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Short communication

The force required to remove the frameless 0-suture IUD anchoring system: comparison between pre- and postmenopausal women

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Abstract

Objective: The objective of this short communication is to measure and compare the force needed to remove the implanted "0-suture" GyneFix® intrauterine contraceptive device (IUD) and the "0-suture" FibroPlant™-LNG intrauterine system (IUS) from the uterus of pre- and postmenopausal women.
Study design: A nonrandomized comparative study in 119 pre- and postmenopausal women. A dynamometer (Pesola®) was used to measure the removal force in newtons.
Results: The results of this study show a mean removal force of 8.5 and 9.5 newtons, respectively (range, 3–11 and 4.5–11), in pre- and postmenopausal women, which is significantly different ($p = 0.003$).
Conclusions: The force needed to remove the IUD/IUS anchored in the myometrium of the uterine fundus of pre- and postmenopausal women is higher than the removal force found in previous studies in which the IUD consisted of a slightly thinner anchoring thread (00 instead of 0 suture). The statistically significantly different removal force between the two groups has no clinical implications. The difference may reflect the increased compactness of the uterine tissue in the postmenopausal uterus.

Keywords: "Frameless" intrauterine device (IUD) and system (IUS); GyneFix®; FibroPlant™-LNG; Removal force

1. Introduction

The performance of a frameless intrauterine device (IUD) depends in the first place on the retention of the active compound in the uterine cavity. The considerable force needed to dislodge the frameless GyneFix®, provided with a 00-size knotted anchor, from its anchoring site in the fundal myometrium of the uterus is an indication of the reliability of the implantation method. This force is approximately four times higher than the force needed to remove a T-shaped IUD, which is between 1.0 and 1.7 [1,2]. This may explain why expulsion of conventional copper IUDs are not uncommon.

In the present study, the removal force was measured when a 0-size knot, instead of the slightly smaller 00-size knot, was used. This knot was selected to optimize the uniformity of the knot and, at the same time, to improve retention of the IUD. In addition, the removal force was compared between pre- and postmenopausal women.

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2. Materials and methods

2.1. Description of the GyneFix IUD and FibroPlant-LNG IUS

GyneFix has been described previously in this journal [3]. The FibroPlant-LNG intrauterine system (IUS, Fig. 1) is a development of the GyneFix IUD and is currently in clinical development for contraception and intrauterine treatment (menorrhagia, hormone replacement, etc.). It is a multicomponent system consisting of a polypropylene 0-suture thread, identical with the current GyneFix anchoring system, the proximal (fundal) end is provided with a single knot. Attached thereto is a 3.5-cm long and approximately 1.6-mm wide fibrous delivery system, releasing approximately 14 μg of LNG per day. The system is effective for at least 3 years. The fiber is fixed to the anchoring thread by means of a metal clip 1 cm from the anchoring knot. The anchoring knot is implanted into the myometrium of the uterine fundus using the GyneFix insertion instrument [4].

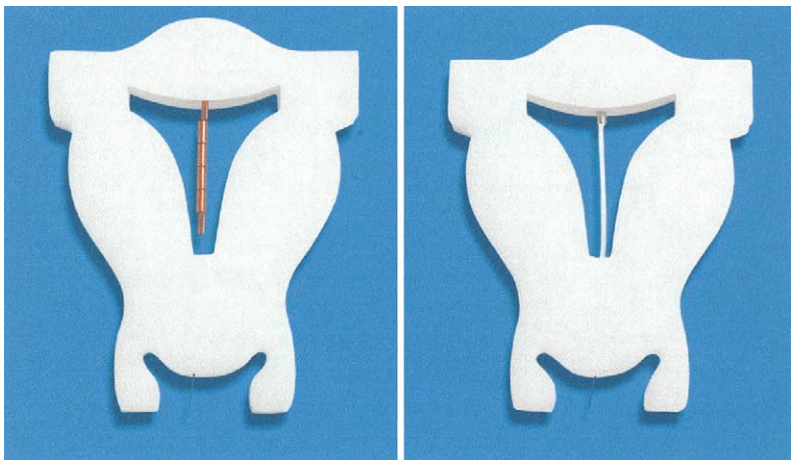

Fig. 1. GyneFix IUD (left) and FibroPlant-LNG IUS (right) in situ.

2.2. Study population

One-hundred and nineteen women participated in this removal force study. Premenopausal women (n = 47) either had a GyneFix IUD or a FibroPlant-LNG IUS fitted for contraception. Postmenopausal women (n = 72) were fitted with the FibroPlant-LNG IUS for endometrial suppression during estrogen replacement therapy. No pain, bleeding or any morbidity has been reported in association with the implantation of the knot into the myometrium.

2.3. Removal of GyneFix IUD and Fibroplant-LNG IUS

The GyneFix IUD was removed at the end of the license period of 5 years; the Fibroplant IUS after 3 years or earlier in case removal was requested by the woman.

To remove IUD/IUS, a hemostat was applied to the tail and the Pesola® (Switzerland) dynamometer was hooked onto the hemostat. As the IUD/IUS is retained in the uterus solely by the anchoring mechanism, the removal force was read at the precise moment when the anchor dislodged from the fundus of the uterus. The force was measured to the nearest integer. The removal force was compared between the two groups of premenopausal and postmenopausal women. All removals were conducted in consecutive patients as they came to the clinic for follow-up examination. Although the devices are different, the anchoring system is identical, allowing the force to dislodge the anchor of the two devices to be compared. Statistical analysis was carried out using the Mann–Whitney test to compare the removal force between the two groups [5].

