

The 'frameless' intrauterine system for long-term, reversible contraception: A review of 15 years of clinical experience

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Abstract

Aim: The development of the 'frameless' intrauterine system (IUS) is a response to the growing need to develop high-performing, long-acting, reversible, and acceptable contraceptives with a high continuation of use.

Methods: This is a review of 15 years of clinical experience in randomized controlled and non-randomized clinical trials.

Results: The IUS has a similar failure rate as the TCU380A Intrauterine device (IUD), considered the 'golden standard' IUD, which is attributed to the optimal target delivery of the copper ions in the upper part of the uterine cavity. Its performance is further optimized by the atraumatic design, which reduces partial and total expulsion and minimizes the side-effects and discomforts experienced with conventional 'framed' IUDs. The mini IUS is likely to further reduce the menstrual blood loss due to the very small size. The safety of the anchoring concept is beyond doubt as was demonstrated in all clinical studies covering 15 000 woman-years experience.

Conclusions: Young nulliparous/nulligravid and parous women may significantly benefit from the advantages the 'frameless' IUS, which could be strategically important to help in reducing the increasing number of unintended pregnancies and induced abortions worldwide. Furthermore, the 'frameless' IUS has been shown to be highly effective for emergency contraception and for immediate postabortal insertion. The long lifespan of the IUS could constitute a cost-effective reversible alternative to irreversible female sterilization.

Keywords: contraception, copper-releasing, frameless, GyneFix, intrauterine device.

Introduction

Cavimetric studies have shown that it is not easy to design a universal intrauterine device (IUD). Indeed, uterine cavities differ considerably in all women, and the uterus is subject to changes in size and volume dur-

ing the menstrual cycle.^{1,2} These changes are most pronounced at the time of menses. It is therefore unreasonable to expect one standard-sized IUD to fit uterine cavities with different sizes and volumes. Clinical experience has shown that incompatibility between the IUD and the uterine cavity can lead to partial or total

Received: 18 August 2002.

Accepted: 10 January 2003.

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Figure 1 Three generations of IUDs, (from left to right) Lippes Loop, 1960; Tcu380A, 1980; GyneFix-mini, 2000.

expulsion of the IUD, pain, unintended pregnancy (due to partial expulsion), and abnormal and heavy uterine bleeding leading to removal of the IUD. The Lippes Loop (Ortho-McNeil Pharmaceutical, Raritan, NJ, USA), developed in the 1960s, had a high discontinuation rate due to side-effects caused by its large surface area and size (Fig. 1). Another major development was the smaller TCu200 and later the TCu380A or Paragard (Ortho-McNeil Pharmaceutical, Raritan, NJ, USA), which benefitted from the discovery of copper as a potent antifertility agent. As a consequence, the size of the plastic frame could be much reduced. It seemed logical that the T-shaped design would cause less distortion of the endometrial cavity. Although incompatibility problems and the effect of the TCu380A IUD on menstrual bleeding are significantly reduced compared to the Lippes Loop, bleeding, pain, and expulsion problems still occur and there is therefore room for improvement.³ For these reasons GyneFix, the 'frameless' intrauterine system (IUS) was developed.

Description of the anchoring concept

The 'frameless' intrauterine contraceptive system is unlike conventional 'framed' IUDs. It consists of a length of non-biodegradable 0-size monofilament sur-



Figure 2 The GyneFix IUS (standard) *in situ*.

gical thread with a varying number of copper tubes mounted on it; six copper tubes for the standard IUS and four in the case of the mini IUS. With each device, the upper and lower tubes are crimped onto the thread to keep them in place. The total surface area of copper with standard IUS is 330 mm² and 200 mm² with mini version.

The upper extremity of the thread ends in a knot (Fig. 1) which is implanted into the myometrium of the uterine fundus using a specially designed insertion instrument, thereby permanently securing the device in the uterine cavity (Fig. 2).

The anchorage site was studied histologically in hysterectomy specimens with an IUS that had been inserted up to 4 years previously.⁴ The maximum histological reaction observed was 0.5 mm around the anchoring knot (Sewell scoring system⁵). This demonstrates the safety and long-term compatibility of the anchoring system.

