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New intrauterine technologies for contraception and treatment in nulliparous/adolescent and parous women

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Abstract

The IUD (intra uterine device) is a highly effective method of contraception that is underused. New developments in intrauterine technology, smaller frameless copper and levonorgestrel-releasing devices, could help increase the prevalence of use in adolescents and nulliparous women. Because adolescents and young nulliparous women contribute disproportionately to the epidemic of unintended pregnancies, long-acting methods of contraception, particularly IUDs, should be considered as first-line choices for interval, emergency and immediate post-abortal contraception in this population of women. As the uterine cavity is generally much smaller in this group than in older women, adapted IUDs may be very useful. Compatibility of the IUD with the small uterine cavity leads to high acceptability and continuation of use, a prerequisite to reduce unintended pregnancies. A strategic advantage of IUDs is that, unlike the Pill, they are genuinely 'fit-and-forget'. In use, they are much more effective than Pills in this age group. However, copper intrauterine devices do not offer protection against sexually transmitted infections (STIs) and, therefore, they are not always the methods of first choice for teenagers and nulliparous women. New evidence, however, from the World Health Organization and the American College of Obstetricians and Gynecologists, shows that IUDs can be used and that they are safe for most women, including adolescents.

Key words: Adolescents, contraception, frameless copper IUD, frameless levonorgestrel-releasing IUS, nulliparous women, unintended pregnancy.

Introduction

Each year, about 80 million unintended pregnancies occur in the world (38% of all pregnancies). Approximately half of these pregnancies result in induced abortions and half in unintended births. Unintended pregnancies may put the woman and her family in a difficult position especially if she is confronted with the abortion decision and the potential negative consequences associated with the unplanned childbearing, including child health and development issues, relationship instability and compromises in education and employment that may exacerbate poverty (Guttmacher Institute, 2009).

These unintended pregnancies are attributed to non use of contraception (about 50%), inconsistent or incorrect use (about 45%) and 5% due to method failure. It seems extremely hard for many women (especially for the young) to use a method correctly and consistently. The typical failure rate of the Pill is approximately 5% (Trussel and Ellertston, 1998). Between 40 and 60% of new Pill users discontinue the Pill during the first year. The average duration of Pill use in the USA is only 4.8 months. The same phenomenon has been observed in Western Europe, where 50% of adolescents stop using the Pill after 3 months. Oral contraceptive noncompliance is the main reason for the occurrence of an unintended pregnancy.

Oral contraceptive Pills (OCPs), male condoms and female sterilization are the contraceptive methods most commonly used in Europe and the United States. Frequently cited reasons for discontinuing a method when contraception is still desired include: side effects, difficulty of use, safety concerns and lack of access to health care. Furthermore, personal beliefs and preferences influence a woman's willingness to use a contraceptive method correctly.

Table 1. — Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of traditional and long-acting methods of contraception and the percentage continuing use at the end of the first year (Adapted from Trussell, 1998). Failure rates during typical use show how effective the different methods are during actual use (including inconsistent or incorrect use). Failure rates during perfect use show how effective methods can be, where perfect use is defined as following the directions of use.

Contraceptive Method	% of women experiencing an unintended pregnancy within the first year of use		% of women continuing use at one year
	Typical use	Perfect use	
Chance	85	85	
Spermicides	26	6	40
Periodic abstinence	25	1-9	63
Cervical cap	20-40	9-26	42-56
Sponge	20-40	9-20	42-56
Diaphragm	20	6	56
Withdrawal	19	4	
Condom			
- Female	21	5	56
- Male	14	3	61
Pill	5		
- Progestin only		0.5	
- Combined		0.1	
IUD/IUD/IUS			
- Copper T380A	0.8	0.6	78
- GyneFix*	0.0-0.3	0.3	95
- Mirena	0.1	0.1	81
- Femilis*	0.0	0.1	90
- Fibroplant*	0.0-0.1	0.1	90-95
Injectables	0.3	0.3	70
Female sterilisation	0.5	0.5	100
Male sterilisation	0.15	0.10	100

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Table 1 shows the percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of traditional and long-acting methods of contraception and the percentage continuing use at the end of the first year.

