

CURRENT DEVELOPMENT

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CURRENT STATUS OF FRAMELESS ANCHORED IUD FOR IMMEDIATE INTRACESAREAN INSERTION

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Abstract

Immediate postpartum intrauterine device (IUD) insertion deserves great attention as it can provide immediate, timely and convenient contraception plus the added benefit of preventing repeat unintended pregnancies. Although women post vaginal delivery can benefit from immediate post-placenta contraception, women undergoing Cesarean section clearly need contraception, as an inter-delivery interval shorter than 18 months places them at a high risk for uterine rupture. The main drawback of currently available framed IUD devices for immediate postpartum insertion of an IUD is their high expulsion and displacement rates when inserted immediately postpartum after both vaginal and Cesarean delivery. Current research suggests that a brief window of opportunity exists of 10 minutes for insertion of conventional IUDs after which time expulsion rates both immediately and over time are greatly enhanced. This paper summarizes the current research conducted to overcome the expulsion problems associated with conventional T-shaped devices as well as through the use of an anchored frameless device.

In the 1970s and 1980s, attempts were made to solve the expulsion problem by modifying existing devices, such as adding absorbable sutures (Delta-T) or additional appendages. These attempts proved to be clinically unsuccessful as the catgut suture added to the transverse arms did not provide sufficient resistance to prevent downward displacement and expulsion. An anchoring technique to suspend a copper IUD to the fundus of the uterus was developed in Belgium in the 1980s and has been the subject of extensive ongoing clinical research since 1985. Recently the frameless copper releasing anchor IUD, GyneFix, has been tested for postplacental insertion. Initially, the anchor was modified by the inclusion of a biodegradable cone which was added below the anchoring knot. Clinical studies confirmed the adequacy of this approach suggesting that it was technically possible to anchor an IUD immediately following Cesarean section as well as after vaginal delivery with minimal incidence of expulsion. However, it was found that removal of the IUD was difficult in a number of women who requested early removal, due to the slow disintegration time of the cone. Based on these prior experiences, a new approach for anchoring of a frameless IUD immediately after delivery of the placenta was invented and developed specifically for use immediately post-Cesarean delivery. Beyond providing convenient and timely contraception the intended use allows a woman adequate time to recover from both the surgery and the burden of childbirth, while ensuring adequate future contraception. It is anticipated that it will also have an added benefit of allowing a greater number of women to have follow-on vaginal deliveries.

The anchoring procedure is conducted under direct vision. It can be performed immediately after placental removal without the burden of timing restraints. It consists of the precise placement of the anchor of the frameless IUD immediately below the serosa of the uterus, followed by fixing the anchoring knot in place with a very thin absorbable suture. Early stage studies have confirmed the suitability and ease of use of this approach with additional clinical trials currently being conducted. The anchoring technique is easy, quick, safe and effective with no expulsions at 12 months. The method is considered a major advance, suitable for general use due to its simplicity requiring limited training.

Key words: Cesarean section, copper IUD, expulsion, frameless IUD, postpartum IUD

INTRODUCTION

According to a United Nations (UN) Report of 2014, the world's population reached 7.2 billion in 2014 and is expected to increase by more than 2 billion by 2050 [1]. Future growth will occur mostly in developing countries, driven by the level of fertility. Despite the significantly higher levels in life expectancy achieved over the past decades, many countries will fail to meet the targets of the Programme of Action of the International Conference on Population and Development due to a high unmet need for contraception. Current projections show a continued increase in population in the near future with the global population expected to reach between 7.5 and 10.5 billion by 2050. According to the projections, the populations of Africa and Asia will increase substantially in the coming decades. In contrast, because of persistent below-replacement fertility, the population size in a number of countries is expected to decline.

In many countries with improved healthcare and economic growth, women's desire for a new pregnancy has lessened and many seek to postpone their first pregnancy. Due to urbanization and economic development, more women routinely practice contraception to avoid unwanted or mistimed pregnancies. Yet, 85 million unintended pregnancies occurred worldwide in 2012 [2]. The key objective of the '2012 London Summit on Family Planning (Family Planning 2020)' is "to revitalize global commitments to family planning and access to contraceptives as a cost-effective and transformational development priority" [3]. Preventing unintended pregnancies is an integral component of achieving the UN Millennium Development Goals, most notably Goal 5: improving maternal health [4].

DEVELOPMENT OF THE IMMEDIATE POSTPARTUM IUD INSERTION AND FIXATION METHOD (IPPIF)

Importance of immediate postpartum contraception

In order to reduce the contraceptive gap in many developing countries, immediate postpartum insertion of a copper intrauterine device (IUD) or a levonorgestrel system is very attractive as another pregnancy is not immediately desired. The level of acceptance and patient motivation at this critical time is therefore high [5].