When the Lippes Loop is compared to the GyneFix-mini version, it can be seen that a sixfold reduction has been made in the overall size of the intrauterine IUS, resulting in considerably fewer incompatibility problems in women fitted with this new generation IUS. These advantageous design characteristics result in

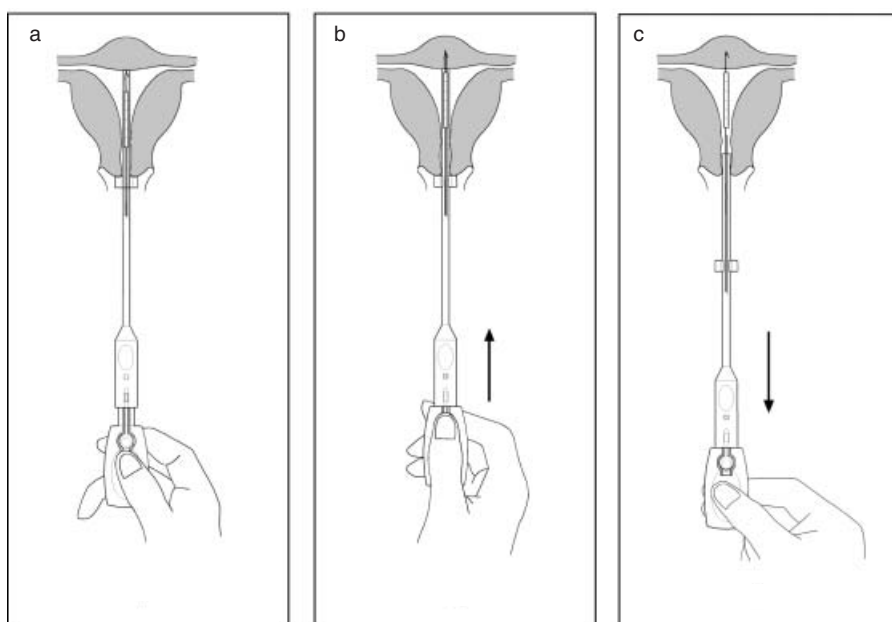


Figure 3 Insertion procedure of GyneFix Mark II. (a) Step 1: insertion of the instrument up to the uterine fundus; (b) Step 2: anchoring of the device by pushing the inserter forward slowly and gently; (c) Step 3: removal of the inserter.

enhanced performance and acceptability of this new concept (see below).

Insertion

The Mark II inserter is a GyneFix applicator which has been developed to simplify insertion of the IUS. It has been found over the years that the occurrence of IUD expulsion is, in part, related to the degree of skill and manual dexterity of the person inserting the device. It is therefore essential that the insertion technique should be simplified wherever possible. Insertion should also be easy to demonstrate. If the insertion procedure can be 'de-skilled' the learning curve will be shorter and progress to proficiency sped up.

One of the greatest challenges in the development of the frameless implant system was to keep the number of insertion steps as low as possible as this would tend to minimize insertion failure, particularly at the beginning of the learning process. With the Mark II inserter the number of steps has been reduced from seven or eight to three, making insertion both simpler and easier (Fig. 3). Clinical experience with the Mark II inserter suggests that the insertion technique is simple and effective. A field test conducted in the UK revealed that only one failed insertion occurred in 285 insertions, and that this was due to a technical error. The Mark II inserter is well accepted by 99.6% of doctors.

Efficacy

Data on efficacy from large-scale, long-term international multicentre randomized and non-randomized comparative studies in parous and nulliparous women covering 15 000 woman-years of experience are available.⁵ Clinical studies with this new concept have been conducted since 1985.