Advantages-Disadvantages of the Pill

The World Health Organization (WHO) demonstrates that there still are too many unintended pregnancies even in countries where contraceptives are freely and easily available. This means that new and more acceptable contraceptive methods must be made available to women (World Health Organization, 2002). Notwithstanding the disadvantages of most methods of birth control, women continue to use them because, according to the WHO, they have not sufficient knowledge about alternative methods which could protect them against unintended pregnancy.

The International Agency for Cancer Research (IACR) Working Group of the World Health Organization in 2005 concluded that combined estrogen-progestogen oral contraceptives (OCs) are cancerigenic to humans. There is a small increase in the risk of breast cancer in current and recent users of oral contraceptives. However, ten years after cessation of use, the risk appears to be similar to that in never-users. The risk of cervical cancer increases with duration of use of combined oral contraceptives. The risk of hepatocellular carcinoma is increased in long-term users of combined oral contraceptives. At the same time, the Working Group stressed that there is also convincing evidence that oral contraceptives have a protective effect against some types of cancer. The risks of endometrial and ovarian cancer are consistently decreased in women who used combined oral contraceptives. However, these cancers are approximately 10 times less common than breast cancer. The Working Group concluded that both beneficial and adverse effects other than cancer have been established for combined hormonal contraception but that a rigorous risk/benefit analysis would be of use to put the different effects in perspective, and assess the overall consequences for public health (Cogliano *et al.*, 2005a; Cogliano *et al.*, 2005b).

Table 2. — Contraindications for oral contraceptive use.

Contraindications for Pill use	
The metabolic syndrome: Diabetes High blood pressure Lipid metabolism disturbances Obesitas Disturbances of the blood clotting mechanism	History of deep venous thrombosis Migraine, particularly when focal with visual loss Cancer (hormonal dependent) Severe obesitas Women > 35 and smoking Liver and gallbladder disease

Several other side effects are also common in OC users such as migraine, weight gain, loss of libido but, and more importantly, increased future risk of cardiovascular and metabolic disease, in contrast with hormonal intrauterine systems (see absolute contraindications for Pill use in Table 2) (American Society for Reproductive Medicine 2004). In addition, many breastfeeding women do not want to use oral contraceptive because of concerns for possible hormonal side effects due to the presence of hormones in their milk.

The challenge of LARC

LARC stands for **Long Acting Reversible methods of Contraception** (National Institute of Clinical Excellence, 2005)**.** From the foregoing, is clear that methods, which are dependent on memory and motivation, such as the Pill, are not the ideal solution, especially in the younger age groups. For years, 'the Pill' has been synonymous with contraception. This has regrettably helped to maintain ignorance of any alternatives beyond condoms and sterilization, although acceptable alternatives have demonstrated their superior effectiveness. There are several long-acting methods that are safe and minimize the risk of unintended pregnancy. These are: copper intrauterine devices, progestogen intrauterine systems, progestogen-only injectable contraceptives, progestogen-only subdermal implants.

With injectables, implants and IUDs, the inherent efficacy is so high, and proper and consistent use is almost guaranteed, that studies invariably demonstrate extremely low pregnancy rates. It appears that the most effective method for an individual woman or couple is a method which minimizes the risk of imperfect use.

Long-acting injectables, implants, IUDs and hormone-releasing intrauterine systems are methods which point the way forward. They have a proven record of very high efficacy, many years of effectiveness, convenience, cost effectiveness, suitability for a wide variety of women and, in general, high user satisfaction. They offer also discretion and privacy. Unfortunately, some of them (e.g., injection, implants) also have disadvantages because they disrupt the menstrual cycle causing breakthrough bleeding, or occasionally heavier bleeding. They can also cause systemic hormonal side effects and some of them (e.g., injectables) cause bone loss.

The advantage of intrauterine methods

Intrauterine devices and intrauterine systems are particularly attractive as they have the advantage of acting locally, avoiding potentially dangerous systemic effects. They have less impact on menstrual pattern after the first few months. New developments in intrauterine technology are providing smaller frameless devices. They may be ideal for use in younger women with a small uterus because they are small, effective and well tolerated. They are much more effective than Pills in this age group (See table 1). Moreover they are long-acting and reversible. So, the reward is substantial. In the current situation, they should be offered more frequently as first line methods, in combination with condoms if required, particularly after the first unintended pregnancy has occurred.