Coital-dependent methods may be used inconsistently during the postpartum period by couples who think conception is less likely during this period but their effectiveness is unfortunately very low for a variety of reasons. Oral hormonal use has all the conventional limitations seen in women including adverse effects and reduced effectiveness. As a contraceptive used during the postpartum period, the IUD has distinct advantages: it is easy and painless to insert as the cervix is dilated or the uterine fundus is easily accessible in case of Cesarean section; it does not affect breastfeeding, as do many systemic contraceptive methods; the usual post-insertion bleeding and spotting occurs simultaneously with lochia;

the postpartum period may also be a convenient time during a woman's life to have an IUD inserted, since it may be one of the few times she is in contact with medical services; they can be more readily inserted with reduced training. In addition, IUDs do not require regular user compliance giving clinical effectiveness comparable to surgical sterilization procedures. If a woman is contemplating that she may no longer desire additional children but is reluctant to undergo permanent surgical sterilization, a long acting IUD offers an equally effective means of contraception but has the critical component of being reversible. Furthermore, when the IUD is inserted immediately after delivery the method is safe as there is no increased risk of infection, bleeding and pain or uterine perforation [6]. However, when conventional framed IUDs inserted in the postpartum environment are compared with interval insertion, the postpartum insertion of conventional designed IUDs carry a higher risk of expulsion [5]. In general, immediate postplacental insertion of IUDs has unacceptable high total expulsion rates both immediately post insertion and over time. In addition to full expulsions, high displacement rates have been observed [7, 8]. Inadequate positioning may effect overall efficacy and will likely have a significant negative impact on patient tolerability.

Postpartum insertion of conventional framed IUDs needs to take place within a very narrow window of less than 10 minutes of placental delivery (immediate postplacental). If the device is not inserted within that time restraint expulsion rates increase substantially. Recommendations suggest that the next opportune time for insertion is about six weeks after birth, when a woman returns for a routine postpartum care visit [9].

The main challenge of postpartum IUD insertions is to reduce the immediate and delayed expulsion/displacement rates typically encountered. The risk of expulsion is lower for insertions done within 10 minutes of delivery than for those done between 10 minutes and hospital discharge [10]. One multisite study found that after six months, the cumulative expulsion rate was 9% for immediate postplacental insertion, compared with 37% for insertions done between 24 and 48 hours after delivery, or about one out of three women. The expulsion rate following immediate insertion after vaginal delivery is consistently higher than that following immediate insertion after Cesarean delivery (7.5-22.6% versus 0.0-13.9%) [5]. Çelen et al found an expulsion rate at one year of 17.6% in post-Cesarean section patients [11]. There are no differences between copper and LNG-IUDs as the expulsion rates and displacement rates appear similar [9, 12].

The risk of expulsion can be reduced substantially with appropriate training in postpartum insertion techniques. From a technical perspective postpartum insertion can be performed before hospital discharge but with an added risk of expulsion/displacement but it should not be done between 48 hours and about six weeks postpartum because of an increased risk of expulsion and perforation [9].

Many women do not return to obtain contraception after they leave hospital, or before their postpartum visit at 6-8 weeks. It is therefore important to offer women

the option of having an IUD inserted immediately after delivery to avoid an unplanned pregnancy. It has been calculated that 41% will have sexual intercourse within 6 weeks after delivery [13]. Ovulation, without or with the return of menses, may already return before that time in non-breastfeeding women and in women who are not exclusively breastfeeding [14]. Many unintended pregnancies could be avoided by providing immediate postpartum IUD placement [15]. It appears that one solution to minimize the number of expulsions/displacement encountered is to attach the IUD to the fundus of the uterus immediately postpartum.

Importance to prevent uterine rupture following previous Cesarean section delivery

Uterine rupture is one of the most catastrophic emergencies when the interpregnancy or interdelivery interval is too short [16-20]. Rupture of the uterus occurs when a full-thickness disruption of the uterine wall that also involves the overlying visceral peritoneum (uterine serosa) is present. It is associated with significant and sometimes massive bleeding and fetal distress and needs prompt Cesarean section, uterine repair or hysterectomy [21]. In contrast to frank uterine rupture, uterine scar dehiscence involves the disruption and separation of a preexisting uterine scar.

Women undergoing Cesarean section need contraception, as an interdelivery interval shorter than 18 months is considered a risk factor for uterine rupture. According to a study by Zhu et al. [22], the optimal interpregnancy interval for preventing adverse perinatal outcomes is 18 to 23 months. In a study that evaluated the risk of uterine rupture related to the interdelivery interval, the rates of uterine rupture were 1.3%, 1.9% and 4.8%, after an interdelivery interval of 24 months, between 18 and 24, and fewer than 18 months, respectively [23]. In these women, a low IUD expulsion risk is therefore paramount.