GyneFix is a highly effective intrauterine contraceptive system. Failures range from 0.0/100 users to 2.5/100 users (cumulative rates) during the first year up to 9 years of use (data from published and unpublished randomized and non-randomized comparative clinical trials.⁶⁻⁹ The long-term efficacy has been confirmed in a WHO conducted randomized comparative clinical trial [Rowe, personal communication]. These figures are lower, but not significantly lower, than those of the TCu380A IUD in a major randomized clinical trial (0.4/100–3.2/100 users), which is still considered the most effective copper IUD, and similar to those seen with the levonorgestrel-releasing IUS.¹⁰

Furthermore, annual pregnancy rates do not increase over time. This excellent level of efficacy has been consistent during the whole clinical development period and continues, as before, following European market introduction.

This high effectiveness of the GyneFix IUS is attributed to the fact that framed devices become displaced

or partially or totally expelled in 5–10% of users, resulting in accidental pregnancies.^{7,11,12}

The higher pregnancy rate in the first year with the frameless IUS in the WHO study can be explained by deficiencies in the insertion procedure and the shortcomings of the prototype inserter (Flexigard) resulting in unnoticed expulsion and accidental pregnancy.⁶

The high initial and ongoing effectiveness of the 'anchored device' is attributed to its constant release of spermicidal copper ions in the upper part of the uterine cavity. This may explain why clinical trials with the mini IUS suggest a similar efficacy as the standard IUS.¹³

Useful lifespan

Long duration of action is important for IUD users as well as providers as it may reduce certain health risks, such as pelvic infection, related to frequent replacement of the device. Also, less frequent insertion would reduce cost, inconvenience, and pain. Calculations of the useful lifespan of the frameless IUS, based on weight and surface measurement of IUSs, which were *in utero* between 10–12 years, show that the copper-releasing IUS may be considered a long-lasting device providing effective contraception for 10 years or more. The copper surface area does not decrease substantially over time, which could compromise contraceptive efficacy, and fragmentation of the copper tubes, resulting in total copper loss, does not occur, which is more likely with conventional copper IUDs that have copper wire on the vertical stem.

The performance characteristics of the frameless IUS and its long effective lifespan accounts for the high cost-efficiency of this IUS and is significantly more cost-efficient than IUDs with a shorter lifespan. When compared to other birth control methods such as female sterilization, the IUS is likely to be much more cost-effective with similar low failure rates. Studies showed 10-year pregnancy rates of 2–4/100 users with various tubal sterilization methods.¹⁴ Besides, many women do not want to have an irreversible method and in some countries sterilization is not available.

Potential advantages of the frameless copper-releasing IUS over conventional framed copper IUDs (e.g. TCu380A, MLCu375)

Studies have shown that parous as well as nulliparous women have been highly satisfied with the use of GyneFix.^{6–9,11,15–22}

When properly inserted, the frameless IUS offers several important advantages:

- High efficacy,^{6–9,11,13,17–21}
- Efficacy does not decrease with time,^{6,7,9,11}
- Low expulsion rate,^{6–9,11,17–21}
- Reduced bleeding,¹³
- Reduced pain complaints,^{7,8,11,13,17,22}
- Long duration of action.⁹

The design characteristics of the frameless IUS makes it 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 conventional framed IUDs.

Side-effects

Infection

The risk of pelvic infection, which may lead to infertility, ectopic pregnancy, and chronic pelvic pain is one of the major concerns for IUD providers as well as for women. It is known that this is a misinterpretation of the data and has unfortunately resulted in many unintended pregnancies, by limiting women's access to a long-term contraceptive method. There is good scientific evidence that the risk of pelvic inflammatory disease (PID) is not increased after the first month following insertion of the IUD. Investigations by WHO showed that the risk of PID is limited to the first 20 days after insertion.²³ A recent re-assessment of pelvic inflammatory disease, possibly attributable to an intrauterine device, confirmed that the risk is similar to women who do not have an IUD inserted.²⁴ The rate of PID in IUD users is low even in regions where the prevalence of sexually transmitted infections (STIs) is high.²⁵ Clinical evidence has shown that previous use of a copper IUD is not associated with an increased risk of tubal occlusion among nulligravid women.²⁶

