ORIGINAL ARTICLE

Randomised controlled trial assessing the acceptability of GyneFix® versus Gyne-T380S® for emergency contraception

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Abstract

Objective. *To assess insertion-linked pain and the short-term user-acceptability and safety of the GyneFix® as compared with T-framed intrauterine devices (IUDs).*

Design. *A randomised controlled trial in an outpatient clinic setting.*

Method. *Women requesting an IUD for emergency contraception (EC) were allocated to either the short-term arm (GyneFix® versus Nova-T200®, or the long-term arm (GyneFix versus Gyne-T380S®, and then randomised within each group. Visual analogue scores were used to assess the women's perception of the pain associated with insertion, which was patient-blinded. Follow-up was double-blinded, at 6 weeks, with bleeding and pain recorded over this time.*

Results. *A total of 175 women received an IUD in the long-term arm. The short-term arm was discontinued due to low recruitment (17 women at 20 months) and therefore the results relate to the long-term arm only. Outcome was known in 98% of subjects. The actual insertion procedure was scored as more painful for the GyneFix, both by the women ($p = 0.013$) and the doctors making their assessment of the women's pain ($p = 0.04$). The women with GyneFix described less pain in the subsequent 30 days after insertion ($p = 0.005$). Only 13% of women with GyneFix requested removal as compared with 20% with Gyne-T380S, with the difference being attributed to removal due to pain. The bleeding pattern was similar for those using GyneFix and Gyne-T380S.*

Conclusions. *Our study suggests that although the actual fitting may be more painful, pain is less during the 6 weeks after insertion of GyneFix and fewer women discontinue its use because of pain, as compared with Gyne-T380S. The high overall continuation rate of all emergency IUDs at 6 weeks and low morbidity seen in this study favours more frequent IUD insertion where unprotected intercourse has occurred, given also its higher efficacy over oral hormonal EC.*

Key message points

- **Continuation rates are good for intrauterine devices (IUDs) inserted for emergency contraception.**
- **Thus, greater use of IUDs after unprotected intercourse should also improve long-term contraceptive efficacy.**
- **GyneFix, as compared with Gyne-T380S, although more painful to insert is associated with less pain in the initial weeks subsequent to insertion, which may enhance its continuation rate.**

Introduction

Copper intrauterine devices (IUDs) were shown in 1976[1] to be a highly effective form of emergency contraception (EC). They show three main advantages over oral hormonal EC. First, efficacy is higher for a copper IUD, with pregnancy rates not exceeding 0.1%[2] as compared with 1% for progestogen-only emergency contraception.[3] Second, a copper IUD can be inserted at least 5 days after unprotected intercourse, or up to 5 days after the earliest estimated day of ovulation.[4] In this situation the copper IUD may act by preventing implantation, whereas when used long-term it usually prevents fertilisation.[5] Third, an IUD may subsequently provide ongoing contraception for 5 years or more.

Yet copper IUDs also have distinct disadvantages over oral hormonal EC that limit their use. These include the need for an insertion procedure, which may be painful, and its associated risk of pelvic infection. Such disadvantages are often perceived to be particularly problematic for the young and nulliparous, which make up a large proportion of those women presenting for EC.

Regarding the risk of pelvic infection, a meta-analysis including 22 908 IUD insertions found this to be increased above the background population risk only during the first 20 days after insertion.[6] This risk should be minimised by pre-screening for *Chlamydia trachomatis*, and using prophylactic antibiotics when the result is not available.[7]

If in addition the drawbacks of pain during insertion of an IUD, and pelvic pain and bleeding in the weeks thereafter, could be reduced or even eliminated, the highly effective IUD method might be used more widely, both for EC and as a long-term method.

Pain and bleeding are believed to be associated with the size, configuration and intrauterine positioning of a rigid IUD frame. In the mid-1980s, in an attempt to reduce these side effects, the International Study Group on Intrauterine Drug Delivery Systems developed a flexible, frameless IUD: the GyneFix®.[8] Other advantages postulated for this frameless device include a lower expulsion rate due to its anchoring system,[9] less insertion-linked discomfort and less cramping immediately after the insertion because of the absence of a frame.

