Contraception xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Contraception

journal homepage: www.elsevier.com/locate/con

Original research article

Comparison of expulsions following intracesarean placement of an innovative frameless copper-releasing IUD (Gyn-CS®) versus the TCu380A: A randomized trial☆

Ceren Unal [a], Ahmet Eser [a], Elif Tozkir [a], D. Wildemeersch [b,*]

[a] Zeynep Kamil Women's and Children's Disease Training and Research Hospital
[b] Reproductive Health Consultant Intrauterine Devices and Systems, F. Rooseveltlaan 43/44, Ghent, Belgium

ARTICLE INFO

Article history:
Received 3 January 2018
Received in revised form 25 March 2018
Accepted 28 March 2018
Available online xxxx

Keywords:
Postpartum IUD
Cesarean section
Frameless IUD
Anchoring technology
TCu380A
IUD expulsion

ABSTRACT

Objective: The intent of this study (primary outcome measure) is to assess the expulsion rate of a newly developed copper releasing frameless intrauterine IUD GyneFix® Cesarean Section (Gyn-CS®) at 3 months' follow-up, compared to the TCu-380A IUD, inserted immediately postplacental expulsion following cesarean section delivery.

Study design: This is a randomized trial from one hospital research center in Istanbul, Turkey. Eligible pregnant women, the majority undergoing elective cesarean delivery (n=106), and the remaining emergency cesarean section cases (n=34), received intracesarean insertion of Gyn-CS or TCu380A insertion. Follow-up ended with a 3 month-visit. The Zeynep Kamil University Hospital Ethics Committee approved this study.

Results: The study explores the retention of 140 insertions, 70 Gyn-CS and 70 TCu380A. There were two follow-up visits after discharge from hospital at 6 weeks and 3 months. A single Gyn-CS expulsion occurred after approximately 6 weeks likely a consequence of improper anchoring. Expulsion was more common in the TCu380 A IUD group (11.4% vs 1.4%, p=.039). There were 4 removals for medical reasons in the Gyn-CS patients and 4 in the TCu380A patients, respectively, with 4 non-medical removals occurred, 2 in each group. No serious adverse events (e.g., PID, perforation) were reported. At the study conclusion of 3 months, 61 Gyn-CS (88%) and 54 TCu380A (79%) IUDs remain in place.

Conclusion: This immediate postplacental study in cesarean section patients suggests that the anchoring technique employed resulted in the excellent retention of Gyn-CS. Insertion was easy, safe and quick requiring minimal physician training. The possibility of direct visualization of the anchor by ultrasound at insertion and follow-up allows the surgeon to verify the position of the IUD serving to enhance provider and patient confidence and assurance.

Implications: The frameless anchored intrauterine IUD is effective in minimizing displacement and expulsion. The results of this study suggest that the Gyn-CS IUD is appropriate for wider intracesarean use.

1. Introduction

Immediate postplacental insertion (within 10 min of delivery of the placenta) of copper-bearing or hormone-releasing IUDs is safe and acceptable, although in contrast to interval insertion, it carries a higher risk of expulsion [1]. In general, the current techniques of postpartum IUD insertion using conventional IUDs are far from being optimal, both immediately post insertion and over time, as the IUD is not uniformly retained in an optimal position within the uterine cavity. In addition to complete uterine expulsions, high displacement rates also occur which are likely accompanied by side effects (e.g., bleeding, pain) and early removal due to embedment and cramping [2–7]. Since the 1980s, many trials with conventional IUDs attempting to reduce the expulsion and displacement rate of postpartum IUDs have failed indicating the need for further research [8].