The PID rate has been very low in all major clinical studies conducted with the frameless IUS, including a significant number of insertions in nulliparous women.^{6–9,11,17–21} In the past, the IUD was not recommended for nulliparous women and for those with a small uterine cavity. However, due to innovation in IUD design, enabling a considerable reduction in the size of the device, WHO suggests that the benefits of IUDs generally outweigh the risks in women of any age, whether parous or not and, in addition, IUDs can be inserted in women younger than 20, provided that these women are at low risk of sexually transmitted infections. However, WHO advises against the use of

IUDs in women who have had PID in the previous three months.²⁷

Bleeding

Increased menstrual blood loss is the main reason for discontinuing the use of IUDs. The magnitude of this increase in menstrual blood loss is related to the size of the device. With larger types of non-medicated IUD, such as the Lippes Loop, the blood loss is about 70–80 mL, which is approximately twice that of normal menses. The amount of excess bleeding is less (50–60 mL) with the smaller copper devices such as the copper T series. Clinical trials suggest that both the mini and standard GyneFix reduce the incidence of heavy blood loss due to the small size of the foreign body, however, comparative studies, which could actually quantify the blood loss have not been published.^{11,13}

The frameless IUS, although providing progress in terms of contraceptive performance and patient acceptability, does not itself reduce menstrual bleeding. This can be achieved by delivering intrauterine progestins.^{28,29}

In order to reduce menstrual blood loss, especially in women with heavier menstrual periods prior to IUD use, a GyneFix-levonorgestrel (LNG)-releasing system was developed, based on the anchoring technology, but without copper. Clinical trials with this IUS suggest a substantial reduction of the amount of menstrual bleeding due to the effect of LNG on the endometrium.³⁰ The estimated reduction in menstrual bleeding is at least 80–90% in women with normal menstruation as well as with women with idiopathic menorrhagia.³¹

Pain

Clinical trials suggest that both the mini and the standard IUS rarely cause complaints of pain due to the small size and flexibility of the frameless IUS.^{6–8,11,16,22} With conventional framed IUDs, incompatibility between the device and the endometrial cavity causes myometrial distension of the uterus. Depending on the degree of the disharmony, severe cramping pain can be caused resulting in abnormal bleeding and partial or complete expulsion of the IUD. The mini IUS is convenient for young women with a small uterine cavity for whom framed IUDs are generally less suitable.¹⁶

Perforation

The perforation rate of conventional IUDs usually quoted is 1–3/1000 insertions.¹² However, the inci-

dence of this complication ranges from 0.0 to 8.7 per thousand insertions,³⁴ and is directly related to the skill of the individual performing the insertion. One major reason for perforation is the failure to establish the size and orientation of the uterus by careful pelvic examination. This is particularly important where there is sharp ante- or retroflexion of the uterus, and where it is not straightened with traction using a tenaculum prior to insertion.

Neither perforation, diagnosed either at insertion or later, nor translocation of the IUS has been recorded in large international multicentre clinical trials published to date.^{6–8,11} A small number of insertion-related perforations have, however, been reported after market introduction of the frameless IUS, which may be attributed to inexperience with the technique of insertion. This is in agreement with clinical experience, which shows that the majority of cases of perforation is detected during the learning process, and occur exclusively in connection with insertion. The highest rate that has been observed is 1.4/1000, but this rate fell to approximately 1/1000 with increasing experience.³² At least one perforation has occurred, which was attributed to migration of the IUS.³³ However, migration seems only possible if a partial perforation occurred at the time of insertion. As the IUS is frameless and flexible, it is unlikely that the device is forced through the uterine wall by uterine contractions, as has been suggested as a possible mechanism of perforation with framed IUDs.³²

Studies have shown that cervical traction in a caudal direction reduces the median uterocervical angle, from 75° to 10° and moderate cervical traction straightens the uterus, and the routine use of a tenaculum theoretically should make insertion of an IUD safer.³⁵ A prerequisite, however, is that traction should be applied until the insertion of the IUD has been completed. In addition, clinical experience shows that access to the uterus, and straightening of the utero-cervical axis, is facilitated by using the lithotomy position, which should be recommended for all IUD/IUS insertions.