GyneFix has now been evaluated in over 10 000 woman-years of use worldwide, both in parous and nulliparous women. It has been shown to be a highly reliable contraceptive following interval, postpartum, and postabortal insertions with generally favourable results.[8,10]

It appears to be effective when fitted for EC.[11,12] It is licensed for use in all European Union countries. It has been marketed in the UK since 1998, and is currently licensed for 5-year use.

To date there has been no randomised trial involving nulliparous women comparing the GyneFix with other copper IUDs, nor when used for EC. Yet it is in these situations that the manufacturer particularly recommends use of the GyneFix. We therefore decided to assess the performance of this novel IUD – in comparison with established IUD models – when used for EC (anticipating many of such users to be nulliparous). We designed the study to compare ease and pain of fitting, and pain and bleeding in the weeks thereafter. We did not attempt to compare rates of expulsion, perforation or contraception failure, which would have required assessing many more women for a longer time period.

We chose the comparator IUDs on the basis of the woman's ongoing contraceptive intentions. At the time of commencing the study, the Nova-T200® was the most widely used IUD model in the UK for EC, being perceived by physicians to be somewhat easier to insert than the Gyne-T380S®, at least in nulliparous women. However, a solid body of clinical evidence indicates that the Nova-T200 (with an exposed copper surface area of just 200 mm^2) has a much higher accidental pregnancy rate compared to the Gyne-T380S when used as a long-term contraceptive.[13] Hence, we felt the Gyne-T380S to be the most appropriate comparator where the woman indicated in advance that she anticipated long-term use or was undecided, but the Nova-T200 where the woman was certain she wished to use the device just to cover the short-term contraceptive emergency.

Methods

Ethics approval

The project was reviewed by the local research ethics committee of the Camden and Islington Community Health Services Trust, London, UK.

Description of IUDs used

The GyneFix (interval version)[8,10] consists of six copper sleeves threaded on a length of polypropylene thread, giving a total exposed copper surface area of 330 mm^2. A knot on the proximal end of the thread is anchored in the myometrium of the uterine fundus at a controlled depth of 10 mm, using a specially designed inserter.

The Gyne-T380S[14] is a T-shaped IUD that has a polyethylene frame wound with 314 mm^2 of copper wire on the stem, and collars each containing 33 mm^2 of copper at the ends of its transverse arms. The total exposed surface area of copper is approximately 380 mm^2. The device includes a monofilament polyethylene tail, which aids in removal of the IUD.

The Nova-T200[14] consists of a T-shaped polyethylene frame, with copper wire wound just on the stem, and giving a smaller total exposed surface area of copper of approximately 200 mm^2. The device includes a monofilament polyethylene tail.

Admission procedure

Women were self-selected from among the patients attending the Margaret Pyke Centre for EC, between December 1998 and December 2000. This centre is an open-access specialist National Health Service (NHS) contraception service in central London. Of those requesting the IUD method, 192 women agreed to be randomly assigned to receive the GyneFix, the Gyne-T380S or the Nova-T200, taking into account their intentions regarding short- or long-term use.

We screened all women for their clinical suitability for an IUD insertion and to meet our eligibility criteria. We applied the following exclusions: suspected pregnancy, lactation, current pelvic infection, immunosuppressive therapy, history of bacterial endocarditis, valvular heart disease, any prosthesis which could be prejudiced by blood-borne infection, Wilson's Disease, and previous attempted IUD insertion during the current menstrual cycle. Exclusion also applied after gynaecological examination, but prior to randomisation, if the uterine cavity was found to be markedly distorted, or sounded to less than 5.5 cm depth.