Importance of reversibility

Sterilization options in developed countries are routinely offered to women at the time of delivery. The timing and technical issues make this option attractive to both patients and physician alike. Many women accept the option but a larger number are reluctant to make such a drastic and final decision concerning their reproductive health. Less invasive sterilization techniques will clearly be more attractive to women, particularly reversible long-acting methods. Presently, all sterilization methods used today are irreversible. The critical question is: Do women really like the irreversibility associated with current methods? Studies showed that a significant proportion of women do not if they had the choice between reversible or irreversible methodologies. This is especially critical in younger women who may have further social, economic or fertility related changes over time. For many, older women, reversibility is not as critical a requirement as they have the expected number of children they want and desire to terminate fertility with a permanent method. However, it is likely that if given the choice the vast majority of women, both young and older, would prefer

an easily reversible methodology which keeps their reproductive option open. In a study conducted in the United Kingdom in women who were counseled for tubal sterilization, 68% chose to be sterilized, but the remainder selected a reversible contraceptive method [24]. The authors commented that accurate information and informed counseling is important as many women are not well-informed about other highly effective and long-term reversible contraceptive methods.

Sadly, many women in the world are irreversibly sterilized against their will, mainly after Cesarean section. Forced and coerced sterilizations are still performed, both in developed and developing countries. Cases are known and accused before court of hidden or secret coercion for sterilization performed during cesarean section deliveries without consent [25]. A reversible contraceptive method with clinical effectiveness comparable to surgical methods could eliminate many of these abominable acts.

If forced and coerced sterilizations may diminish progressively, regret can be avoided completely by selecting a 100% reversible method. Regret is common; the overall frequency of regret within 14 years after surgical sterilization is approximately 20.5% for women below 30 years of age at the time of the intervention, and 5.9% in those above that age [26, 27]. Young age and individual social circumstances are key indicators for future regret.

The availability of adequate contraception immediately post Cesarean delivery may have an added benefit in reducing the number of Cesarean sections performed worldwide. By allowing for adequate timing between pregnancies full uterine recover would be achieved thus allowing women to achieve follow-on vaginal delivery. Studies have shown that 40 to 80% of women can successfully achieve vaginal births after Cesarean section (VBAC) [20]. By increasing the ability of a women to have follow-on vaginal deliveries, it is likely that the growing worldwide trends for Cesarean deliveries will be diminished.

Immediate postplacental insertion of an IUD (IPPI) – First attempts to reduce the risk of expulsion

Early attempts to solve the expulsion problem were made in the 1980s. Delta-T devices, using catgut strands tied on the horizontal arms of the T-body, modifications of standard Lippes Loop D and TCu220C IUDs, were designed for postpartum insertion (Figure 1). In a study conducted in the United States of America, 100 women received the modified CuT220C (Delta-T IUD) shortly after delivery: 65 insertions were within 10 min, 22 insertions were between 11 and 60 min and 13 women had insertions between 1 h and 55 h following vaginal delivery (5, 28). Expulsion rates were 8.5% among women who had insertions within 30 min of placental delivery compared with 55.6% among women who had insertions between 31 min to 55 h.

A pooled analysis examined data from nine sites around the world (one each in Australia, Bangladesh, Brazil, Costa Rica, Panama, Taiwan and Turkey and two sites in Egypt) where IUD insertion occurred less than 10 min after placental delivery compared with data from two sites (Chile and Thailand) where IUD insertion

