost 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 [5]. They found that pain during use of the IUD is related to the disparity between the size of the uterine cavity and that of the IUD. Particularly a too wide IUD was found to be cumbersome. This study only examined the use of IUDs in parous women. Another study in 60 nulliparous women found an average width of the uterine cavity of 23.5 ± 0.94 mm [6]. Later, additional studies were conducted that examined the uterine width at the fundal level (fundal transverse diameter) in parous as well as nulliparous women. These studies found that the mean width of the uterine cavity in 795 nulliparous and parous women between 15 and 40 years of age is ~24–26 mm (Tab. 1) [7]. Based on the technology available at the time, these studies utilized cavimeters to physically measure the width of these women's uterus.

These early findings have since been substantiated using less invasive external modern uterine imagining techniques that allow for precise and accurate uterine measurements *in vivo*. The width of the normal uterine cavity was also assessed through the use of three-dimensional (3-D) ultrasonography as illustrated below (Fig. 1). The technique allows for multiple images to be collected along with precise uterine dimensions of not only the width but also the length of the uterine cavity itself.

Table 2 shows the mean fundal transverse diameter in nulliparous and parous women, with mean age of 29 years, obtained after 3-D imaging. Young nulliparous women of < 29 years were not included in this study [8].

The uterine cavity width was also recently measured, again with 3-D ultrasound, in a study in Finland conducted in 165 young nulliparous women, and found a *median* transverse fundal diameter of the uterine cavity of 24.4 mm. One hundred and one (62.7%) women had a transverse diameter at the fundus of < 24.4 mm (Tab. 3). Thus a very large segment of the female population have substantially smaller uterine widths. The smallest diameter observed in the study was 13.8 mm [9].

With respect to the longitudinal uterine plane, a separate study obtained precise measurements of the total uterine length

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Table 1. Fundal transverse diameter (mm) according to age and parity (Cavimetric measurements. Mod. from [7]).

Age	**15–19**	**20–24**	**25–29**	**30–34**	**35–39**
Mean ± SD	24.8 ± 2.5	23.9 ± 3.0	24.8 ± 3.2	24.7 ± 3.3	24.9 ± 1.1
No of women	28	221	232	175	96
Parity	**0.0**	**0.1(+)***	**1**	**2**	**3(+)**
Mean ± SD	23.1 ± 3.1	23.8 ± 3.3	24.5 ± 3.0	25.7 ± 3.5	26.0 ± 2.3
No of women	493	124	103	62	13

* 0.1(+) = no parity, one abortion or more

Table 2. Fundal transverse diameter (mm) and uterine volume according to gravidity/parity (3-D measurements). Mod. from [8].

Gravidity/Parity (n [%])	**0 (n = 91)**	**1 (n = 38)**	**> 1 (n = 81)**
0	91 (100.00)	18 (47.3)	3 (3.7)
1	20 (52.6)	9 (11.1)	69 (85.1)
Mean transverse diameter (range)	27.1 (20.2–34.1)	29.6 (22.9–36.3)	31.1 (24.6–37.5)
Mean volume* (cm^3) (SD)	55.3 (25.7)	66.4 (29.2)	103.1 (33.1)

* Much of the increase in uterine volume occurs after pregnancy and is due to the uterine muscle which becomes thicker; the cavity, however, does not change much.
SD = Standard Deviation

Table 3. Fundal transverse diameter (mm) in 165 Finnish nulliparous women. Mod. from [9].

	Range	**50th percentile measure**	**No (%) under 50th percentile**
Fundal width (mm)	13.8–35.0	24.4	101 (62.7)

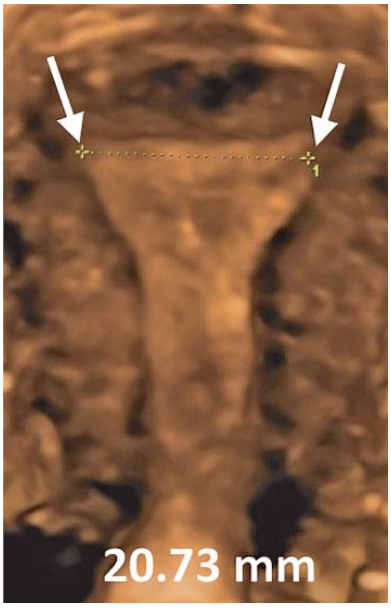

Figure 1. 3-D ultrasound illustration of the measurement of the transverse width of the uterine cavity (arrows show the transverse distance which is 20.73 mm in this case). © D. Wildemeersch