The World Health Organisation and the American College of Obstetricians and Gynecologists (ACOG) support the use of appropriate intrauterine methods in young women and suggests that the benefits of intrauterine contraceptives generally outweigh the risks in women of any age, whether or not they have had children (WHO, 2007; ACOG, 2007). In addition, WHO and ACOG approve the use of these methods in women under 20 years of age, provided that they are at low risk of sexually transmitted infections. 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 (Hubacher *et al.*, 2001). Fecundity also rapidly returns to normal after IUD removal (Penny *et al.*, 2004; Hov *et al.*, 2007).

Uterine cavities differ considerably in size and shape

Uterine cavities differ considerably in size and shape, and the uterus is subject to changes in size

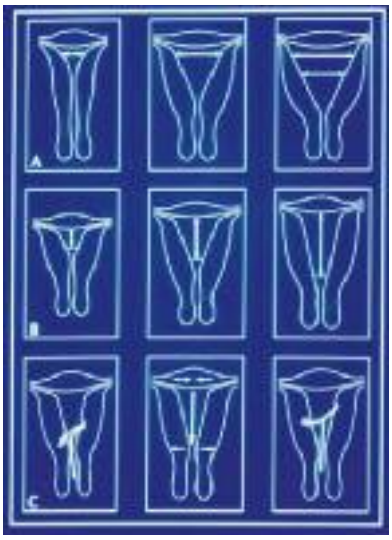

Fig. 1. — Different sizes and shapes of uterine cavities. (A. Differences in width; B. Differences in length; C. Functional changes and examples of incompatibility).

and volume during the menstrual cycle (Hasson, 1984; Kurz, 1984). These changes are most pronounced at the time of menses. Therefore, it would be unreasonable to expect one standard-sized IUD/IUS to fit uterine cavities that differ in size and volume from woman to woman and from time to time in the same woman (Fig. 1). Clinical experience has shown that incompatibility between the IUD/IUS and the uterine cavity can lead to partial or total expulsion, pain, unintended pregnancy, and abnormal or heavy uterine bleeding leading to removal of the device (Kamal *et al.*,1971; Roy *et al.*, 1974; Petersen *et al.*, 1990).

The Lippes Loop, developed in the 1960s, had a high discontinuation rate due to side effects (e.g., abnormal bleeding and pain) related to its large surface area and size. Thus, it seemed logical that the smaller TCu200, and later the TCu380A or Paragard® (Duramed Pharmaceuticals Inc., USA), would have better acceptability and continuation rates, thanks to their use of copper as a potent antifertility agent and T-shaped design causing less distortion of the endometrial cavity.

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 width of most uterine cavities is often smaller than the width of the IUD itself (Figs. 2 and 3). When the uterine cavity is much longer than the IUD, the device becomes partly or completely lodged in the lower uterine isthmic segment, triggering uterine activity that may promote expulsion and give rise to cramping pain. Expulsion rates up to

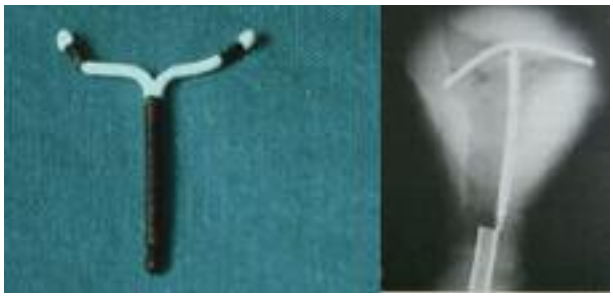

Fig. 2. — Examples of severe incompatibility caused by too long crossarms of the IUD (left: courtesy of Dr. A. de Castro; right: courtesy of Dr. K-H Kurz).

20% have been reported in adolescent nulliparae using traditional IUDs (Weiner *et al.*, 1978). Recently, a study with the Mirena® conducted in adolescent women in New Zealand found an expulsion rate of 8% after one year of use (Paterson *et al.*, 2009). The most important factor in reducing IUD side effects, including expulsion, is the elimination of distortion of the uterine cavity (Howard Tatum, inventor of the T-shaped IUD) (Tatum, 1996).

Appropriate intrauterine contraception for adolescents and nulliparous women

The gynaecological 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 (Hollingworth, 1995). The presence of the girl's mother may be considered to provide confidence.

