New Technologies for Intrauterine Contraception and Treatment: Design that Fits

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Thomas Staudinger
Maurice Kienel

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New Technologies for Intrauterine Contraception and Treatment: Design that Fits
D. Wildemeersch

A strategic advantage of intrauterine devices and systems is that, unlike the Pill, they are genuinely ‘fit-and-forget’. In use, they are more effective than Pills, particularly in adolescents and nulliparous women, as they have a relatively high continuation of use. The World Health Organization concluded that IUDs can be used and that they are safe for young women, including adolescents. Because adolescents and young nulliparous women contribute disproportionately to the epidemic of unintended pregnancies, suitable long-acting methods of contraception, such as the IUD or IUS, should be advocated as first-line choices for interval, emergency and immediate post-abortal contraception in this population of women.

However, a major drawback is that they do not fit in uterine cavities of many women. Uterine cavities of nulliparous women are usually smaller than those of parous women. As current copper IUDs and the, at present, only available LNG-IUS may not be suitable for many young women, new developments in intrauterine technology, smaller frameless and framed copper and hormone-releasing devices, could help increase the prevalence of use, particularly continued use of this method in women, including in adolescents and nulliparous women, and help reduce the number of unintended pregnancies and induced abortions. J Reproduktionsmed Endokrinol 2011; 8 (Special Issue 1): 222–6.

Key words: frameless and framed copper IUD, levonorgestrel IUS, contraception, unintended pregnancy, adolescents, nulliparous women

Introduction: One Design does not fit all Uterine Cavities
Intrauterine devices and intrauterine systems, apart from being long-acting, are particularly attractive as they possess all characteristics listed in Table 1. Moreover, they act locally, avoiding potentially serious systemic adverse effects. A recent re-assessment of the risk of pelvic inflammatory disease attributable to an intrauterine device concluded that intrauterine devices do not affect the fertility of adolescents [2]. Fecundity also rapidly returns to normal after IUD removal [3, 4]. In addition, the levonorgestrel-releasing intrauterine system may offer some protection against sexually transmitted infection [5].

However, uterine cavities differ considerably in size and shape, and the uterus is subject to changes in size and volume during the menstrual cycle [6, 7]. These changes are most pronounced at the time of menses. These individual variations in size and shape of the human uterus are probably greater than variations of the human foot (H.M. Hasson). Therefore, it would be unreasonable to expect one standard-sized IUD/IUS to fit in uterine cavities that differ in size and volume from woman to woman and from time to time in the same woman. Clinical experience has shown that dimensional incompatibility between the IUD/IUS and the uterine cavity can lead to partial or total expulsion, perforation of the uterine wall, pain, unintended pregnancy, and abnormal or heavy uterine bleeding leading to removal of the device [8–10].

Research has shown that if the width of the uterine cavity is too small, side effects and complications are likely to occur. The crossarms of standard T-shaped IUDs are frequently too long for a large number of uterine cavities, as the average transverse diameter of the uterine cavity in the majority of women is smaller than the span of the crossarms of the IUD (Fig. 1). The average transverse diameter of the uterine cavity at the fundal level in nulliparous women between 15 and 34 years of age, as well as in many parous women, is much smaller than the length of the crossarms of most currently used T-shaped IUDs resulting in dimensional problems. The length of the crossarms of the TCu380A IUD and the Mirena® LNG-IUS is 32 mm. The average fundal transverse dimension in nulliparous as well as parous women is only around 25 mm.

Recent 3-D sonography studies compared women with abnormally and those with normally located IUDs with respect to their indication for sonography and found that the proportion of patients whose principal indication for sonogra-
The Advantage of Intra-uterine Methods that Fit

The frameless copper-releasing GyneFix® IUDs and the frameless FibroPlant® LNG-IUS were developed to optimize harmony with the uterine cavity of parous and nulliparous women in an attempt to reduce the side effects and expulsion rates of conventional IUDs, and consequently, increase continuation of use (Fig. 3).

Figure 4 illustrates the position of the frameless and flexible IUD/IUS in uterine cavities which differ in size and shape as well as the absence of dimensional incompatibility even if the fundal transverse diameter is extremely small.