(TUL), observed in 551 parous and nulliparous women (only 3% were nulliparous) which showed that 59% of TULs were within a 1-cm range (7.1–8.0 cm) and 87% were within a 2-cm range (6.6 to 8.5 cm). The mean was 7.5 cm [10]. In the Finnish study referenced above, conducted in 165 nulliparous women, the TUL varied between 4.42 and 8.8 cm [9]. The cavity length, measured from the internal os to the fundus, was only between 2.14 and 5.09 cm with a mean of 3.53 cm. However, the cavity length was < 32 mm in 32.9% of women. These studies clearly indicate that a wide degree in uterine width and length exists in women.

When evaluating the size and shape of the uterine cavity, 3-D ultrasound is the easiest method to also diagnose uterine anomalies or other gynecological conditions such as adenomas which may affect IUD/uterus compatibility. Unfortunately, screening for congenital or gynecological uterine anomalies is not practical to carry out routinely but may occasionally still have substantial clinical impact in the selection of an appropriate IUD. Overall, about 5.5% uterine anomalies are diagnosed in an unselected population. Arcuate uteri are the most common abnormalities affecting 3.9% of all women. Subseptate or septate uteri have a prevalence of 2.3%. Bicornuate uteri are uncommon (0.4%) and 0.1% of cases present a unicornuate uterus. The prevalence of uterus didelphys is approximately 0.3% in an unselected population [11, 12]. The European Society of Human Reproduction and Embryology and the European Society of Gynecological Endoscopy proposed an updated classification system to provide a comprehensive clinical orientation of congenital anomalies of the uterus. Anomalies are classified into the following main classes based on anatomical deviations derived from the same embryological origin (Fig. 1): U0 or normal uterus; U1 or dysmorphic uterus; U2 or septate uterus; U3 or bicorporeal uterus; U4 or hemi-uterus (Fig. 2) [13].

On the other hand, the uterine shape and dimensions during the different phases of the menstrual cycle modulate the relationship between the IUD and the host endometrial cavity. Researchers found that uterine contraction frequency shows an increase during the follicular phase, followed by a period of uterine quiescence during the luteal phase [14]. Figure 3A shows the anatomical and functional changes of the uterine cavity during the cycle. If these contractions are severe, they can compress, distort, displace, and expel the IUD, particularly if the IUD is too big and is not capable of adaptive changes [1]. The impact of the uterine forces can be quite severe as illustrated in Figure 3B for a T-IUD. Embedment can cause significant pain and bleeding for the patient, requiring removal.

In premenopausal women, a parity-related enlargement in uterine size is observed between nulliparous and parous women. The increase in volume is attributed predominantly due to an increase in thickness of the uterine wall since the uterine cavity width does not change much [8, 15]. A significant increase of the uterine volume occuring towards the end of the menstrual cycle is also observed [16]. However, minimal changes are seen with respect to the width of the uterine cavity itself (Tab. 2).

The length of the IUD does not seem to be important clinically with respect to expulsions however it may contribute to

overall uterine compatibility and patient acceptance. Some researchers have concluded that an IUD with a shorter vertical length appears unnecessary, since current models fit most women, including nulligravid women [17]. However, research has determined that approximately 1/3 of uterine cavities of nulliparous women are shorter than the length of the stem of the current IUDs [9]. When the length of the stem is equal or longer to that of the endometrial cavity, irritation of the isthmus region will trigger myometrial contractions that promote pain, translocation, expulsion or embedment.

It should also be realized, that malformation of the uterus may be a reason for IUD problems and side effects such as malposition of the IUD, displacement, partial and total expulsion of the IUD, and uterine perforation, and should be considered if any of these events occur.

Implications for IUD Users

The transverse uterine cavity dimensions are often smaller than the length of the transverse arm of most used conventional IUDs (e.g., Paragard IUD and Mirena®) which is 32 mm with both devices, resulting sometimes in distortion, displacement, and expulsion of the IUD. The length of these devices is 36 and 32 mm, respectively. Based on the uterine measurements presented above these conventional devices are substantially larger than the uteri of many women.