At study entry we questioned patients about their future contraceptive intentions. If a woman was sure that she wished to use the IUD only to cover the 'emergency' cycle, with removal at the end of the 6-week observation period, she was assigned to Group A: GyneFix vs Nova-T200. If a woman wished to consider using the IUD long-term as her ongoing method then she was assigned to Group B: GyneFix vs Gyne-T380S. Where undecided, we allocated women to Group B.

Randomisation and blinding

Randomisation was prepared in advance for each of Groups A and B, using random sampling tables and balanced in blocks of 10. The name of the IUD model to be used was printed on a piece of paper, which was placed in a sealed envelope labelled with the patient trial number. The randomisation envelope was not opened until after the gynaecological examination and uterine sounding. Because the devices were different in appearance and required different insertion techniques, it was not possible for the physician to be blinded as to which device was inserted. During fitting we took care to prevent the woman discovering the identity of the IUD. Indeed, the type of device fitted was not revealed to the woman until the end of the 6-week observation period, and after she had chosen whether or not to continue with the IUD, and stated her main reason for discontinuation if relevant.

We obtained each woman's written consent after discussing possible risks and benefits, and prior to IUD fitting. We took a medical, obstetric and gynaecological history, and performed a beta-human chorionic gonadotrophin Clearblue urine pregnancy test and a gynaecological examination. We screened for *C. trachomatis* carriage at IUD insertion, and offered prophylactic doxycycline 100 mg twice daily for 7 days.

To minimise any possible influence on the women's expectations of pain, all co-investigators worked from a standardised counselling text to inform the women of the method of IUD insertion. We encouraged all women to accept premedication with mefenamic acid 500 mg at least 30 minutes prior to their IUD fitting. We discussed local anaesthesia in advance. At the women's request, at any time after commencement of the procedure, we gave 10 ml 1% lignocaine into the anterior cervical lip and paracervical tissue.

Insertion procedure

Each inserting doctor was trained in IUD insertion and had successfully fitted at least 10 GyneFix devices prior to commencing the study. We used Allis forceps 18 cm long to hold and straighten the cervix, substituting this with single-toothed Vulsellum forceps if we encountered repeated slipping. Prior to randomisation we sounded the uterus using a centimetre-graded plastic sound, to establish cavity length and exclude distortion. If we could not insert the plastic sound through the internal cervical os, we attempted with a curved metal sound, prior to proceeding if necessary to metal Hegar dilators. We then inserted the

randomly assigned IUD model according to the manufacturers' instructions, and the inserting clinician noted whether insertion was easy or difficult.

Pain assessment

Visual analogue scales (VAS) as well as verbal descriptions were used to document each woman's perception of her degree of pain. Before commencing the IUD fitting each woman was shown how to complete a VAS (i.e. to draw a vertical line where she felt appropriate along a horizontal line 100 mm in length, the left end representing no pain at all, and the extreme right end the worst pain she could imagine). Prior to fitting, the woman completed a VAS to measure her anticipated pain of insertion. She completed further VAS scores at 5 minutes from the time we removed the IUD inserter tube (of the pain during insertion and the pain at 5 minutes), and again at 10 minutes (to measure the pain at 10 minutes). To ensure consistency, all time intervals were determined using a stopwatch, starting from the moment of removal of the IUD inserter tube. At 5 minutes after insertion each woman chose one from a list of 13 words that best described her experience of the insertion (see Table 4). At 10 minutes after insertion each woman completed a VAS, indicating her overall distress due to the entire insertion procedure (including emotional distress about the need for EC) using a similar horizontal line 100 mm in length, the left end representing no distress at all, and the right end the worst distress she could imagine. The inserting doctors completed a similar VAS to record their own assessment of the woman's pain.

Follow-up procedure

Where staff availability allowed, the nurse at the follow-up appointment had not also been involved in the initial fitting, and was thus blinded as to which IUD was *in situ* (as was each woman). We arranged follow-up for 6 weeks (± 1 week) from the date of fitting, after which each woman elected to continue with the same device, change to another method of contraception, or stop all contraceptives.