Most marketed IUDs worldwide rely on uterine retention methods based on their size and design, with the vast majority using the conventional T-shape configuration. An alternative retention methodology utilizing a simple uterine implantation technique is marketed in Europe for interval and post-abortion insertion under the name GyneFix® (Contrel Research, Ghent, Belgium). This retention system has now been modified to allow for simple and rapid implantation for use in the immediate postpartum period following cesarean delivery. The use of a uterine implantation procedure for anchoring of drug delivery systems was first introduced in Belgium in 1985 at the University of Ghent and subsequently in internationally conducted clinical trials [9,10]. The initial device for implantation in the immediate postpartum environment utilized a biodegradable cone (polycaprolactone) which was added

☆ Funding source: Contrel Research provided the Gyn-CS devices free of charge.
* Corresponding author.
E-mail address: dirk@wildemeersch.com (D. Wildemeersch).

https://doi.org/10.1016/j.contraception.2018.03.034
0010-7824/

below the "anchor" of the frameless device. Although a markedly lower expulsion rate was seen when compared to that reported for conventional T-shape IUDs, early removal for medical or at patients request at 42 or 90 days was sub-optimal, requiring excessive force [11]. The difficulty at removal led to the redesign of the device, its inserter and modification of the retention methodology. The present paper reports on the experience with this next generation device and applicator with follow-up of three months as compared to that seen with TCu380A designed to demonstrate a significant reduction in the expulsion rate.

2. Materials and methods

2.1. Screening and informed consent

All scheduled and unscheduled (emergency c-sections) participants were enrolled by the investigators (CU, AE) during antenatal care based on compliance with the inclusion and exclusion criteria, their previous obstetrical history, and their wish to participate in the study. The subjects were considered for inclusion if they had an intact and anatomical normal uterus and were able to make a follow-up visit at 6 weeks and again at 3 months. Women with a known anomaly of the uterus (i.e., fundal fibroid or congenital anomaly), possibly precluding anchoring of the Gyn-CS in the fundus of the uterus, were excluded, as were women with a recent genital infection. The study was explained to all participants along with potential benefits of the method and possible risks. Only healthy pregnant women with an uneventful pregnancy were admitted in the study. The study was approved by the Ethics Committee of the Zeynep Kamil University Hospital, Istanbul, Turkey with informed consent being obtained from all participants.

2.2. Description of the GyneFix® CS IUD

The frameless GyneFix Cesarean Section (Gyn-®) IUD (Contrel Research, Ghent, Belgium), with visualized anchor, is similar in design to the original GyneFix differing in the distance between the anchoring knot and the first copper cylinder and a modified inserter designed to facilitate implantation following cesarean delivery. The extended distance is required to compensate for the greater thickness of uterine fundus encountered during pregnancy prior to complete uterine involution which typically occurs approximately 2 months post-delivery. The IUD contains 5 copper cylinders with a total weight of the copper of 350 mg and the effective copper surface area is~300 mm^2 (Fig. 1A) and is intended to provide long-term non-hormonal contraception. Immediately below the anchoring knot a thin stainless-steel marker, 2 mm long and 0.5 mm wide, is added to allow for verification of the positioning of the IUD via ultrasonic means at both insertion and subsequent follow-up. The approved contraceptive lifespan of the IUD is 5 years comparable with that of the original GyneFix IUD. The Gyn-CS IUD is preloaded onto a specially designed inserter adapted with a modified safety tip which precludes its use in any other conditions other than after cesarean delivery (Fig. 1B).

2.3. Randomization

Allocation to either of the two treatment groups was done according to a randomization scheme generating blocks of 10 women using a computer-generated table. The pharmacy of the hospital assigned the proper device prior to the surgical intervention. The investigators had no access to the treatment sequence and the type of device was concealed to them until the operation. As the devices and insertion procedures differ completely between the devices, investigator blinding was not possible, but participants were blinded with respect to the device they received until released from the study.

2.4. Insertion of the GyneFix® CS IUD

Immediately following cesarean delivery and manual removal of the placenta, while bleeding is controlled, the uterus was lifted out of the abdominal cavity. Prior to insertion, the cavity was manually inspected for abnormalities precluding proper placement of the intrauterine IUD. The applicator was then inserted through the surgical incision up to the fundus in the midline. The broad applicator tip was easily palpated through the exterior fundal wall to determine positioning, without any risk of penetration or perforation of the fundal wall. The stylet carrying the IUD was then pushed forward until it became visible on the exterior surface to the uterus. The applicator was then removed, and forceps placed on the tail of the IUD. The noose of the anchoring system was then threaded with a biodegradable suture material such as Vicryl® 3–0 suture (Ethicon, Somerville, NJ, USA) or a generic equivalent (Fig. 2). The threaded anchor was then retracted one millimeter below the serosa by exerting traction on the tail of the IUD. The passage of the anchor through the denser serosa layers was clearly felt. One end