It is debatable if removal of a copper IUD from the abdominal cavity, if the woman is asymptomatic, is an absolute necessity.³⁶

Expulsion

When inserted correctly, spontaneous expulsion of the IUS occurs in less than 1/100 women observed over a 5-year period of use. The initial studies with the implant technology, followed by ultrasonographic and histological evaluation of the anchor site and assess-

ment of the traction force required for retrieval of the IUS validated the concept of the anchoring principle.^{4,37,38} These studies also showed that the anchor knot does not migrate over long period of time. With conventional IUDs, young and nulligravid/nulliparous women are particularly prone to complete and partial expulsion of the IUD. Long-term multicentre clinical trials using the current GyneFix insertion instruments have showed low expulsion rates (which include failed insertion – see below) in both parous and nulliparous women ranging from 0.5 to 3.0/100 users during the first three years of use, compared to expulsion rates of between 2.7 and 7.4/100 users with the TCu380A IUD.^{6,9,11,17} High partial and total expulsion rates (up to 17/100 users during the first year of use) have been reported, particularly in nulliparous women using conventional IUDs.^{39–41} Partial expulsion significantly reduces the contraceptive efficacy of the IUD.^{42,43}

Most expulsions occur within a few months following insertion. The higher expulsion rates observed at the beginning of the learning curve with the anchored IUS are attributed to a lack of familiarity with the new anchoring technique. The term ‘insertion failure’ has a broader meaning when applied to the GyneFix as it includes failure to implant the knot in the fundal myometrium. Failure to implant the knot means that the device stays in the uterine cavity but not attached to the uterine wall as intended. This results in the expulsion of the frameless IUS within days or weeks of the attempted insertion.

Ectopic pregnancies

More than 1% of pregnancies in North America and Northern Europe are ectopic.⁴⁴ The GyneFix IUS, like copper IUDs with a large copper surface area (TCu380A, MLCu375), offers significant protection against ectopic pregnancy. This may mean that sufficient copper ions need to be delivered in the upper part of the uterus and oviducts to obtain optimal protection and does not necessarily imply that devices with less than 300 mm² of copper offer less significant protection. This could be particularly the case with the frameless IUS, which guarantees release of copper in the fundal area of the uterus, if the IUS is properly attached to the uterine wall. Clinical studies with the mini IUS do not suggest a reduced protection against ectopic pregnancy caused by the significantly reduced copper surface area.¹³ It is important to note that an estimated 30–40% of the copper surface of IUDs is inef-

fective as no copper release occurs from the copper wire in contact with the plastic frame.^{45,46} This contrasts with the frameless IUS of which 100% of the copper surface area is exposed to the uterine fluid.

A history of previous ectopic pregnancy should not be considered as an absolute contraindication to the use of the GyneFix IUS as other risk factors or markers, such as the possible exposure of the woman to lower genital tract infections.

Return of fertility

Previous studies with copper-loaded IUDs have demonstrated a rapid return of fertility after removal of the IUD, and return of fertility appears to be more rapid than following discontinuation of combined oral contraceptives and following the use of injectables. Vessey and colleagues reported that the percentage of women who delivered within 18 months of discontinuing contraception was 87.5% for past users of IUDs, 78.9% for those who had used oral contraceptives, and 87.2% for past diaphragm users.⁴⁷ The lower return to fertility rate with oral contraceptives may be due to the effect of the hormones on ovarian function.

A multicentre study conducted in women who requested removal of the GyneFix for pregnancy shows that the conception rate matches the pregnancy rate achieved by a population who had discontinued the use of barrier methods of contraception.⁴⁸

Emergency contraception

Copper IUDs can be inserted up to 5 days after unprotected intercourse to prevent pregnancy and provide ongoing contraception. They work by preventing fertilization and implantation of the zygote and are therefore not abortifacient agents.⁴⁹ The majority of women requesting emergency contraception are young and nulliparous.⁵⁰ As the frameless IUS is very small, it is suitable for these women for continuous use, if they are at low risk of STIs. Copper IUDs for emergency contraception are more effective in preventing unwanted pregnancy (pregnancy rate <0.1%) than postcoital pills, such as levonorgestrel emergency contraceptive pills, since efficacy decreases more rapidly with time.⁵¹ When efficacy is a priority, the IUD is the emergency contraceptive of choice.⁵²