Those women who requested IUD removal were allocated, by consensus decision with the nurse, to prespecified categories (see Table 8). We took care to distinguish non-method-related reasons, e.g. no need for contraception, from possible adverse method-related events, e.g. bleeding or pain.

At the 6-week follow-up visit we asked each woman to recall the duration of pelvic pain she experienced on the day of insertion subsequent to the fitting. We asked if she did or did not experience pelvic pain in the 30 days subsequent to the day of insertion. We also asked her to complete a VAS to measure her late recall of the pain of IUD insertion.

Adverse events

Follow-up included a pelvic examination to verify the presence of the IUD. Expulsion and perforation were categorised as either partial or complete, and confirmed by ultrasound and X-ray as appropriate. Pelvic inflammatory disease (PID) was defined as a history of lower abdominal pain not starting prior to insertion, associated with cervical excitation and adnexal tenderness on examination, together with one of the following: pyrexia (> 38ºC), white cell count > 10 000/ml or erythrocyte sedimentation rate > 15 mm/hour.

Bleeding diaries

We required each woman to complete a diary record card for 30 days, commencing on the day after IUD insertion, documenting the occurrence of bleeding, and possible other events, including pain. We asked her to categorise her vaginal loss into bleeding (requiring the use of sanitary protection such as pads or tampons) and spotting (requiring no or only light sanitary protection). We calculated the total number of days of any bleeding and spotting, including any menstrual period, over the same time period. We obtained the woman's subjective assessment of quantity of the first menstrual period as compared with previous experience of menstruation prior to the IUD fitting.

Statistical considerations and data analyses

Outcome measures. Our primary outcome measure was pain at insertion. Secondary outcome measures included continuation rates, pain subsequent to insertion, bleeding, and reasons for discontinuation of the IUD.

Power calculations. We calculated sample sizes so as to be adequate to demonstrate a difference between the GyneFix and the comparator IUDs by a minimum reduction of 50% in the mean VAS scores of the insertion-linked pain (completed at 5 minutes). We decided[15] that we would need to look for a fall from 15 to 7.5 mm (SD 16). Based on a power of 80% and statistical significance at the 0.05% level, we calculated we would need to recruit 108 women to GyneFix, plus 54 women to each of the comparator IUDs. On deciding to eliminate the short-term arm of the study (see Results), we re-calculated that 75 women would be required in each of the GyneFix and the Gyne-T380S groups.

The data were transcribed into, and analysed with the aid of, the Statistical Package for the Social Sciences (SPSS) (SPSS, Chicago, IL, USA) software package, version 9. We compared the VAS scores relating to pain experiences during the insertion procedure (during fitting, and 5 and 10 minutes after) between the two IUD models and with the scores of the anticipated pain of insertion. Categorical data were compared using Chi-squared tests, with Fisher's exact test being used when frequencies were small. Continuous data were compared using two sample *t*-tests. For all statistical analyses $p < 0.05$ is considered significant, and 95% confidence intervals (CI) are quoted.

Analysis of adverse events

We included events reported as occurring in the 6 weeks (± 1 week) following insertion in the analysis (even though confirmation of the event, e.g. ultrasound scan confirming an IUD expulsion, might not become available until later).

Results

Numbers recruited

We randomised a total of 192 women: 175 to the long-term arm of the study (90 to GyneFix and 85 to Gyne-T380S) and 17 to the short-term arm (10 to GyneFix and seven to Nova-T200). Due to low recruitment to the short-term arm we decided after 20 months to discontinue this arm.

Our analysis is confined to comparing the GyneFix with the Gyne-T380S. We have included only those women allocated to the long-term arm. Separate analyses including and excluding the 10 women requesting a short-term IUD who received a GyneFix did not make a significant difference to the results obtained.

Demographics

There was no significant difference between the randomised groups in terms of age, parity and previous experience of vaginal examination and IUD use (Table 1). The prevalence of *C. trachomatis* on the pre-insertion endocervical swab was 2%.