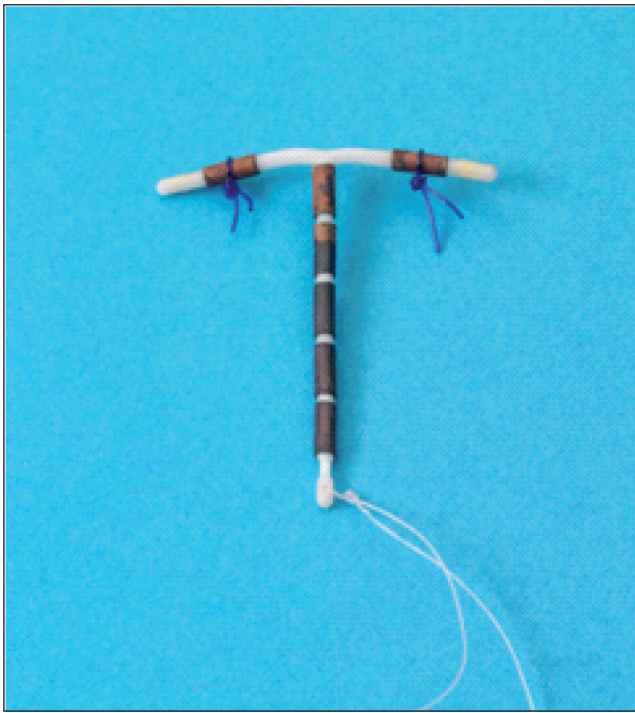


Fig. 1. Delta-TCu380 postpartum IUD. Two strands of catgut were knotted on both transverse arms of the T in an attempt to provide better retention of the IUD in the uterine cavity.

occurred from 2 to 23 h, 24 to 47 h and 48 to 72 h after placental delivery [29]. Multiple types of copper-bearing IUDs, as well as Lippes Loop and Delta-T devices were used. After adjustments for age and parity, the authors estimated the expulsion rate to be 9.5% among women

with IUD placement less than 10 min after placental delivery compared with 28.8% to 37.3% among those in the latter insertion groups. The addition of catgut to the horizontal arms of the T-IUD was not found to be any benefit.

Immediate postplacental insertion and fixation of an IUD in the uterine fundus after vaginal delivery

Gyne-T 380 postpartum IUD

The Gyne-T 380 postpartum (PP) IUD has a double-knotted loop of 2-0 chromic catgut suture around the top of the vertical arm, which is inserted approximately 1 cm into the fundal myometrium [30]. A special inserter had to be designed for the Gyne-T 380 Postpartum IUD. The inserter was equipped with a plastic V-tipped rod that was controlled manually, permitting the clinician to determine accurately the depth of the insertion into the uterine wall. The rod delivered the knotted loop of 2-0 chromic catgut into the uterine wall to a depth of no more than 1 cm (Figure 2 A and B). When the insertion was completed, the transverse arms of the T were flush with the endometrial surface at the top of the fundal cavity. After insertion, the catgut dissolved over the next 4 to 6 weeks, leaving the IUD free in the endometrial cavity. By this time the uterus had involuted to its normal prepregnancy shape and size.

Prior to finalizing the Gyne-T PP IUD the fundal thickness of the well-contracted postpartum uterus was measured. Multiple measurements showed a range of 2.1 to 5.1 cm and a mean of 3.1 cm. These measurements differ greatly from the thickness of fundus of the Cesarean section uterus, measured in 25 women which was on average 1.5 ± 0.4 cm, with range from 0.7-1.9 cm.