Different versions of GyneFix® have been clinically tested in large multicenter randomized and non-randomized clinical trials. The high effectiveness has been demonstrated in a randomized comparative study conducted by the WHO and others [26–28]. Failures range from 0.0/100 users to 2.5/100 users (cumulative rates) during the first year up to 10 years of use in published randomized and non-randomized comparative clinical trials [29]. The smaller GyneFix® version has a similar high efficacy [30]. In addition, clinical trials demonstrated, for the first time, the absence of a significant effect of the tiny IUD on menstrual blood loss (Tab. 2) due to the very small size and optimal harmony with the uterine cavity, leaving the cavity totally undisturbed [31]. This is important since abnormal bleeding and pain are the two major reasons for IUD discontinuation [32]. Kivijarvi et al. found clinical anemia in 10% of users of copper IUDs after 12 months exposure and iron deficiency, as judged by the ferritin levels, could be demonstrated.
Intrauterine Contraception

Table 2: Menstrual blood loss evaluation in users of the small GyneFix® 200 IUD. Characteristics of the study group (n = 60, 23 parous and 37 nulliparous women) and analysis by the pictorial bleeding assessment technique, measuring the difference in menstrual score (MS) before and during use of the GyneFix® 200 IUD.

<table>
<thead>
<tr>
<th>Age</th>
<th>MS at insertion</th>
<th>MS at last follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>30.4</td>
<td>116.7</td>
</tr>
<tr>
<td>SD</td>
<td>8.5</td>
<td>52.9</td>
</tr>
<tr>
<td>Median</td>
<td>30.5</td>
<td>110.5</td>
</tr>
<tr>
<td>Range</td>
<td>17–46</td>
<td>28–265</td>
</tr>
</tbody>
</table>

Wilcoxon matched-pairs signed-ranks test: p = 0.596 (n. s.).

There is No Increased Risk of Perforation with the Frameless, Anchored IUD/IUS

Of the 5346 insertions (4808 interval and 543 immediately post-abortal) conducted in clinical trials with the frameless copper-releasing IUD, there were no perforations [26]. In the two large post-marketing trials conducted in Belgium and Spain with GyneFix® in over 12,000 women, the rate was 1.2–2.0/1000 insertions which is similar to the quoted perforation rate occurring with traditional IUDs [44]. The risk of perforation can be reduced by proper training (see below) and by visualization of the anchor by ultrasound. The manufacturer of the frameless GyneFix® and frameless FibroPlant® LNG-IUS incorporated a small metal particle in the anchoring system rendering the anchor highly visible on ultrasound examination (Figs. 5, 6) (patent pending). This allows assessment of the proper position of the anchor in the muscle of the uterine fundus following insertion and at follow-up. In the rare event of perforation of the uterine serosa, or in case of doubt, the frameless IUD/IUS can be removed and a new insertion can be performed immediately or at a later date.

Training Aspects

As the frameless technology is new, familiarity with the insertion procedure may be acquired only after a number of insertions have been completed, depending on the skill of the provider. Experience has shown that insertion failures and expulsions, in parous as well as null...
liparous women, can be minimized to very low rates if providers attend a training course organized by the manufacturer. Proper training is essential to properly insert the GyneFix® and will result in optimal performance and high continuation of use. Following training, providers can become proficient by conducting training by themselves in an appropriate “home” uterine model (Fig. 7) before they start insertions in their patients.

**Conclusion**

Many unintended pregnancies and induced abortions can be avoided by providing intrauterine devices that cause a high continuation of use. Nulliparous women who need or want a non-systemic contraceptive option may benefit from a smaller framed IUD/IUS or from the frameless copper or a frameless LNG-releasing system. Among nulliparous women, where the issue of incompatibility may be more pronounced, clinical studies suggest the high tolerance and high continuation rates of the frameless IUD and IUS [29, 45]. In addition, if properly inserted, expulsion of the IUD/IUS is rare.

Young men and women are a highly vulnerable population. They deserve to be informed and to have access to high-quality and effective reproductive health care assistance. High-performing, forgettable, long-acting, reversible, and well-tolerated contraceptives, with a high continuation of use are needed to reduce unintended pregnancies in young women [46]. However, outdated perceptions about appropriate patient candidate for long-acting methods among health care providers continue to negatively impact their use. These myths should be vigorously dispelled.

Finally, the gynecological examination, and insertion of an IUD, in young nulliparous women and adolescents, may be challenging. IUD fitting should be done with extreme care and with attention to comfort and pain relief as pain scores may be quite high with vagal reactions [34, 47]. The use of misoprostol may be useful to maximize comfort and facilitate IUD insertion by softening the cervix and reducing the chance of complications such as perforation, pain and bleeding [48].

**Acknowledgment**

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Conflict of Interest

Dirk Wildemeersch, MD, PhD, is a Belgian gynaecologist and Medical Director of Contrel Drug Delivery Research, an organization which was established to manage clinical research and to develop and study innovative drug delivery technologies, aimed at finding improved methods for prevention and treatment of gynecological conditions, improvements to birth control methods, and higher levels of safety, user acceptability, compliance and quality of life for women. Contrel is the manufacturer of GyneFix® and FibroPlant® and Femilis®.

The research organization also provides insertion training for doctors. The funds generated are used for conducting further research and to participate in humanitarian projects.

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