Table 1 *Demographics of the randomised women*

Demographics	GyneFix® (n = 90)		Gyne-T380S® (n = 85)	
	n	%	n	%
Age at insertion (years)				
15–17	0	0	2	2
18–19	3	3	5	6
20–24	28	31	25	29
25–29	26	29	27	32
30–34	22	24	11	13
35–39	6	7	7	8
40+	5	6	8	9
Parity[a]				
Nulliparous	74	82	62	73
Parous	16	18	23	27
Previous TOP/miscarriage	52	58	35	41
No previous pregnancy	31	34	38	45
No previous vaginal examination	4	5	6	8
Question not asked (i.e. data missing)	*4*		*6*	
IUD use previously	14	16	13	15
Chlamydia-positive[b]	1	1	3	4

[a]Some women with previous TOP/miscarriage were also parous.
[b]Treated with IUD *in situ*.
IUD, intrauterine device; TOP, termination of pregnancy.

Numbers followed up

We achieved follow-up in 169/173 women (98%). (For 2/175 women the IUD was removed on the day of insertion.) The majority of women (162, 94%) were seen in person and examined; in 142 (88%) of these women follow-up was double-blinded, with the clinician involved not having been present at the time of IUD fitting. Follow-up was by post for four women (2%) and by telephone for three women (2%). In telephone follow-up we did not obtain VAS scores. More than half the women did not attend their planned follow-up appointment, and required reminding to attend for review, 35 (20%) attending later than 7 weeks after insertion. The timing of the follow-up visit was similar whichever device had been inserted.

Variables with IUD insertion

There was no statistically significant difference between the two groups in terms of the proportion receiving analgesia (pre- and peri-insertion), the use of Vulsellum (toothed) rather than Allis forceps, the use of a metal sound or Hegar dilators for cervical dilatation, inserting doctor, and the ease of insertion reported by the doctor (Table 2).

Failed implantation with the first GyneFix device occurred in four women, although in three of these a subsequent attempt with a second device was successful. In the fourth woman no further insertion attempt was made, and she was excluded from the study. There were no failed Gyne-T380S insertions.

Pain analysis

Pain of insertion. By chance, the pre-insertion anticipated pain was significantly higher in the GyneFix group than the Gyne-T380S group (p = 0.005, Table 3). We can be certain that this was a chance finding because this score was recorded prior to randomisation, and thus before either the woman or the medical staff had any way of knowing which device was to be inserted. The VAS score indicating the actual pain of insertion (recalled at 5 minutes after insertion) was also significantly higher for the GyneFix group (p = 0.013). This was matched by the assessments from the inserting doctors who perceived the insertion procedure to be significantly more painful for those women receiving a GyneFix (p = 0.04).

The difference was no longer statistically significant when analysis excluded those women who received local anaesthesia (the VAS of pain during insertion was 54 ± 23 for GyneFix and 48 ± 24 for Gyne-T380S, p = 0.12).

In choosing one word from the list provided to describe the insertion procedure, more women having the GyneFix chose the word 'sharp', whilst more having the Gyne-T380S chose the word 'cramping', but these differences were not significant (Table 4). A similar number from each group felt that the fitting procedure would deter them from using an IUD again in the future [15 (17%) for GyneFix and 12 (15%) for Gyne-T380A].

Pain after insertion. Significantly fewer in the GyneFix group recalled experiencing pain in the 30 days following the day of insertion (p = 0.005, Table 5). There was also a trend towards those in the GyneFix group recalling a shorter duration of pain on the insertion day (p = 0.056).

Bleeding analysis

In terms of the number of bleeding episodes and of the number of actual days of either spotting or bleeding for the subsequent 30 days after insertion, there were no significant differences between the two groups (Table 6).