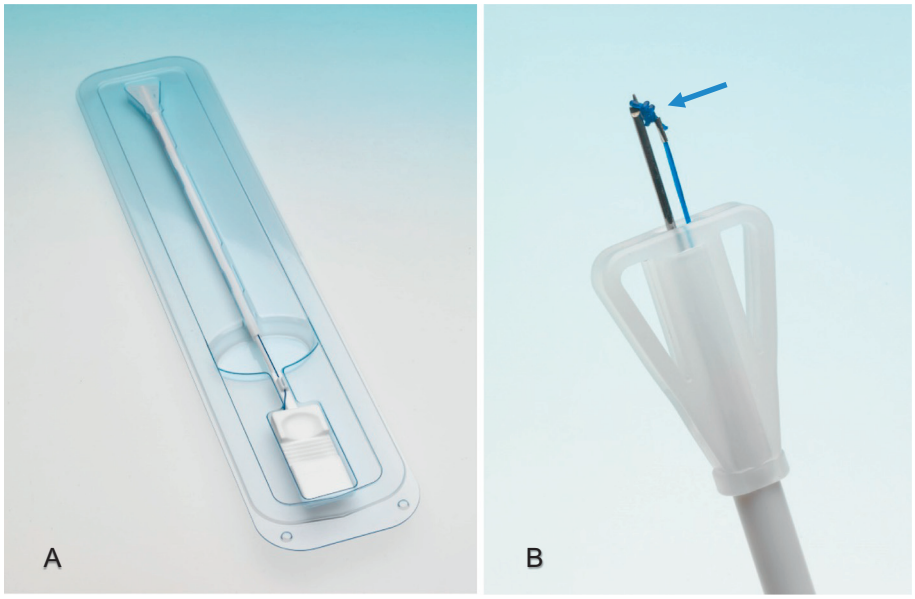

Fig. 1. (A) Specially designed inserter for Gyn-CS® (global patents pending). (B) The front end of the inserter is equipped with a triangular tip to be positioned against the fundal wall and serves to prevent perforation with the applicator. Anchoring knot (arrow), positioned on the tip of the stylet, to securely suspend the IUD to the fundus of the uterus.

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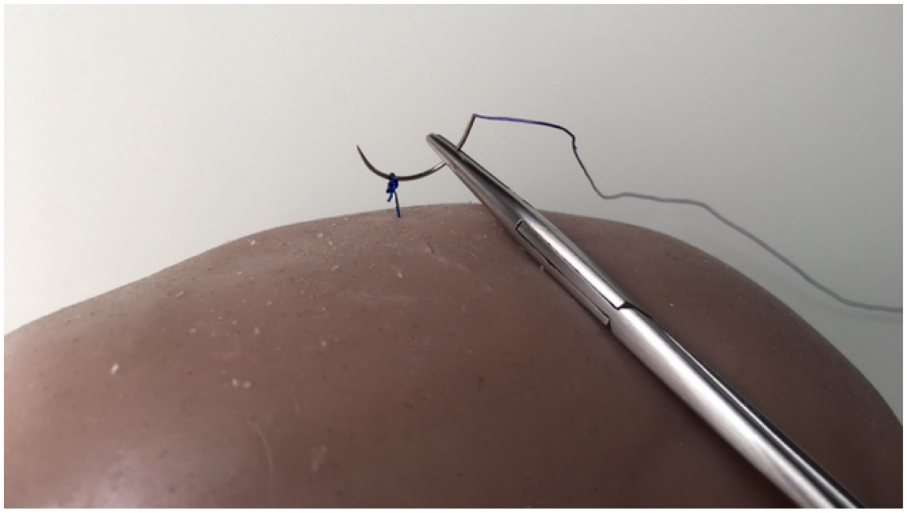