In order to circumvent this spatial incompatibility researchers have adapted the basic T-shaped IUDs. The transverse arm of a T-shaped IUD was shortened from its standard length of 32 mm to the individually measured transverse diameter or slightly less (Fig. 4). They found that the fundal transverse dimension is of paramount importance with respect to IUD acceptance, as women tolerated the IUD much better. These geometric relationships promote IUD retention and stability while minimizing endometrial/myometrial trauma.

Precision Intrauterine Contraception to Promote High Continuation of Use

Providers of IUDs should realize that the only way to obtain comfort during IUD use and a high continuation rate is by using an IUD that is not wider than the width of the uterine cavity. The new smaller version of Mirena®, named Jaydess (Skyla® in the USA), has a transverse arm length of 28 mm. The results of initial clinical trials are encouraging [18], but this 28 mm transverse arm may still be too long for many women as the IUD cavity width is less than 24 mm in many of them. Figure 5 illustrates the width of the uterine cavity in nulliparous women. The smaller the transverse width, the more likely incompatibility problems may occur. Note that current T-shaped IUDs with transverse arm of 32 mm are too wide for the uterine cavities displayed in Figure 5.

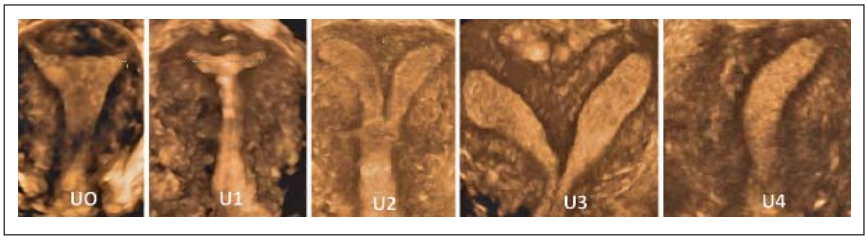

Figure 2. Classification of main uterine anomalies adapted from ESHRE/ESGE [13]. From left to right: Class UO or normal uterus, Class U1 or dysmorphic uterus, Class U2 or septate uterus, Class U3 or bicorporeal uterus, and Class U4 or hemi uterus. © D. Wildemeersch

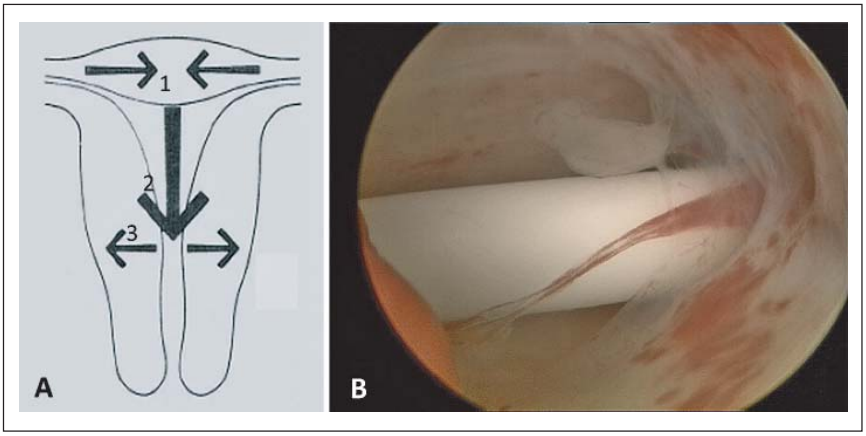

Figure 3. (A): Anatomical and functional changes of the uterine cavity on cycle day 1: (1) contracted fundus with reduced transverse diameter; (2) relaxed isthmus with increased transverse diameter; (3) definite fundus-to-cervix muscle propagation waves. Mod. from [10]. **(B):** The effect of uterine forces on an IUD causing embedment of the transverse arm. © D. Wildemeersch