Serious adverse events

The numbers of women were too small to meaningfully assess serious adverse events; however. no significant differences were noted between the two groups. The one perforation with GyneFix, which caused unilateral pelvic pain, was confirmed by X-ray 18 days after insertion, and the device removed laparoscopically. Two expulsions occurred in each group, and there were no episodes of pregnancy or of PID, as defined previously.

Table 2 *Variables within the IUD fitting procedure*

Variables	GyneFix® (n = 90)		Gyne-T380S® (n = 85)	
	n	%	n	%
Pre-insertion analgesia				
Mefenamic acid	86	96	80	94
Paracetamol	2	2	3	4
None	2	2	2	2
Local anaesthetic used	27	30	18	21
Vulsellum forceps used	0	0	4	5
Hegar dilators used	16	18	9	11
Metal sound used	23	26	18	21
Failure of initial procedure	4	4	0	0
Ease of IUD insertion				
Easy	75	83	73	86
Difficult	14	16	12	14
Failed	1	1	0	0
Doctor performing insertion				
Doctor 1	62	69	49	58
Doctor 2	9	10	19	22
Doctor 3	14	16	12	14
Doctor 4	4	4	4	4
Doctor 5	1	1	1	1

IUD, intrauterine device.

Table 3 *Pain of IUD insertion: visual analogue scores*

VAS (mm)	GyneFix®			Gyne-T380S®			Difference in means (95% CI)	p
	Mean	SD	n[a]	Mean	SD	n[a]		
Anticipated insertion pain (measured pre-insertion)	52	19	89	43	22	85	9 (3–15)	0.005 (S)
Pain during insertion (recall at 5 minutes)	57	24	89	48	24	85	9 (2–16)	0.013 (S)
Pain at 5 minutes after insertion	19	16	88	20	17	85	–1 (–6–4)	0.81 (NS)
Pain at 10 minutes after insertion	16	17	89	16	18	85	0 (–5–5)	0.78 (NS)
Overall distress (recall at 10 minutes)	47	28	88	40	28	84	7 (–1–15)	0.11 (NS)
Pain during insertion (recall at 6 weeks)	55	26	85	53	25	81	2 (–6–10)	0.52 (NS)
Doctor's perception of insertion pain	57	18	88	51	21	85	6 (0.1–12)	0.04 (S)

[a]The numbers differ because not all women completed each of the VAS scores.
IUD, intrauterine device; S, significant; NS, not significant; VAS, visual analogue scores.

IUD removal

At the follow-up visit at 6 weeks the decision as to whether to continue using the IUD was made by each woman prior to unblinding. Removal was requested by 20% of those with the Gyne-T380S and 13% of those with the GyneFix (Table 7). This excludes those women in whom expulsion or perforation had occurred. This small difference between the groups appears to be primarily due to a greater number requesting removal because of pain with the Gyne-T380S.

Discussion

Randomised comparative studies have concluded that for T-shaped IUDs failure rates, removal rates for bleeding or pain, and expulsion rates are significantly higher in nulliparous compared with parous women.[16] GyneFix has been proposed as an ideal IUD for nulliparous women because of its slimness, and its postulated lower risk of menorrhagia and dysmenorrhoea. However, previous randomised trials comparing the GyneFix with framed IUDs have not recruited nulliparous women, although nulliparous women have been included in various non-comparative studies.[9,11]

In this study, in which 78% of the women were nulliparous, the GyneFix compared favourably with the Gyne-T380S overall. Results suggest that the GyneFix may be more uncomfortable to insert, but that it is less painful in the 30 days thereafter, such that requests for removal due to pain are significantly less likely at 6 weeks.

The result of the significantly higher pre-randomisation and pre-insertion score for *anticipated* pain in those then allocated to receive a GyneFix as compared to those receiving a Gyne-T380S must be due to chance. However, it could also signify a higher level of anxiety in this group of women which, at least in part, could account for the higher insertion-linked pain scores. Interestingly, these women also recorded higher levels of 'overall distress' at 10 minutes post-IUD insertion, although the difference was not statistically significant compared to recipients of the Gyne-T380S.