Fig. 2. This figure shows the threading of the biodegradable suture through the noose of the anchoring knot prior to pulling the knot one mm below the serosa.

of the Vicryl absorbable suture was then secured to the serosa and knotted with its other end. The purpose of the Vicryl suture was to ensure retention while involution of the uterus occurs. Once uterine tone is returned to normal after several weeks, the Vicryl suture dissolves and retention is identical to that seen with the conventional anchored device. Finally, the tail was passed through the cervical canal and trimmed. In the first 30 patients, the tail was left long and was looped in the cervix using forceps. In the remaining women, the tail of the Gyn-CS IUD was trimmed in the lower uterine segment to avoid the tail protruding too long in the vagina and to prevent inadvertent pulling at the tail. The entire procedure takes approximately 3 to 4 min to perform. The Gyn-CS device as well as the applicator are currently CE-marked and approved for use as a long-term contraceptive system throughout the EU.

2.5. Insertion of the TCu380A IUD

Insertion of the TCu380A IUD was accomplished using a sponge forceps for correct placement of the IUD in the fundus of the uterus. The tail was left long.

2.6. Follow-up

Following insertion, women were re-examined at discharge, at 4–6 weeks and again at 3 months after insertion. An ultrasound examination was conducted at each visit in addition to a gynecological examination and the distance between the serosal surface and the anchor (SA distance) was measured (Fig. 3).

2.7. Study outcomes

The primary outcome measure of the study is expulsion of the Gyn-CS IUD in comparison with that of TCu380A IUD, in addition to ease and safety of the insertion procedure. The secondary outcome measures included side effects: bleeding, pain, other medical reasons (e.g., infection, perforation, ectopic pregnancy), and continuation rates of Gyn-CS vs TCu380A.

2.8. Data analysis

A sample size calculation revealed that 214 women (107 in each of the groups) would be sufficient to detect a difference in expulsion rate after 3 months of 9%, with 80% power at a 5% significance level, using a two-sided Fisher's Exact Test. It was assumed that 10% of IUD expulsions could be expected in the TCu380A group and approximately 1% in the Gyn-CS group at 3 months follow-up. It was initially planned to include 200 subjects in the study during the first 6 month and to follow-up participants during the next 6 months; however, recruitment was slower than anticipated and only 70 women in each of the groups could be recruited (yielding a final study power of 56%) during the

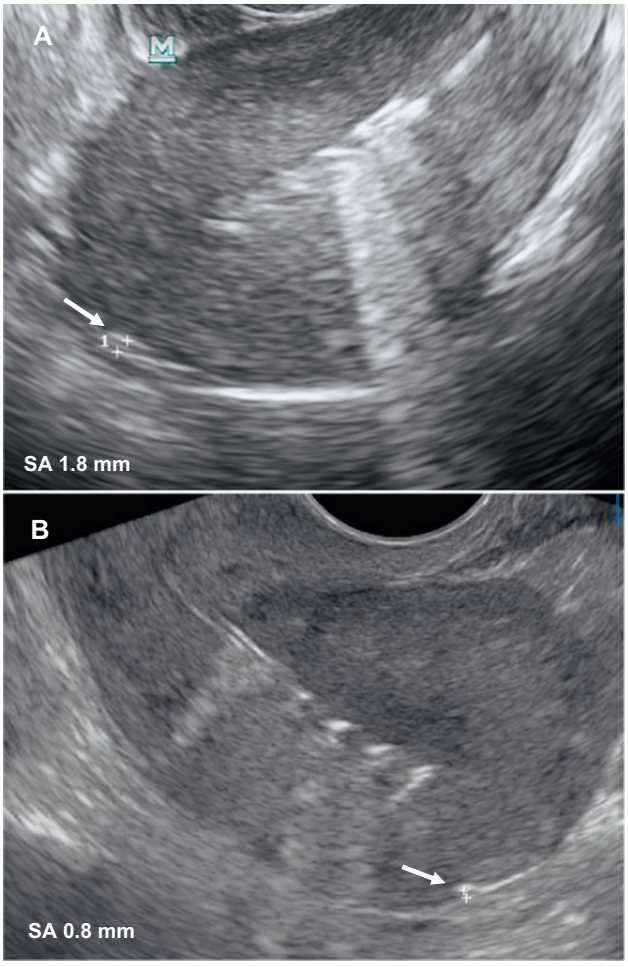

Fig. 3. 2D ultrasound at 6 to 7 weeks post-insertion showing the Gyn-CS implant with anchor marker securely attached to fundus of the uterus. (A) Serosa-Anchor distance (SA-distance): 1.8 mm from the serosa; (B) Anchor point at 0.8 mm from the serosa.