Experience, especially in the UK, has shown the significant potential of the frameless IUS for emergency contraception.⁵³

Immediate postabortal insertion

The frameless IUS could constitute a useful new option in the prevention of repeat abortion. In limited clinical trials, no expulsion of the IUS occurred following immediate insertion after termination of pregnancy up to 13 weeks gestation.^{9,18-21} However, there were four 'early' expulsions, clustered in one center, in a multi-center clinical trial conducted with 212 postabortal women in China during the first 6 months follow-up [unpublished data]. This contrasts with expulsion rates following first-trimester abortions ranging at two years from 5 to 14/100 users with framed IUDs (Lippes Loop, TCu220C, and the Copper 7), reported by WHO.⁵⁴ Since many terminations are carried out in young nulliparous women, the use of conventional IUDs in postabortal insertion will, in theory, result in higher rates of pregnancy, expulsion, and removals for medical reasons.

Immediate postplacental insertion

Since 1984, a technique for the insertion and fixation of an anchoring system to suspend an IUD/IUS in the uterine cavity immediately postdelivery was tested in Belgium, Hungary, and China. Several different types of anchor were tested in pilot and multicenter trials. These studies revealed that the immediate postplacental insertion and fixation technique (IPPIF) is safe and is not associated with increased risk of perforation or infection. It was concluded that a frameless, anchored IUS and insertion instrument could be developed into a practical postplacental contraceptive suitable for general use.⁵⁵⁻⁵⁷

An alternative for tubal sterilization

Long-term, large-scale studies conducted with the frameless IUS show that the system maintains its high efficacy for more than 10 years without decreasing efficacy [unpublished and published data].⁹ This long duration of action of the IUS found in clinical trials was confirmed by *in vitro* studies [GyneFix, unpublished data].

The IUS offers several important advantages when compared to female sterilization. Unlike female sterilization, the IUS is inserted like any IUD in a clean examination room by trained doctors and other health care professionals using routine equipment and facilities. Apart from offering a similar efficacy as female sterilization, and long-term contraception, the advan-

tages of IUDs and GyneFix, compared to tubal sterilization include the avoidance of surgical complications, such as anesthetic accidents, hematoma, and wound infection.^{14,58}

Intrauterine devices also avoid the main drawback of sterilization, which is that it is difficult to reverse without further surgery and is often not successful. Published figures indicate that regret is not uncommon, particularly among women sterilized at young ages, with low parity, or those who subsequently experience change in family structure. Up to 20% of sterilized women in the US request a reversal operation.⁵⁹

Service issues

Training

As GyneFix is a new technique, familiarity with the insertion procedure may be acquired only after a number of insertions have been completed, depending on the skill of the provider. Doctors, midwives, nurses, or other health care providers may insert the IUS provided that they have been properly trained in family planning, have received practical training in IUD insertion in general and appropriate training in insertion of the frameless IUS in particular.

Timing of insertion

The frameless IUS can be inserted at any time during the menstrual cycle. However, the provider should rule out the presence of a pregnancy, if insertion of the device is planned in the second half of the menstrual cycle. If insertion immediately after spontaneous or induced first trimester abortion is considered, complete evacuation and proper contraction of the uterus should be ensured. In case there is concern about the risk of infection caused by insertion of the IUD after the abortion procedure, the use of prophylactic antibiotics (for example 200 mg of doxycycline 1 h before or at the time of the IUD insertion) may be a prudent precaution. However, studies did not show any protective or beneficial effect of the prophylactic use of doxycycline.³⁴

A period of at least 6 weeks postpartum should be allowed until the uterus has regained its normal size and the subject preferably has had at least one normal menstrual period.