The uterine volume increases with the presence of menarche, age and parity ($p < 0.05$) (Fig. 4). Nulliparous and primiparous adolescents younger than 18 years old have a smaller uterine volume than nulliparous and primiparous women 20 to 40 years old ($p < 0.001$) (Da Costa *et al.*, 2004; Holm *et al.*, 1995).

Frameless intrauterine systems

The frameless GyneFix® copper IUD and the frameless FibroPlant® LNG-IUS

Although incompatibility problems and the effect of T-shaped IUDs on menstrual bleeding are significantly reduced compared to the older plastic IUDs (e.g., Lippes Loop), these devices still leave room for improvement, due to the prevalence of abnormal and heavy menstrual bleeding, pain, and expulsion. It is for these reasons that the frameless copper-releasing GyneFix® IUDs and the frameless Fibro-

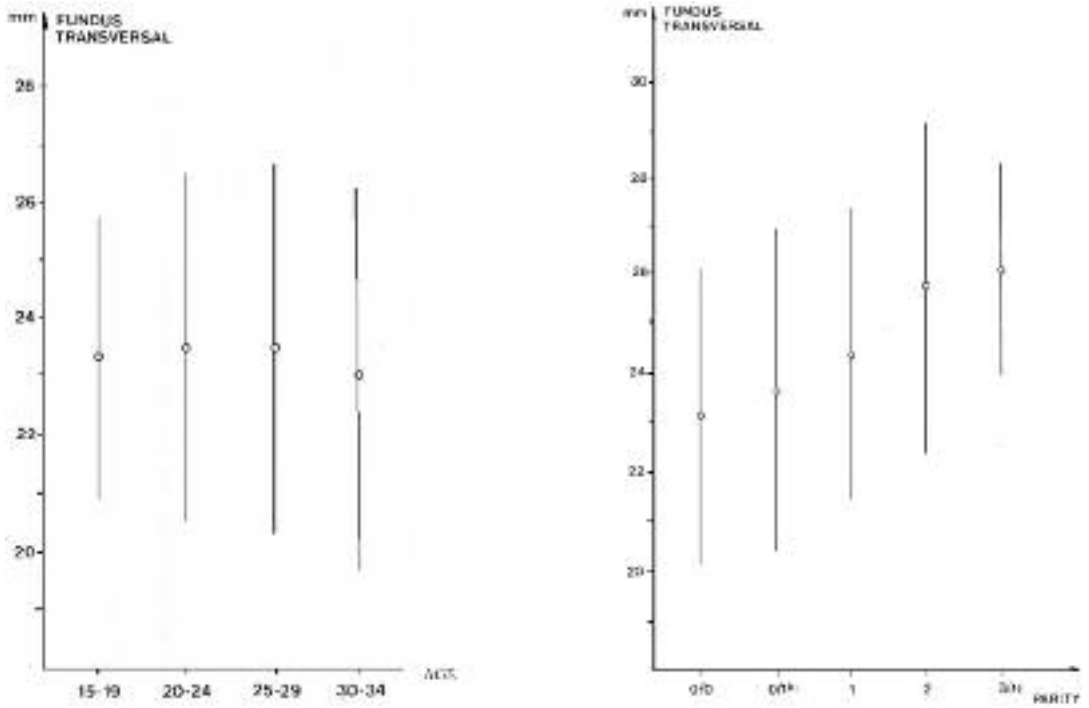

Fig. 3. — The average width of the uterine cavity at the fundal level in women between 15 and 34 years of age is much smaller than the length of the crossarms of most currently used T-shaped IUDs (Kurz, 1984). The length of the crossarm of the TCu380A IUD is 32 mm. The figure shows the mean values and standard deviations of the fundal transverse diameter relating to age (left) and parity (right).