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time period reserved for the trial. This protocol deviation was communicated and accepted by the Ethics Committee (EC).

The median and range (minimum – maximum) were used to report continuous variables. Absolute frequency and percentages were used to report categorical variables. The age distributions in the two device groups were compared using a Mann–Whitney U test; frequencies were compared using Fisher's Exact tests. Two-sided *p*-values are reported. All data analyses were carried out in R version 3.4.1 [12].

3. Results

This report concerns 140 subjects, 70 with a frameless Gyn-CS IUD, and 70 with the TCu380A IUD. All insertions were performed by two experienced investigators (CU, AE), appropriately trained in the insertion procedure of the Gyn-CS during one supervised cesarean section and well versed in insertions of TCu380A. The trial started in June 2016 and concluded one year later in June 2017, which was the scheduled month of closure. The primary outcome measure was device expulsion. During antenatal care, 160 women were questioned to participate in the study and were screened according to the eligibility criteria. Only five women declined participation in the study. Of the 160 eligible patients, 140 women (70 per arm) signed an informed consent form and were eventually enrolled into the study. This number included 34 emergency cesarean section cases.

Fig. 4 shows the study flow diagram. The age and parity distribution of the 140 women in this analysis as well as their obstetrical history and other characteristics is shown in Table 1. The baseline characteristics are equivalent in each group. All women have a similar mean age and age range, come from low and middle economic classes, have relatively low education, and are living on the Asian side of Istanbul. Median age in the Gyn-CS group is 30 years (22–40); only 1 among them being primiparous, 69 are multiparous with 64 having previous c-section delivery. In the TCu380A group, the median age is 32 years (20–41); among them 1 was primiparous with 59 having previous c-section delivery.

Median follow-up of women in the Gyn-CS group was 96 days (range 25–126 days), while median follow-up for women in the TCu380A IUD group is 88 days (range 15–151) days. All removal requests occurred within the first 6 weeks after insertion. The remaining participants continued for the full duration of the study. Table 2 shows the study results at 3 months. Originally, 140 participants entered the study with three women not participating in the final statistical analysis: 1 in the Gyn-CS and 2 in the TCu380A group, respectively, as they did not return for follow-up (LFU).

All insertions were successful and no failed insertions occurred. At the 3-month visit post-insertion, 61 Gyn-CS IUDs were in place (excluding the one lost-to-follow-up case); there were a total of 5 medical removals: 2 for suspected endometritis, 2 for pain (one had comorbidity Morbus Crohn), 1 other removal because of an undefined tail problem,