Excluding data from women who received local anaesthetic resulted in no statistically significant difference in insertion-linked pain experience between GyneFix and Gyne-T380S.

This study found no difference in the duration of bleeding subjectively experienced between devices. A quantitative menstrual blood loss study in Brazil on 40 parous women also found no evidence of reduction in the volume of bleeding with the GyneFix as compared with the Gyne-T380S.[17]

Most randomised trials comparing GyneFix with the Gyne-T380A have found no statistically significant difference in discontinuation rates for bleeding or pain.[12,18] Although Wu et al., in a randomised controlled trial of 607 parous women in China,[19] found cumulative rates of removal due to bleeding and/or pain to be statistically significantly lower with GyneFix (0.7%) than with TCu380A (3.1%) at 1 year, there was no statistically significant difference at 3 years (4.5% with GyneFix vs 6.3% with TCu380A).

Table 4 *Pain of IUD insertion: descriptions chosen (only one answer allowed)*

Description of pain insertion (measured 5 minutes after insertion)	GyneFix® (n = 88)		Gyne-T380S® (n = 84)	
	n	%	n	%
Throbbing	2	2	1	1
Sharp	26	30	18	21
Hot burning	2	2	1	1
Tender	2	2	3	4
Sickening	5	6	4	5
Shooting	10	11	9	11
Cramping	24	27	30	36
Aching	4	5	3	4
Splitting	2	2	2	2
Fearful	0	0	1	1
Stabbing	7	8	11	13
Heavy	1	1	0	0
Punishing	3	3	1	1

IUD, intrauterine device.

Table 5 *Acceptability: pain experienced after IUD insertion*

Pain after IUD insertion (recalled at follow-up)	GyneFix® (n = 86)		Gyne-T380S® (n = 83)		p
	n	%	n	%	
On day of fitting					
None	3	4	3	4	0.056[a] (S)
< 1 hour	30	35	14	17	
1–6 hours	27	31	30	36	
6–12 hours	6	7	13	16	
12+ hours	20	23	23	28	
In the 30 days after IUD insertion	50	58	65	78	0.005 (S)

[a]Test for trend over total period of time.
IUD, intrauterine device; S, significant.

Table 6 *Acceptability: bleeding in first 30 days after IUD insertion*

Bleeding in first 30 days after IUD insertion	GyneFix® (n = 78)		Gyne-T380S® (n = 78)		Difference in means (95% CI)	p
	Mean	SD	Mean	SD		
Episodes of bleeding	1.9	0.9	2.1	0.9	–0.2 (–0.5–0.1)	0.303 (NS)
Days of spotting	7.5	5.3	6.6	4.3	0.9 (–0.6–2.4)	0.227 (NS)
Days of bleeding	7.4	4.2	8.2	3.6	–0.8 (–2.0–0.4)	0.217 (NS)

IUD, intrauterine device; NS, not significant.

If there is a difference in discomfort between framed and frameless devices this may well be more apparent in the nulliparous uterus. A non-comparative cohort study of GyneFix in 820 women found lower removal rates for bleeding/pain for the nulliparous than the parous women (0.5% vs 3.3% at 36 months).[9] Our study, unlike previous comparative studies, has predominantly nulliparous women. Although our numbers are small, we found that pain accounted for the difference in discontinuation between the two devices, with fewer women using GyneFix stating pain as their main reason for removal.

The age distribution of the women in our study reflects a London commuter population, and may not be representative of those requesting EC in community practice, where the vast majority of women are aged under 25 years. However, this will not have impacted our comparison between devices, since age distribution was similar in the two groups we studied.

We were encouraged that 81% of the subjects opted to continue use of the IUD beyond 6 weeks (this excludes the four women lost to follow-up). Most were previously using either condoms or had no regular method of contraception and thus for many the request for IUD EC would significantly reduce their long-term risk of unwanted pregnancy.