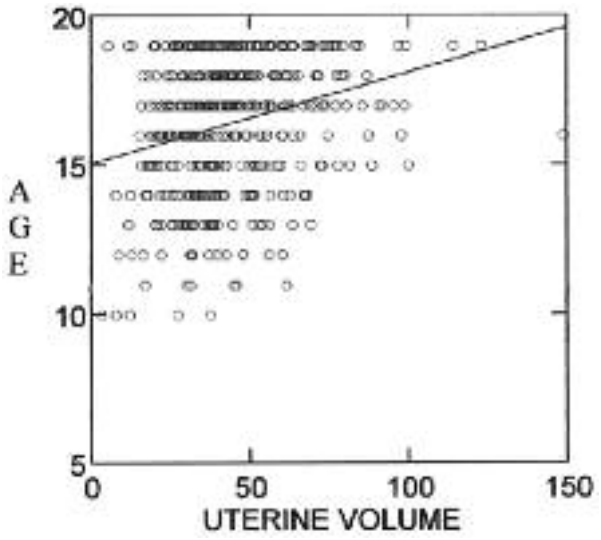

Fig. 4. — Relationship between age and uterine volume (UV, cm^3) in 477 patients 10 to 19 years old (courtesy of Dr. A.G. Da Costa).

Figs. 5 and 6. — The figures above show the small frameless GyneFix® 200 IUD (left) and the frameless FibroPlant® LNG-IUS (right), inserted in a foam uterus.

Plant® levonorgestel-releasing intrauterine system (LNG-IUS) were developed (Figs. 5 and 6).

Figure 7 illustrates the position of the frameless and flexible IUD in the uterine cavity as well as the absence of any 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 superior effectiveness has been demonstrated in a randomized comparative study conducted by the WHO (Meirik *et al.*, 2009). Failures range from 0.0/100 users to 2.5/100 users (cumulative rates) during the first year up to 9 years of use in published randomized and non-randomized comparative clinical trials (Wildemeersch and Rowe, 2003). The smaller GyneFix® version has a similar high efficacy but clinical trials demonstrated, for the first time, the absence of a significant effect of the tiny IUD on menstrual blood loss (Table 3). This could be important since abnormal bleeding and pain are the two major reasons for IUD discontinuation (Wildemeersch and Rowe, 2004).

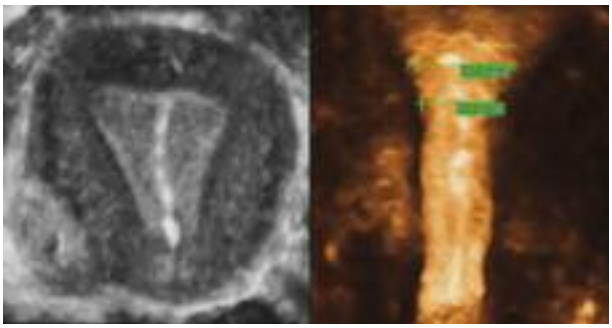

Fig. 7. — 3-D ultrasound of GyneFix®, illustrating the compatibility of the frameless IUD with the uterine cavity of a parous woman (left) (courtesy of Dr. P. Villars) and in a young nulliparous woman (right) (courtesy of Dr. S. Jandi).

Table 3. — 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 of the visual menstrual bleeding scores (MS) before and use of the GyneFix® 200 IUD.

	Age	MS at insertion	MS at last follow-up
n = 60			
Mean	30.4	116.7	115.2
SD	8.5	52.9	51.1
Median	30.5	110.5	110.0
Range	17 – 46	28 – 265	28 – 260

Wilcoxon matched-pairs signed-ranks test: P = 0.596 (NS).

Removal rates for abnormal bleeding and pain complaints with the small GyneFix® version have been low (< 1/100 women per year at 3 years) compared to a study conducted with the LNG-IUS Mirena® in young nulliparous women, where a removal rate for pain at one year of 31% was observed (Suhonen *et al.*, 2004).

The high efficacy of the small GyneFix® is attributed to the fact that the inner and outer copper surface areas of the hollow IUD are exposed to the uterine environment and that the total copper surface area releases copper ions. This is a fundamental difference compared to conventional IUDs. Only in the case of sleeves (GyneFix® consists of a number of copper tubes attached to an anchoring thread) is the nominal and the effective surface area the same. When copper wire is used, that part of the wire lying against the plastic body is ineffective and should not be calculated as a part of the effective surface area (Kosonen, 1980). Other researchers confirm these findings: "The portions of the wire winding in contact with the plastic surface give off hardly any copper" (Wagner, 1999). Chantler writes: "It has been shown that there is negligible corrosion of the copper in contact with the plastic core and that this area should be discounted in the calculation of the active surface area of the copper" (Chantler, 1984). The effective copper surface area of the TCu200 IUD is only 120 mm^2 and of the TCu380A IUD, 252 mm^2. This research also showed that copper release is lower the more the winding of the copper wire is tighter. This is the case with high-load copper IUDs such as MLCu375 en TCu380A. One could conclude that 40% of the copper wire is 'ineffective'. This explains the high efficacy of the small GyneFix® 200 IUD which is less than 1.0 at three years of use (Cao *et al.*, 2004), and the absence of increase in annual pregnancy rate with GyneFix® as the surface area of the frameless GyneFix® decreases very little over time. With conventional IUDs, the copper wire erodes causing a decrease in copper surface area.