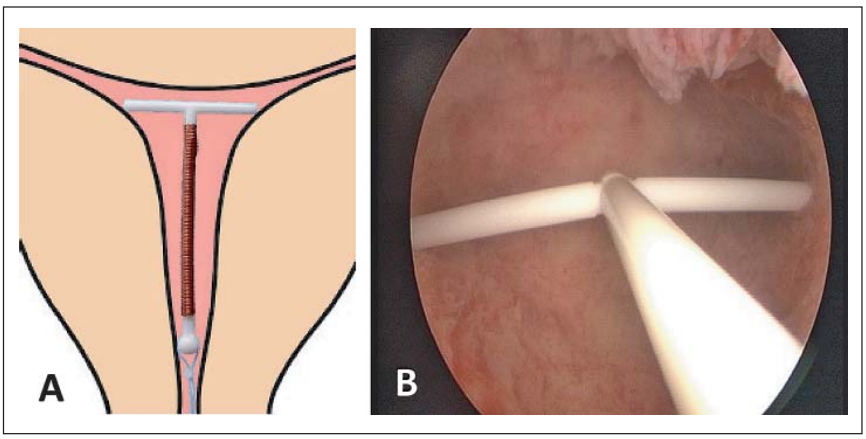

Figure 4. (A): Adapted T-shape intrauterine device with transverse arm of 18 mm. Mod. from [7]. **(B):** Hysteroscopic view of the measurement of the uterine cavity width with an experimental IUD with transverse arm length of 24 mm, fitting snugly in the narrow uterine cavity. © D. Wildemeersch

Rationale of the Frameless Intrauterine device/system (IUD/IUS)

Frameless copper and frameless LNG-IUSs could be the optimal design from a dimensional point of view. The design of

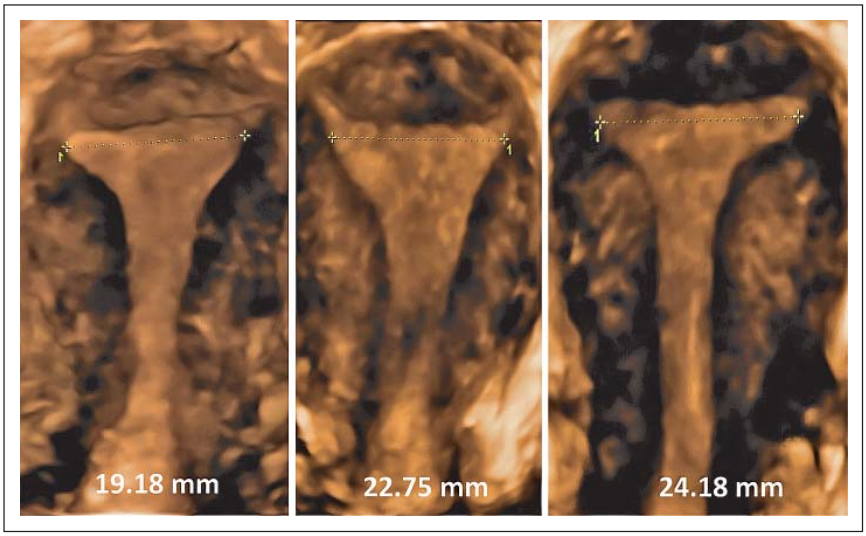

Figure 5. From left to right: 3-D ultrasound pictures of uterine cavities focused on the cavity width which corresponds with that of the majority of nulliparous women. © D. Wildemeersch

the frameless copper IUD, due to its absence of a horizontal crossarm and its flexibility, explains its adaptation to uterine cavities of every size and shape. These characteristics eliminate the ability of the uterus to exert expulsive forces on the frameless IUD devices, in contrast to that seen with the framed T-shape designed IUDs. Consequently, when properly inserted, the frameless IUD offers several important advantages: high efficacy, low expulsion rate, reduced bleeding, usually no pain complaints, long duration of action but most importantly long term comfort. The design characteristics of the frameless IUD would be attractive as a first choice method for many women, especially for those with a small (e.g. nulliparous women) or distorted uterine cavity, and for women who have experienced problems with framed IUDs [19, 20] (Fig. 6). The one-dimensional design of the frameless IUS explains its high acceptability and high continuation of use. An interesting observation is that continuation rates (adjusted for removal for conception request) after the first year with the frameless GyneFix 200 IUD and the frameless LNG-IUS remain high (over 90% at 5 years) due to the low rates of removal for bleeding and pain, whereas these rates reduce by up to 10% each year with conventional T-shaped IUDs yielding continuation rates of only 40 to 50% at 5 years.