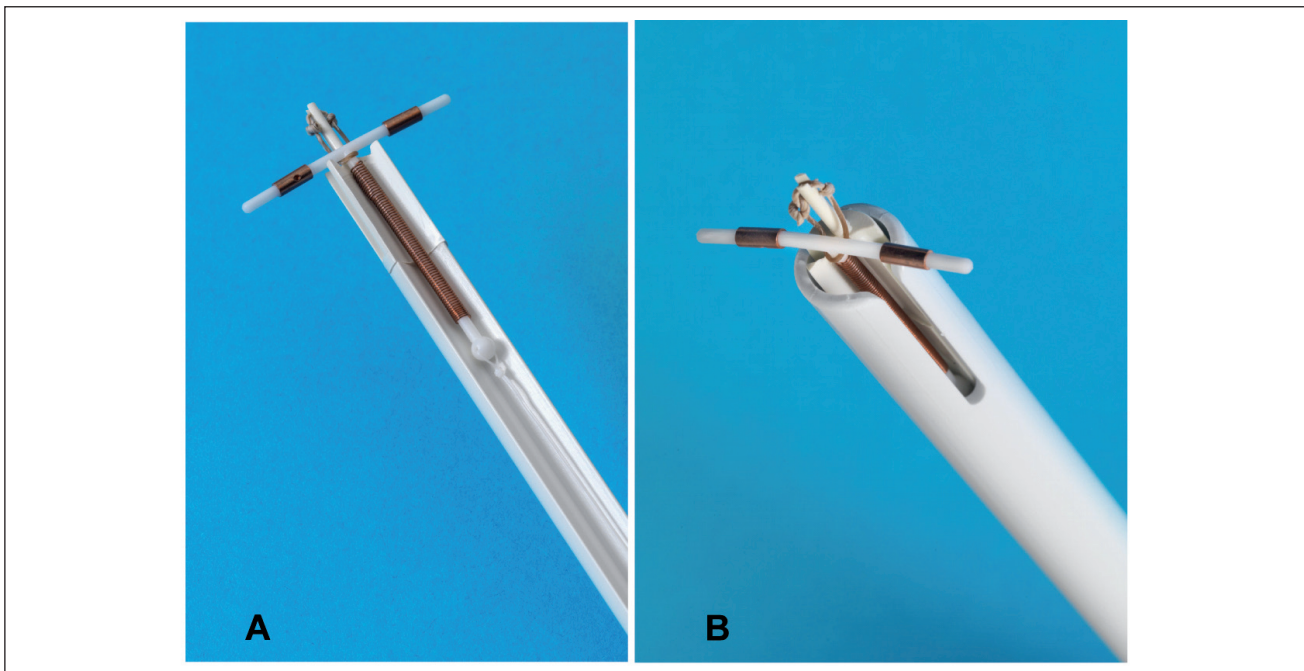


Fig. 2. A and B: Specially designed inserter for Gyne-T 380 Postpartum IUD). It is equipped with a plastic V-tipped pin that is controlled manually to deliver the double-knot of the catgut loop to a specific depth of no more than 1 cm into the uterine wall.

A multicenter, randomized trial was conducted in 300 subjects using the Gyne-T 380 IUD (without anchoring) and 292 subjects the Gyne-T 380 Postpartum IUD (with anchoring) in clinics with adequate follow-up. At 1 year the gross cumulative expulsion rate was 13.2 per 100 cases (39 expulsions) with the Gyne-T 380 intrauterine contraceptive device and 16.2 per 100 cases (46 expulsions) with the Gyne-T 380 Postpartum device. There was no significant difference in the rate of expulsion between the two devices at any time during the year [31].

There were several significant problems with this study as the data demonstrate clearly that there were strong and statistically significant differences among the participating clinics in rates of expulsion. The latter finding suggests that the rate of expulsion in the year after postplacental insertion of the Gyne-T 380 may be governed more by the techniques used during the insertion process and by the hand skills and experience of the clinician doing the insertion than by the shape and size of the device or the use of the suspension technique. In addition, it was detected that the chromic catgut double knotted loop was such that the knots were placed too far apart on the loop and, therefore, could not be inserted in the myometrium. Furthermore, an unknown number of insertions were performed while the parturient was already in her hospital bed and not in the delivery room within the 10 min limit (personal communication).

Immediate postplacental insertion and fixation of the frameless IUD after vaginal and Cesarean delivery

GyneFix® postpartum with cone-shaped anchor

Anchoring technology for use in the immediate postpartum period in combination with the frameless GyneFix IUD was developed by us in 2000 and has been the subject of extensive clinical trials conducted in China. The GyneFix PP IUD is derived from the GyneFix for interval and postabortal insertion. However, below the polypropylene anchoring knot, a cone-shaped biodegradable body (polycaprolactone), 4x4 mm in size, is added to retain the device in the soft muscular tissue of the uterine fundus (Figure 3 A and B). The GyneFix PP IUD was suitable for insertion during Cesarean section as well as immediately following vaginal delivery. The results of these studies (unpublished) are shown below (Table I). They suggested that the expulsion problem of IUD insertion immediately following delivery could be solved with implant technology.

Another study was conducted with GyneFix PP in ~200 women undergoing Cesarean section delivery. The objective was to study the effects of immediate insertion of GyneFix PP IUD during Cesarean section on duration of bleeding during delivery, postpartum hemorrhage, and continuance of lochia and healing of uteruses.