Special uses of the frameless copper IUD

- **Emergency contraception.** In 1976, copper IUDs were shown to be highly effective for emergency contraception (Lippes *et al.*, 1976). They have three main advantages over oral hormonal emergency contraception: 1) Efficacy is higher for a copper IUD, with pregnancy rates not exceeding 0.1% (Trussell and Ellertston, 1995), compared with progestogen-only emergency contraception which reduces the risk of pregnancy only by up to 95% (WHO, 1998). 2) A copper IUD can be inserted at least 5 days after unprotected intercourse, or up to 5 days after the earliest estimated day of ovulation (Webb, 1997). In this situation, the copper IUD may act by preventing implantation; when used long-term, it usually prevents fertilization (Mishell, 1998). 3) Once inserted, an IUD can provide ongoing contraception for 5 years or more.
  A randomized study compared the frameless GyneFix® 330 with the TCu380S for use in emergency contraception. The results of this study suggest that, although the actual fitting of the frameless GyneFix® IUD may be a little more painful (without pain relief measures), it causes less pain during the 30 days thereafter. As a result, requests for removal due to pain are significantly less likely with the GyneFix® 330 at 6 weeks. No pregnancies were reported in this study (D'Souza *et al.*, 2003). Although the GyneFix® 330 was used in this study, not the small GyneFix® 200, the latter device should be preferred for use in an emergency because of its more acceptable bleeding profile. A recent study suggested that women appear to have interest in "same-day" IUD insertion following unprotected intercourse, particularly the higher educated

young women and those who had a prior unwanted pregnancy (Schwarz *et al.*, 2009).

- **Immediate post-abortal contraception.** Women who have an IUD inserted immediately after having an abortion have fewer pregnancies and repeat abortions than women who schedule insertion of an IUD for a follow-up visit (Reeves *et al.*, 2007). The IUD/IUS is also probably the most appropriate birth control method to reduce the number of repeat abortions (Goodman *et al.*, 2008a; Goodman *et al.*, 2008b). Thus, the frameless IUD could constitute a useful new option in the prevention of repeat abortions. In limited clinical trials, no expulsion of the IUD occurred following immediate insertion after pregnancy termination at up to 13 weeks gestation (Batár *et al.*, 1998; Gbolade, 1999). This finding contrasts with expulsion rates following first-trimester abortion from 5/100 to 14/100 users at 2 years with framed IUDs (Lippes Loop, TCu220C, and the Copper 7), as reported by WHO (WHO, 1983).

The frameless Fibroplant® LNG-IUS

The FibroPlant® LNG-releasing intrauterine system (LNG-IUS) is derived from the GyneFix® IUD. It is an anchored levonorgestrel-releasing device; a multicomponent system consisting of a nonresorbable thread with a single knot on its proximal end. The 3.5 cm long and 1.6 mm wide fibrous delivery system is attached to the anchoring thread by means of stainless steel clip located 1 cm from the anchoring knot. The fiber consists of a LNG-ethylene vinyl acetate (EVA) core and an EVA rate-controlling membrane. FibroPlant® has a lifespan of 5 years. The anchoring knot is implanted into the myometrium of the uterine fundus using the same GyneFix® insertion instrument, which secures the implant in the uterine cavity. FibroPlant® is highly visible on ultrasound (Fig. 8); the metal clip enhances the visibility of the system on X-ray. Since FibroPlant® has no frame, it is completely flexible, adapting to cavities of every size and shape. It is, therefore, highly suitable for insertion in small uterine cavities.