Erratic and heavy menstrual bleeding is the most common cause for IUD discontinuation. The impact on menstrual blood loss with copper IUDs can be minimized by reducing the surface area of the foreign body [21]. Thus the larger the device the greater the amount of blood loss a woman experiences during menses. The frameless IUD, due to its ability to release copper from both the interior and exterior surfaces, has a high effective surface area, significantly higher than that of conventional copper IUD which allows a reduction in the overall surface area of the IUD (nominal surface area of 200 mm^2). With the frameless IUD, all

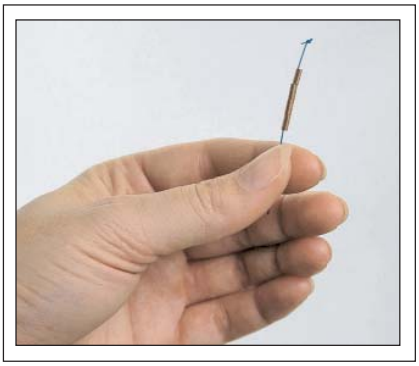

Figure 6. Frameless copper IUD with anchoring knot on the upper end. The anchor is inserted in the fundus of the uterus with a specially designed inserter. © D. Wildemeersch

surface areas are exposed to the uterine environment allowing for comparable efficacy to be achieved through the use of a much smaller device [22, 23]. This is a fundamental difference compared to conventional IUDs and allows for a significant reduction in the overall size of the IUD [24–26]. The smaller the size the lower the impact on the amount of menstrual blood loss. In addition, as the 200 mm^2 GyneFix device does not significantly increase menstrual blood loss due to its overall small size. It would be ideally suited for use in adolescent and young nulliparous women, a population at high risk for unintended pregnancies (Fig. 7, 8). All of these factors serve to increase patient tolerability of these devices with 5 year continuation rates reported in excess of 90% [19].

Conclusion

The late Dr Harrith M Hasson who was honored for his research on the uterine geometry related to IUD performance concluded that "*[…] with few exceptions, the performance record of a IUD is basically determined by its geometric relationship to the host uterine cavity*".

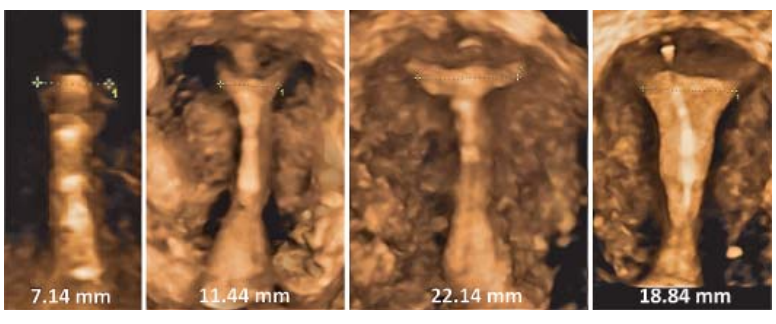

Figure 7. 3-D ultrasound pictures of the frameless copper IUD in three uteri with width between 11.4 and 22.2 mm. Frameless IUDs fit in cavities of every size and shape maximizing performance and resulting in long duration of use. © D. Wildemeersch

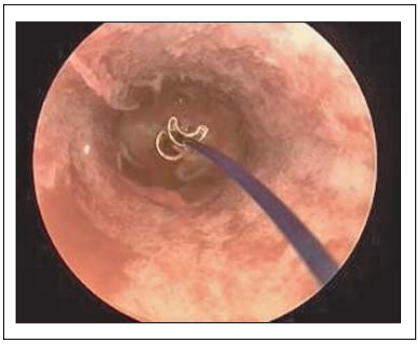

Figure 8. Hysteroscopic view of the frameless copper IUD attached to the fundus of this very narrow uterine cavity. © D. Wildemeersch

In general, all IUDs can be used, also in nulliparous and adolescent women. However, this should be done with caution in the light of current scientific evidence and based on appropriate examination that shows that the uterine cavity is sufficiently large to accommodate these devices [27]. In contrast the anchored, frameless IUDs, have significant advantages over framed IUDs, as they fit in cavities of every size and shape. Unlike conventional T-shape devices, its novel design allows for a one sized device to fit cavities of all sizes and shapes. They can therefore be named "precision intrauterine contraceptives". Many unintended pregnancies and induced abortions could be avoided in young women by providing suitable IUDs that result in a high continuation of use. In addition, when properly inserted, failed insertions and expulsion of the anchored IUD is rare as there is no impact of uterine contractions on the IUD. However, it should be stressed that insertion training is important, even for experienced IUD providers.

Conflict of Interest

N. Goldstuck, T. Hasskamp, A. Pett and S. Jandi declare no conflict of interest.

D. Wildemeersch is the developer of the frameless GyneFix® copper IUD and the frameless FibroPlant® LNG-IUS. Currently he acts as a medical advisor in devising new concepts in controlled release for contraception and gynecological treatment, and receives compensation for some of these activities.

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