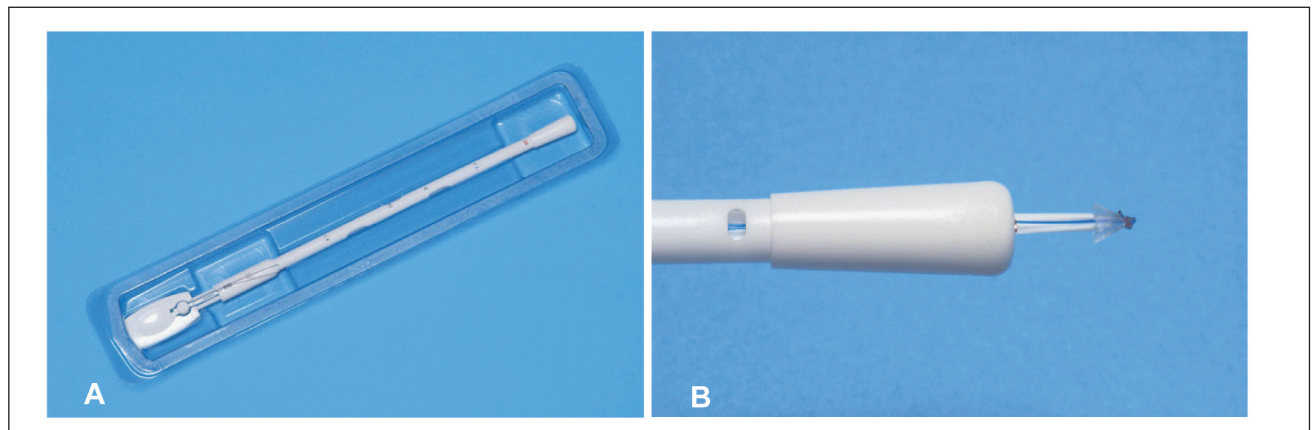


Fig. 3. (A) GyneFix® Post-Partum (PP) in blister package and (B) detail of biodegradable anchor (right). The penetration depth of tip of the cone is 12 mm.

Table I. Expulsion rates of GyneFix PP.

GyneFix PP (Life-table analysis)	Cesarean Section	Vaginal delivery
No. completing 6-month interval	472	381
Expulsion rate (%)		
Complete	2.70	3.03
Partial	0.63	1.02

Two-hundred women used GyneFix IUD contraception during a Cesarean section and 204 women did not use them and served as control group. Follow-up visits were performed at 42 days and 90 days after delivery. There was no significant difference in postpartum hemorrhage, a continuance of lochia, and healing of uteruses was in progress normally. The expulsion rate of the GyneFix PP IUD was 4%, and 86% of the string of the IUD were found in the cervical orifice at 42 days after delivery. It was concluded that immediate insertion of GyneFix PP IUD during a Cesarean section is safe and has no effects on postpartum hemorrhage, continuance of lochia and healing of uteruses [32].

Based on these clinical studies with the GyneFix PP IUD, the method for application immediately post-delivery has shown to be effective and safe. This appears to be an advantage when compared with conventional methods which are not anchored resulting in expulsion or displacement of the device in a high percentage. However, it was found that removal of the GyneFix PP system was difficult in women who requested early removal, as the solid polycaprolactone took too long to degrade. For this reason adaptation of the technology was proposed examining the degradation time and optimizing the insertion system.

GyneFix® CS for intracesarean insertion – a system suitable for general use

Given the ever growing numbers of Cesarean performed worldwide a modification of the current anchoring technology available with GyneFix was made specifically targeting women undergoing Cesarean delivery. Women who have had a Cesarean section and/or are breastfeeding are good candidates for intrauterine contraception such as

long-acting reversible contraceptive methods, or LARC. Post-placental CS IUD insertion is especially valuable as it appears to present fewer problems than after vaginal delivery [33]. In 2014, the technique of suspending the frameless IUD for intracesarean insertion was further optimized. The specially designed applicator is identical with the insertion system used for the commercially available interval insertion, except that the front end of the inserter tube was modified to prevent unintended perforations (Figure 4 A and B). The technique consists of the precise placement of the anchoring knot immediately below the serosa of the uterus, followed by fixing the knot in place with an absorbable suture. The IUD tail is looped in the cervical canal and is cut prior to discharge from the hospital. In case the tail is in the cavity, it usually can be picked-up using a thin, 3 mm alligator forceps when removal is requested.

The anchoring technique has shown to be easy, quick and safe in a pilot trial with no expulsions at 12 months (unpublished). It was readily apparent from the beginning that the technique could be considered a major advance, suitable for general use due to its simplicity requiring very limited training. The lack of any timing restraints affords the surgeon the ability to insert the device at a convenient time after placental delivery, prior to closure of the incision in the uterus.

The position of the anchor in the fundus of the uterus can be identified using sonography by localizing the stainless steel marker attached to the anchoring knot (Figure 5). Although no removal studies have been conducted, removal of the IUD is expected to be similar to the removal after interval insertion of the device [34]. We prefer the frameless IUD over framed IUDs as the latter may cause discrepancy with the uterine cavity and