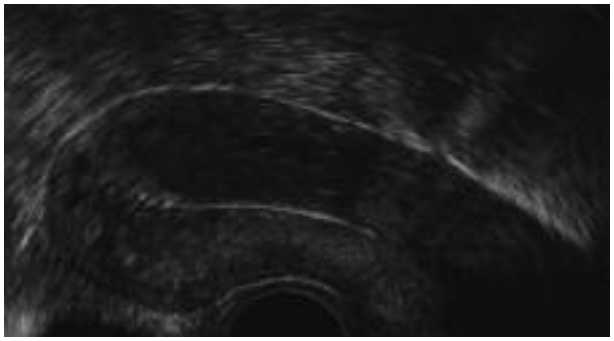

Fig. 8. — Vaginal ultrasound of FibroPlant® LNG-IUS (courtesy of Dr. D. Janssens).

FibroPlant® has the advantage over GyneFix® because it acts as a contraceptive (Wildemeersch and Andrade, 2009) and simultaneously can be used for the treatment of frequently occurring gynaecological conditions. The frameless LNG-IUS could be highly desirable for contraception in young women with heavy menstrual bleeding and dysmenorrhoea. Treatment of idiopathic menorrhagia with FibroPlant® LNG-IUS has been shown to be highly effective resulting in strongly reduced menstrual blood loss and significant increased ferritin levels (Wildemeersch and Rowe, 2004; Andrade and Wildemeersch, 2009). Many young women suffer from dysmenorrhoea; clinical studies suggest that FibroPlant® LNG-IUS appears to be an effective method for the treatment of primary and secondary dysmenorrhea (Wildemeersch *et al.*, 2001). The absence of a frame is particularly advantageous in these women.

Insertion related aspects

Failed insertion and expulsion is rare with the anchored IUD/IUS if properly inserted by following the insertion instructions strictly. Expulsion, mainly due to non-anchoring, has been observed in less than 1% in a 3-year trial conducted with the frameless GyneFix® 200 IUD. In this study the investigators were highly experienced.

The perforation rate with the frameless copper-releasing IUD and the frameless levonorgestrel-releasing IUS has been evaluated in randomized comparative and large non-randomized comparative multicenter clinical trials, including large post-marketing trials (Vrijens *et al.*, 2009). 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. 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. On a total of over 300 insertions with the frameless LNG-IUS, there were two perforations. One occurred early in the study and was attributed to inexperience with the new insertion technique. The second occurred due to forceful pressure with the applicator on the fundus of the uterus.

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. Potential providers

are recommended to attend a training course organized by the manufacturer or to train themselves using a pelvic model. Experience has shown that insertion failures and expulsions, in parous as well as nulliparous women, can be minimized to very low rates (around 1% over a 3-year period) (Cao *et al.*, 2004). Proper training is essential to properly insert the GyneFix® and will result in optimal performance and high continuation of use.

Barriers to use of IUDs

Unfortunately, outdated perceptions about appropriate patient candidate for **LARC** among health care providers continue to negatively impact their use (Table 4). Although intrauterine devices are the most widely used modern reversible contraceptives worldwide, with about 150 million users, they are underused because they are misunderstood (D'Arcangues,

Table 4. — Misconceptions which still exist related to intrauterine contraception*:

Misconception	Answer
Mechanism of action	The primary contraceptive effect of intrauterine contraception is the prevention of fertilization and implantation by interfering with sperm motility and survival. The reaction of the intrauterine foreign body with the endometrium activates the release of leukocytes and prostaglandins which act not only in the uterus but also in the oviduct and cervix to impede sperm and egg development.
Pelvic inflammatory disease	The issue of increased risk or greater severity of infection among IUD users has been a prominent concern. However, the rate of pelvic inflammatory disease (PID) is low, with cases concentrated in the first 20 days after insertion. The reason for the increased risk during the first weeks after insertion is that bacteria in the vagina and cervix can be transported through the cervical canal into the uterine cavity. It is important to tell the IUD user that for the majority of the users, fertility is restored immediately after removal of the device; irrespective if the IUD was used for a few months or for many years. There are certain basic principles which should be respected with regard to the use of IUD in general. An IUD should not be inserted in a woman with certain lower genital tract infections, i.e., acute mucopurulent cervicitis, gonorrhoea and Chlamydia. All potential users should be screened for at least signs and symptoms of these infections and women should be given additional laboratory tests if necessary. Practising aseptic techniques and conducting a follow-up examination at 1-2 months are additional safeguards to prevent infectious complications in IUD users. Patients should also be warned to use a condom if they change to or have another partner.
Use in nulliparous women	Another misconception is that women over 25 years or older are the best candidates for IUD use, and that women over 35 are the ideal candidates. This belief, based on the fear of pelvic infection (PID) and the potential for resulting infertility, is no longer justified. There is no biological reason to conclude that a young woman is at higher risk than an older woman if they have the same sexual behaviour.
Concerns about effectiveness	IUDs protect against intrauterine and ectopic pregnancy, in contrast with the general belief. Users of modern IUDs have a 10 times lower risk of ectopic pregnancy when compared with women who do not use any contraception. The commonly held opinion is that oral contraceptives are more effective than IUDs. Similarly, physicians and the general public are often poorly informed about the effectiveness of IUDs and the effectiveness of contraceptives in general.
IUD expulsion	Total expulsion of an IUD occurs in 5-10% of women during the first year of use, with an increased risk in nulliparous women. The majority of expulsions occur during the first months after insertion, with 1-2% per year thereafter. The frameless, anchored IUDs reduce the risk of expulsion approximately 5 to 10-fold, on condition that the IUD is properly inserted.
Abnormal and heavy menstrual bleeding	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. The small frameless GyneFix® 200 IUD does not increase menstrual blood loss in contrast with all other copper IUDs. All hormone releasing intrauterine systems, on the other hand strongly reduce menstrual blood loss. Many users of hormonal IUDs have bleed free periods. In many countries this is becoming a trend.
Pain	One of the reasons of the underuse of the IUD is the fear of insertion pain. The insertion of an IUD is not usually a painful procedure. However, many women, nulliparous women in particular, fear insertion and this may be an important reason not to select an IUD. Several measures can be used to reduce patient discomfort during the insertion and removal of the IUD: premedication, local anaesthesia, cervix relaxing agents, and anxious patients should ask for it. If doctors attach importance to pain relief, it is likely that many more women will request IUDs as their method of contraception. Pain during use of IUD is mainly caused by the IUD which is too big for the uterine cavity. The uterus differs in size and shape between women. The frameless IUDs/IUS have a higher level of tolerance than traditional IUDs.

* Adapted from UK Faculty of Family Planning (FFPRHC Guidance 2004).

2007). It may surprise many people that the IUD is safer than other forms of contraception (UNDP/UNFPA/WHO/World Bank, 2008).

As a consequence of the enhanced performance of modern IUDs and IUSs, the improved acceptability and retention of the frameless IUD and IUS, and more in particular the health benefits of the hormone releasing intrauterine systems, the number of users of these exquisite methods should drastically increase in the coming decade. However, due attention should also be given to keeping the medical, scientific, and programmatic communities informed about new developments in this field, in comparison to other methods. An emerging body of research has disproved a number of contraindications to intrauterine contraception. Specifically, women of any age or parity and those who are postpartum or post first-trimester abortion are eligible for intrauterine contraception. The benefits of intrauterine contraception also outweigh the risks of a wide variety of medical conditions that might contraindicate the use of combined hormonal contraceptives.

Summary

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. The development of the frameless IUD and frameless LNG-IUS is a response to the growing need to develop high-performing, longacting, reversible, and well-tolerated contraceptives, with a high continuation of use. Most women, and many clinicians, are unaware that post-coital copper IUD insertion is a highly effective form of emergency contraception that also provides ongoing contraception. Discussions about contraception should address risks and benefits associated with IUDs; moreover, same-day post-coital and immediate post-abortal IUD insertion (or referrals to facilities that provide this service) should be offered as an option whenever possible. The consequences of unintended sex and unintended pregnancy are far too great.

Adolescent pregnancy rates in Europe and Canada are approximately 50% lower than those in the USA (Darroch *et al.*, 2001). As adolescent pregnancy remains a huge public health problem, more research is urgently needed to study new IUD methods as those described in this paper, and compare them with existing birth control methods, in adolescent and young women for interval, post-coital and post-abortal contraception in order to reduce the unplanned pregnancy rates in the world (Deans and Grimes, 2009).

Competing interest: Dirk Wildemeersch, MD, PhD, is a Belgian gynaecologist and Medical Director of *Contrel 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 gynaecological 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®. The funds generated are reinvested in research.

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