Ultrasound evaluation

Although not imperative, the proper positioning of the device can easily be checked after insertion and at fol-

low-up using abdominal or vaginal ultrasound, by measuring the distance between the surface of the uterus and the upper border of the first copper sleeve (S-S distance). This distance is on average 12–16 mm.

Removal and replacement

The IUS can be removed from the uterine cavity by exerting traction on the thread (the removal force is on average three to four times the force to remove a T-shaped device).⁶⁰ If the thread cannot be seen, it may have retracted into the uterus, which is rare, or the IUS may have been expelled. Presence of the IUS can be assessed by ultrasound examination, or radiograph in exceptional cases. If the thread is retracted in the uterine cavity, a grasping forceps should be used to retrieve the thread from the cavity, which is usually effective, or removal can be accomplished by hysteroscopy. A new IUS can be inserted immediately after removal. If it is suspected that the IUS is not in the correct position at the time of insertion or thereafter, it should be removed and a new IUS can be inserted immediately or at a later date.

Conclusion

The development of the frameless IUS is a response to the growing need to develop high-performing, long-acting, reversible, and acceptable contraceptives, with a high continuation of use.

The IUS has a similar failure rate to the TCu380A IUD, considered as the 'golden standard' IUD, which is attributed to the optimal target delivery of the copper ions in the upper part of the uterine cavity.

Its performance is further optimized by the atraumatic design, which reduces partial and total expulsion and minimizes the side-effects and discomfort experienced with conventional framed IUDs. The mini IUS is likely to further reduce the menstrual blood loss due to its very small size.

The safety of the anchoring concept is beyond doubt as was demonstrated in all clinical studies covering 15 000 woman-years of experience. Young nulliparous/nulligravid women may significantly benefit from the advantages the frameless IUS, which could be strategically important to help reduce the increasing number of unintended pregnancies and induced abortions worldwide.⁶¹

Proficiency with the insertion of the IUS has been facilitated by the development of the Mark II GyneFix inserter.

Furthermore, the frameless IUS has been shown to be highly effective for emergency contraception and for immediate postabortal and postplacental insertion.

The long lifespan of the IUS could constitute a cost-effective reversible alternative to irreversible female sterilization.

Finally, the frameless IUS is, within a family of innovative contraceptive systems, suitable for a wider range of women's health needs. It includes the new intrauterine drug delivery systems, which is currently in development, sharing the myometrial anchoring system, that allows prolonged, cost-effective, controlled drug delivery for contraception and medical treatment of menorrhagia, dysmenorrhea, and hormone replacement therapy.⁶²

Acknowledgments

The following colleagues participated in the clinical trials with the 'frameless IUS' and provided valuable advice and input in the preparation of this review paper: John Guillebaud, Department of Obstetrics and Gynecology, UCL Medical School and former Director of the Margaret Pyke Family Planning Center, London, UK; Michel Thiery, International Study Group on Intrauterine Drug Delivery, Department of Obstetrics, University of Ghent, Belgium; Patrick Rowe, recently retired from the World Health Organization, Special Programme of Research, Development and Research Training in Human Reproduction, Geneva, Switzerland; David Serfaty, Birth Control and Gynecology Center, Saint-Louis Hospital, Paris, France.

The name 'intrauterine system (IUS)' has been selected to make a distinction between the 'frameless' device and traditional intrauterine devices (IUDs).

This review examines the results of clinical trials since its inception in 1985. The experience with the anchoring concept extends far beyond the clinical experience as reviewed and recently published by the Cochrane Library.⁶³ Although the frameless device has remained the same, several improvements to the instrument for its insertion in the uterine cavity have been accomplished resulting in a much improved and easier insertion technique.

Initial experience with the GyneFix IUS in South-East Asia has been obtained at the Raden Saleh University Hospital in Jakarta, Indonesia and in Brazil at the Centro de Biologia da Reprodução, Universidade Federal, Juiz de Fora.^{64,65}

Competing interest: Dirk Wildemeersch is director of clinical research at Contrel Research, Ghent, Bel-

gium. Control cooperates with organizations in less developed countries to help reduce the number of unintended pregnancies and induced abortions.

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