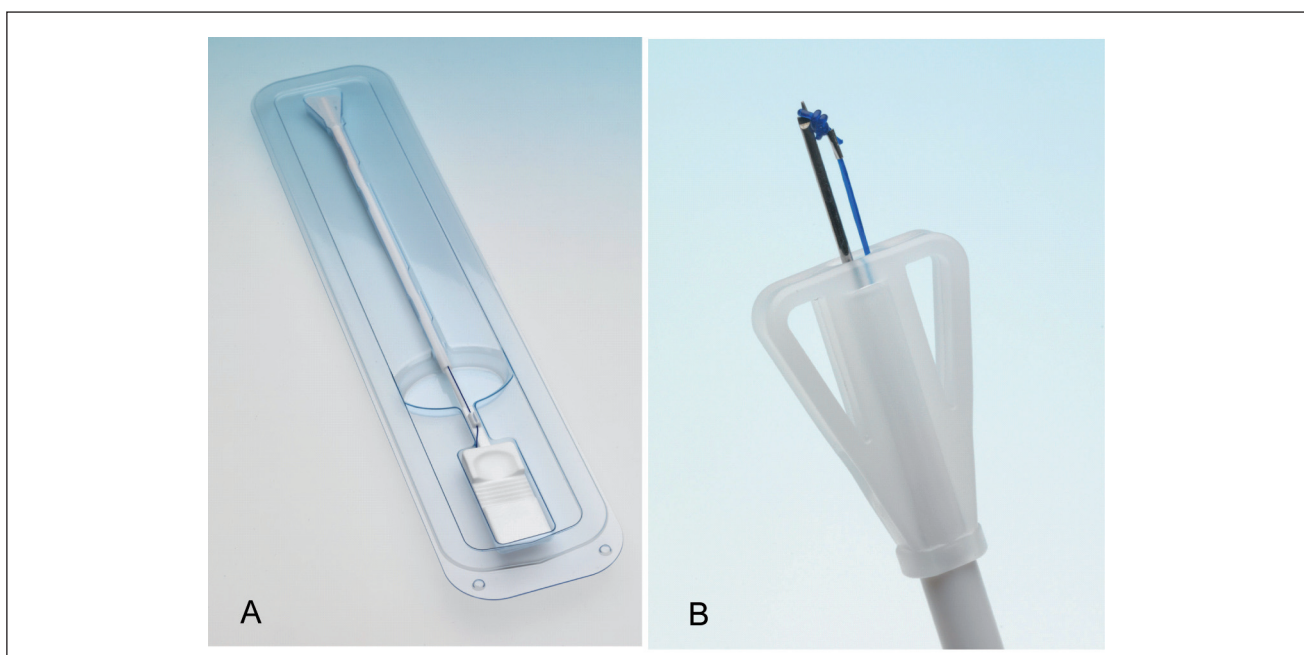


Fig. 4. (A) Specially designed inserter for GyneFix-CS. (B) The front end of the inserter is equipped with a triangular tip to be positioned against the fundal wall and serves to prevent perforation with the applicator. The anchoring knot is positioned on the tip of the stylet (read text for further explanation).



Fig. 5. 2-D sonography showing the position of the anchor in the fundal wall at follow-up (arrow). Its distance from the serosa as well as from the endometrium can be measured.

embedment during involution of the uterus, particularly during prolonged lactation as hyper involution in these women is not uncommon [35]. Uterine compatibility will dictate patient continuation rates and overall patient acceptance [36]. In addition, the availability of adequate contraception immediately post Cesarean delivery may have an added benefit in reducing the number of Cesarean sections performed worldwide. By allowing for adequate timing between pregnancies full uterine recover would be achieved thus allowing women to achieve vaginal delivery.

Further studies and field trials in developing country setting should be initiated to confirm the promising initial results. IPPIF appears to be the only solution to solve the expulsion problem associated with postpartum insertion of IUDs. The method will also expand its use as a strategy to reduce unintended pregnancy and rapid repeat pregnancy in adolescents [37].

CONCLUSIONS AND FUTURE IMPLICATIONS

Contraception after Cesarean delivery is of critical clinical importance if the woman becomes pregnant too soon after the first Cesarean section as the risk of rupture of the uterus is a greatly increased. Uterine rupture remains one of the most catastrophic obstetric emergencies. Short interdelivery and interpregnancy intervals have been associated with the likelihood of uterine rupture and now represent risk factors that should be considered in the management of women contemplating a VBAC. For this reason, many obstetricians and women opt for a following Cesarean section and the saying: “Once a Cesarean section, always a Cesarean section” is practiced in many countries (Figure 6) [38]. After her second Cesarean section, many women do not want further pregnancies and are therefore candidates for long-term contraception. A long interval between pregnancies may promote VBAC.