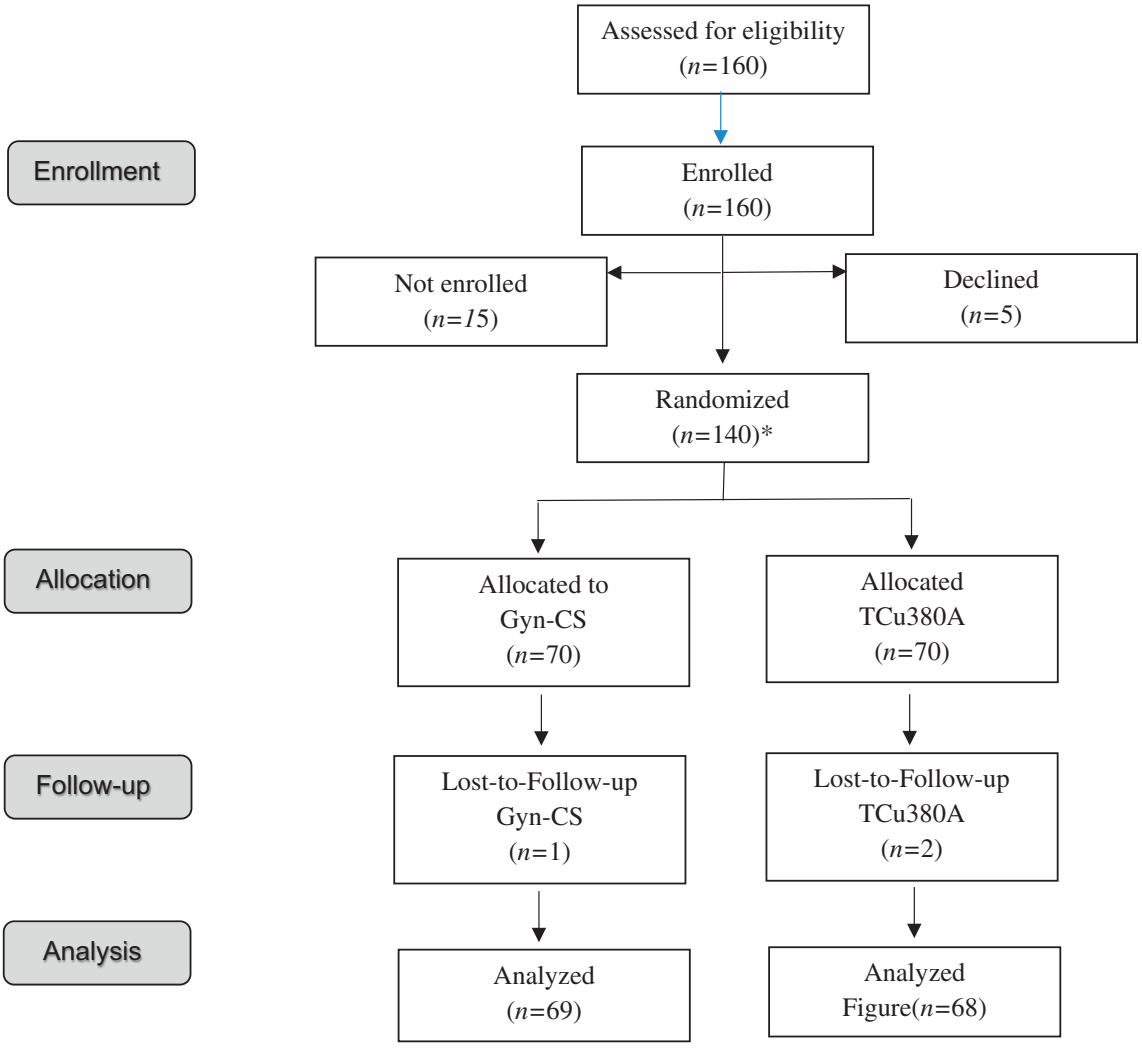

Fig. 4. Flow diagram. A total of 160 women were evaluated to participate in the study with a maximum of 140 women to be enrolled the study. Five women declined to participate and 15 other women were not enrolled as the study ended before they delivered.

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Table 1
Age and parity distribution of the 70 Gyn-CS and TCu380A IUD users, number of previous c-sections, number of elective and emergency c-sections.

	Gyn-CS	TCu380A
Age in years, median (range)	30 (22–40)	32 (20–41)
Parity, absolute number		
1	1	1
2	21	19
3	24	25
4	14	15
5	5	7
>5	5	3
Previous cesarean section, absolute number		
0	6	7
1	31	33
>1	33	26
Elective cesarean sections	54	52
Emergency cesarean section	16	18
Race		
White	70	70
Education		
High School	26	28
Elementary	29	31
No School	15	11
Marital status		
Married	70	70

and 2 non-medical removals: 1 on request by the partner and 1 device inadvertently or accidentally removed by another doctor not familiar with Gyn-CS or patient involvement in the study. One Gyn-CS device was expelled in the beginning of the study, approximately 6 weeks after insertion, which was thought to be caused by improper placement of the anchor too far from the serosa, or due to inadvertent or accidental pulling at the tail during or after the intervention, causing early dislodgement following absorption of the degradable suture. Puerperium was considered normal and excessive bleeding did not occur. Apart from the expulsion case, there were no spontaneous expulsions during follow-up with the Gyn-CS IUD. No pregnancies occurred, and the device was well tolerated. The anchor marker was visible in the fundus of the uterus on ultrasound in all cases at the last follow-up. Only one subject was lost-to-follow-up.