3. Results

The removal force, measured in newtons, was evaluated in 47 premenopausal and 72 postmenopausal women. Virtually all removals were conducted after expiry to replace the IUD/IUS and not for any form of pathology. Table 1 shows the removal force in the two groups of women, according to their reproductive status. The mean removal force is 8.5 newtons in premenopausal women and 9.5 newtons in postmenopausal women, respectively (range, 3–11 and 4.5–11), which is statistically significantly different (p = 0.003) (Fig. 2).

4. Discussion

When inserted correctly, spontaneous expulsion of the GyneFix IUD and FibroPlant-LNG IUS occurs in <1% of women observed over a 5-year period of use. However, in clinical trials, GyneFix expulsion rates range from 0.5 to 3.0% during the first 3 years of use, compared with expulsion rates of between 2.7 and 7.4% with TCu380A IUD. Expulsion with FibroPlant has been very rare, probably because most insertions were performed by experienced doctors [4,6]. In large multicenter trials, it has been found that the majority of expulsions with the anchored IUD and IUS are clustered in some centers, which is attributed to lack of skill and familiarity with the technique of insertion. With conventional IUDs, the highest expulsion rate, up to 17%

Table 1
Difference in removal force (newton) between pre- and postmenopausal women of GyneFix IUD and FibroPlant- LNG IUS: analysis according to menopausal or postmenopausal status

	Pre- or Postmenopausal	
	Pre	Post
n	47	72
Mean	8.5	9.5
SD	2.0	1.6
Median	9.0	10.0
Range	3–11	4.5–11

Mann–Whitney U-test: p = 0.003

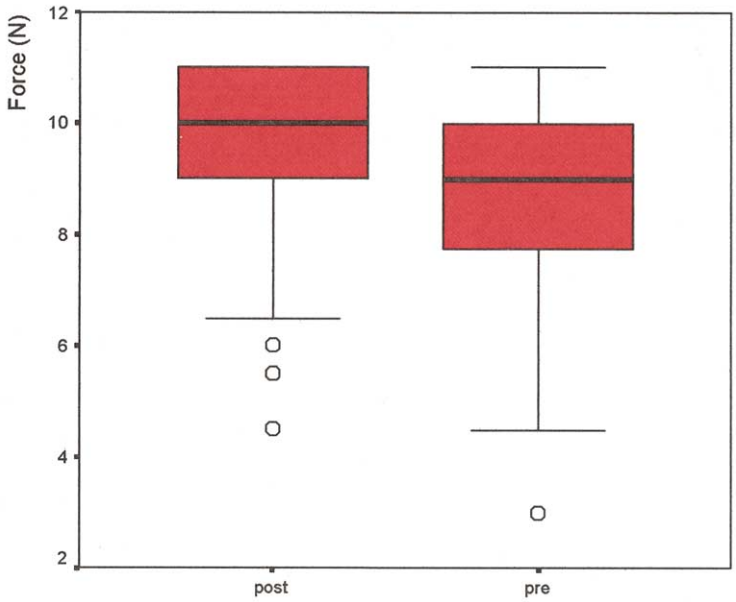

Fig. 2. Box-plot.

during the first year of use, has been reported in nulliparous women [7,8]. Incompatibility between the IUD and the endometrial cavity leads to distortion of the uterine cavity, resulting in uterine contraction and partial or total expulsion of the IUD.

The results of the present study suggest that, with the considerable force needed to dislodge the anchor, spontaneous expulsion should be virtually impossible after correct insertion. It is still advisable to recommend that the woman should avoid dislodgement by inadvertent traction on the IUD/IUS tail and abstain from intercourse and the use of tampons when the anchoring is still relatively weak, as this may increase the risk of expulsion. This is thought to be the case in the first week after insertion. Long-term use of the GyneFix IUD in major clinical trials has shown that late expulsions, after the first 6 months to 1 year following insertion, are relatively rare [6]. That optimal results are possible with GyneFix was demonstrated in a 3-year multicenter study conducted in 392 women (13,700 women-months of observation), which yielded a cumulative expulsion rate of only 0.39 [9]. The difference in removal force between pre- and postmenopausal women may reflect the increased compactness of the uterine tissue in the postmenopausal uterus.

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References

[1] Kurz KH. Role of retention in avoiding expulsion of IUDs. Measuring devices for basic research. Contracept Deliv Syst 1982;9:107–16.
[2] Batár I, Wildemeersch D. The force required to remove an anchored bioactive substance from the human uterus: results after long-term use. Contraception 2004;69:501–3.
[3] Wu S, Hu J, Wildemeersch D. Performance of the Frameless GyneFix and the TCu380A IUDs in a 3-year multicenter randomized comparative trial in parous women. Contraception 2000;61:91–8.
[4] Wildemeersch D, Schacht E, Wildemeersch P. Contraception and treatment in the perimenopause with a novel “frameless” intrauterine levonorgestrel-releasing drug delivery system. Contraception 2002;66: 93–9.
[5] Altman DG. Practical statistics for medical research. London: Chapman & Hall, 1995.
[6] Wildemeersch D, Batár I, Affandi B, et al. The ‘frameless’ intrauterine system for long-term, reversible contraception: a review of 15 years of clinical experience. J Obstet Gynaecol Res 2003;29:160–9.
[7] Roy S, Cooper D, Mishell DR. Experience with three different models of the copper T intrauterine contraceptive device in nulliparous women. Am J Obstet Gynecol 1974;119:414–7.
[8] Petersen KR, Brooks L, Jacobson B, Skouby SO. Intrauterine devices in nulliparous women. Proceedings of the 1st Congress of the European Society of Contraception, Paris, 1990.
[9] Cao X, Zhang W, Zhao X, et al. Three-year efficacy and acceptability of the GyneFix® 200 intrauterine system (IUS). Contraception 2004; 69:207–11 .