As Cesarean section rates are rising steeply both in developed and developing countries, immediate (preferably reversible) contraception with high efficacy and a low side effect profile is an urgent need [39]. In light of the

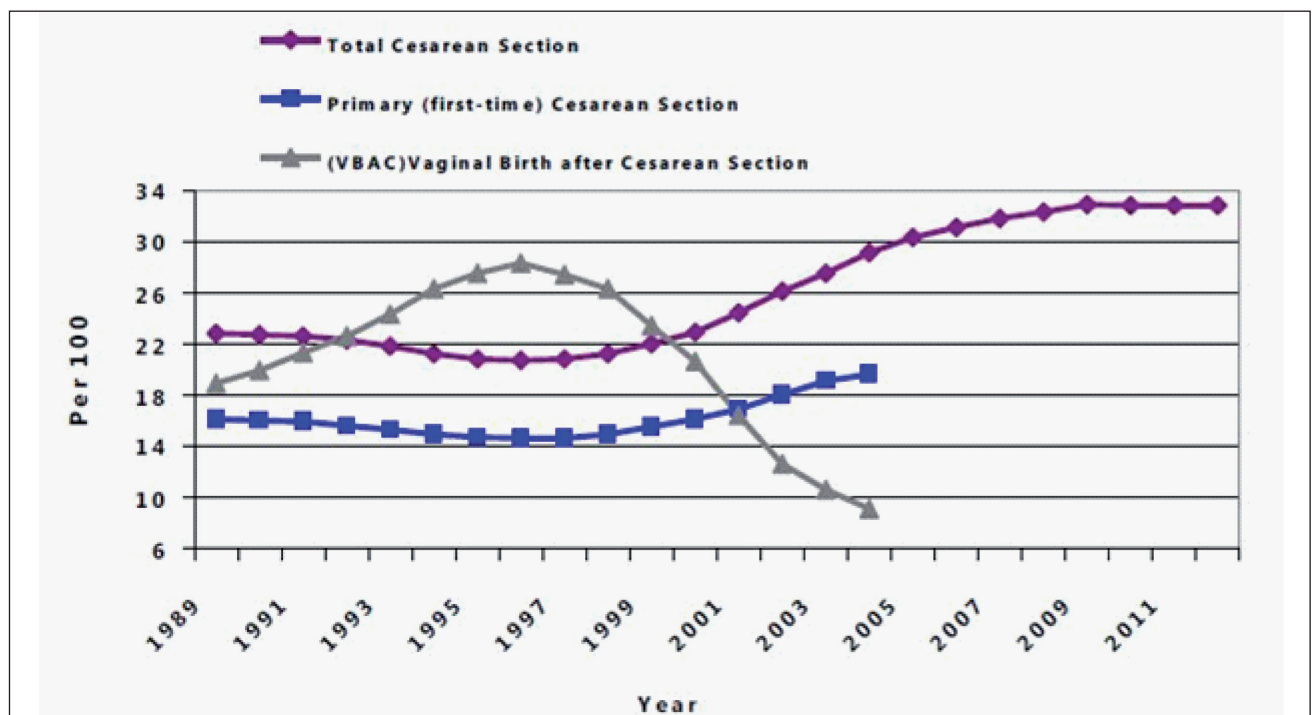


Fig. 6. Cesarean section rates in the United States: “Once a Cesarean section, always a Cesarean section”. Following the first Cesarean section, in the United States, most deliveries are also by Cesarean section [38].

Millennium Development Goal of reducing the worldwide maternal mortality ratio by three-quarters by 2015, and the resolution of the Parliamentary Assembly of the Council of Europe to reduce unintended pregnancy among EU member states, policies promoting the widespread availability of a highly effective and safe immediate postpartum IUD method could represent an important step towards improving women's reproductive health worldwide [40, 41].

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FROM THE VICE-EDITOR

In their excellent mini-review, Drs. Wildemeersch, Goldstuck, and Hasskamp present an up-to-date picture of developments in the field of frameless intrauterine devices designed for immediate intracervical insertion. To attain such a goal in the enlarged postpartum uterus, several specially invented anchoring systems have been successfully tested so far. The description 'frameless' stands for a thin, elastic insert capable of easily adapting to various shapes and dimensions of the uterine cavity. As outlined, intracervical timing seems to be convenient for many women and may be medically justified. Similarly, visual inspection during device placement may be convenient for the physician. Clarity of subsequent sonographic monitoring of the device's position in the fundal wall is of great clinical importance. The reader can clearly see much thought and effort have been put into making these devices and their insertion systems work.

Optimal contraception is expected to be, among others, highly efficient, 100% reversible, and free from adverse effects. The latter still needs to be verified with the new technique, together with the impact of accompanying factors such as puerperal involution of the uterus and healing of the postpartum wound. Although a null expulsion rate was achieved with the new technique, further long-term clinical trials are required to study the fundal position of the anchor after insertion. Similarly, ease of removal of the device over time requires assessment.

We are aware that the public health arm of the United Nations, the World Health Organisation, is looking attentively at such innovations as they may significantly impact healthcare in many countries. Thanks to this illustrative contribution published in our journal *Developmental Period Medicine* we can witness the maturity of achievements in next-generation intrauterine devices which are truly a current development.

Professor Maciej Józwiak