In the TCu380A IUD group, 8 total expulsions (11.4%) occurred at various times during the 3-month follow-up, and were confirmed by ultrasound examination. Additional, a total of 5 removals occurred for medical reasons: 3 devices were removed for suspected endometritis, including pain (n=2) and 2 for abnormal bleeding. Two women were lost to follow-up. Fifty-four TCu380A IUDs were in place at 3 months (excluding the 2 lost-to-follow-up cases).

The tail of Gyn-CS was visible in the vagina in 40 subjects (58%) at the 3-month follow-up visit while the TCu380A strings were visible in only 15 subjects (22%). No data on tail visibility was available for 8 women in the Gyn-CS and 16 in the TCu380A group, respectively.

Table 2
Number of events, comparing 70 intracesarean insertions of the Gyn-CS IUD with 70 TCu380A IUD insertions at 3 months.

Events	Gyn-CS (n=69)	TCu380A (n=68)	p-Value
	n (%)	n (%)	
Accidental pregnancy	0 (0)		
Expulsion	1 (1.4)	8 (11.4)	0.039
Medical removals	4 (6)	4 (6)	1.0
Non-medical removals	2 (3)	2 (3)	1.0
Other medical removals	1 (1)	0 (0)	1.0
Planned pregnancy	0 (0)	0 (0)	1.0
Lost-to-follow-up	1 (1)	2 (3)	1.0
Continuation	61 (88)	54 (79)	0.30

4. Comments and discussion

The results of this postplacental IUD insertion study in cesarean section patients suggest that the implantation technique results in optimal retention of Gyn-CS as there was only one expulsion which upon investigation appeared to be caused by faulty technique (incorrect insertion) or possibly due to inadvertent pulling at the tail during or after the surgical intervention. Despite the reduction in patients enrolled, a statistically significant difference in expulsion rate between Gyn-CS and TCu380 IUD (p=.039) exists. Due to the anchoring in the dense superficial layers of the fundal muscle (1 mm below the serosa), the anchored IUD is optimally retained in the involuting uterus, before and after biodegrading of the suture, which occurs within 4 weeks, minimizing displacement and expulsion. The involution of the uterus coupled with the foreign body reaction, occurring after implantation, will eventually contribute to the firm anchoring of the IUD.

The results of this study suggest that the intracesarean anchoring of Gyn-CS is safe, similarly to the implantation of the frameless GyneFix in the interval and post-abortion uterus [13,14], confirming earlier postplacental studies with the earlier version of the frameless postpartum IUD system [11]. The direct visualization promotes its simplicity. The authors therefore believe that the method is suitable for general obstetrical use and that only limited training is required. The visual technique minimizes the need for extensive provider familiarity and training as providers can learn the technique in a model or by viewing a video film. Supervised in vivo insertion is generally not necessary, although it may still be preferable to build investigator confidence.

The position of the anchor in the fundus of the uterus can be readily identified using ultrasound by localizing the stainless-steel marker attached to the anchor. Gyn-CS itself is also highly visible upon ultrasound. This could be important in the event the tail is not clearly visible. IUD removal is also easy by pulling at the tail, even after a few weeks as the strength of the biodegradable suture diminishes. Two Gyn-CS devices were removed early in the study (2 weeks), presumably before the Vicryl suture was fully dissolved, indicating the possibility of early removal. After absorption of the Vicryl suture, removal of the Gyn-CS IUD is similar to the removal seen after interval or postabortal insertion of the device [15].

Due to its frameless design and its fixation to the fundus of the uterus, displacement and embedment of Gyn-CS is avoided. Displacement of conventional T-shape designed IUDs following postpartum insertion occurs frequently. Displacement results in side effects and complications due to embedment of the IUD occurring during or after involution of the uterus [7]. In an immediate postplacental vaginal delivery study with TCu380A, 44% of subjects experienced malpositioned IUDs upon ultrasound evaluation [6]. Displacement, embedment or malpositioning of TCu380A in our study is not evaluated.

In our study, the tail of Gyn-CS was visible in the vagina in 58% of subjects and in only 22% of TCu380A subjects. This difference is attributed to the stiffer, slightly thicker size of the Gyn-CS tail. In case the tail or strings are not visible, removal can usually be accomplished using an alligator forceps with diameter of 3 mm which is passed easily through the cervical canal. We believe that trimming the tail of Gyn-CS in the lower uterine segment at the time of insertion should be preferred over placing the tail in the vagina as a too long tail may cause inadvertent or accidental removal of the IUD, as happened in at least one case in the beginning of the study. To prevent this from happening, it was decided to trim the tail in the lower uterine segment half way in the study.

There were 5 cases of removal for endometritis which possibly could have been prevented by preoperative cleansing of the vagina, not routinely done in the study setting. Later in the study the few infections were treated with the device remaining in place. Serious adverse events did not occur with either of the two devices.

For maximal patient's tolerance and acceptability, we prefer to use an implantable frameless device over conventional framed IUD designs

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given that the latter can cause discrepancy with the uterine cavity and embedment during involution of the uterus, particularly during prolonged lactation as hyper involution in these women is not uncommon [16]. Optimal uterine compatibility is more likely to enhance patient continuation rates and overall patient acceptance, as many studies have indicated [17,18]. Due to its small size, there is also less impact on menstrual bleeding [19]. For these reasons, a frameless IUD or drug eluting-releasing intrauterine system could be preferable for use in the immediate postplacental period.

Strengths and limitations of the study. As the primary outcome measure is expulsion of the device, the very low expulsion rate of Gyn-CS compared with TCu380A is a very strong argument in favor of the anchored IUD, preventing expulsion and displacement. The short follow-up period (3 months on average), may be considered a limitation. However, most expulsions inserted postpartum occur within the first 6 weeks [20]. As the anchoring technique is an optimization of previous anchoring techniques, the current implantation technique is considered final and has gained CE authorization within Europe. Precise placement of the anchor, approximately 1 mm below the serosa, is easily accomplished under direct vision. In addition, the position of the anchor marker allows to check its position on follow-up ultrasound examination. Adding more cases would further confirm the safety and validity of the optimized technique and its importance in solving the expulsion and displacement problem of conventional IUDs inserted postplacentally. Furthermore, the anchoring technique and its design is the subject of numerous long-term studies, including removal force studies, showing adequacy of the anchoring concept [21] and rapid return of fertility following removal of the implanted devices.

5. Conclusion

Providing immediate, effective and convenient postpartum contraception has the benefit of optimal timing since most women are actively evaluating their future family planning needs. 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 [22]. We conclude that the frameless Gyn-CS IUD, specially designed for intracesarean insertion, could be a major advance, potentially suitable for general use due to the ease and safety if the insertion procedure, requiring limited training. The low expulsion rate will prevent more women becoming pregnant too soon which constitutes an important safety issue during future pregnancy. The device, preferably its high-load 10-year version, could also interest many women as a reversible alternative for tubal sterilization. Additional clinical experience with the Gyn-CS IUD is, therefore, urgently warranted.

Conflict of interest

The authors do not report any conflict of interest.

Acknowledgment

The authors are grateful to Dr. Wildemeersch for revising the manuscript. He was not involved in the conduct and analysis of the study. We are also grateful to Ms. Laura Coppens, Mrs. Roos Colman and Dr. Stefanie De Buyser, Biostatistics Unit, Department of Public Health, Ghent University, Belgium, for providing the statistical analysis of this study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.contraception.2018.03.034.

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Please cite this article as: Unal C, et al, Comparison of expulsions following intracesarean placement of an innovative frameless copper-releasing IUD (Gyn-CS®) versus the T..., Contraception (2018), https://doi.org/10.1016/j.contraception.2018.03.034