Since this study began there have been a number of changes in the availability of IUDs. The Nova-T200 has been discontinued (October 2001) and superseded by the more effective NovaT380®. The size and insertion techniques of these two IUDs are identical. The Gyne-T380S has also been discontinued (1999) due to financial reasons, and the nearest equivalent is the TSafeCu380A®, of which the Gyne-T380S was a modification, having a slightly smaller inserting diameter than the TSafeCu380A.

Future developments may reduce the problems of bleeding and pain associated with IUD insertion. These include a mini-GyneFix (the GF200®) with a copper surface area of just 200 mm^2, and GynePlant® (a frameless device containing both copper and levonorgestrel).[20,21]

Table 7 *Reasons for request for removal of IUD by women*

Reasons	GyneFix® (n = 83[a])		Gyne-T380S® (n = 82[a])		p[b]
	n	%	n	%	
Total	11	13	16	20	0.30
Bleeding	4	5	4	5	1.00
Pain	1	1	7	9	0.03
Other: method-related	1	1	2	2	0.62
Other: personal	5	6	3	4	0.72

[a]Excludes those women in whom expulsion or perforation occurred.
[b]Note small numbers.
IUD, intrauterine device.

Conclusions

Although this study does not show the GyneFix to be superior to the Gyne-T380S for ease of insertion or discomfort, it does suggest that pain is less subsequent to insertion, accounting for higher continuation rates. The high overall continuation rate of both emergency IUDs at 6 weeks and the low morbidity seen in this study, plus its higher efficacy over oral EC, should encourage us to offer IUD insertion more often where unprotected intercourse has occurred.

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Comparative trial of the force required for, and pain of, removing GyneFix® versus Gyne-T380S® following randomised insertion

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Abstract

Objective. *To assess the force required for, and pain of, removal of the GyneFix® as compared with T-framed intrauterine devices (IUDs).*

Design. *A comparative trial following patient-blinded randomisation in an outpatient clinic setting.*

Method. *Women requesting an IUD for emergency contraception were fitted with either a GyneFix or a Gyne-T380S®. For those requesting removal of the IUD, visual analogue scores were used to assess their perception of the associated pain, and a Newton dynamometer was used to measure the force required to remove the device.*

Results. *Removal required significantly more force for GyneFix as compared with Gyne-T380S ($p = 0.004$), but there was no significant difference in pain perceived by women during removal. Interestingly, anticipated pain was worse than actual pain experienced.*

Conclusion. *Although more force is needed to remove the GyneFix as compared with the Gyne-T380S, this does not translate into more pain.*

Key message points

- **More force is needed to remove the anchored GyneFix as compared with the framed Gyne-T380S.**
- **There is, however, no difference in the amount of pain perceived in removing the GyneFix as compared with the Gyne-T380S.**

Introduction

The GyneFix® is a flexible, frameless intrauterine device (IUD), developed in the mid-1980s, in an attempt to reduce the pain and bleeding associated with framed IUDs.[1] It has been marketed in the UK since early 1998, and is currently licensed for 5-year use.

Given that the GyneFix is attached to the fundal myometrium, it is likely that removal both requires more force and is associated with more pain than for a framed IUD which 'sits' unattached within the uterine cavity. Yet to date, no studies have objectively compared the removal of various types of IUDs.

We decided to assess both the force and pain involved in removal of the GyneFix as compared with the Gyne-T380S®. We studied women requesting removal of their device in a previously described randomised controlled trial comparing insertion-linked pain and the short-term user-acceptability and safety of the above devices.[2]

Methods

Ethics approval

The project was reviewed by the local research ethics committee of the Camden and Islington Community Health Services Trust, London, UK.

Description of IUDs used

The GyneFix[1,3] consists of six copper sleeves threaded on a length of polypropylene thread, giving a total exposed copper surface area of 330 mm^2. A knot on the proximal end of the thread is anchored in the myometrium of the uterine fundus at a controlled depth of 10 mm, using a specially designed inserter.

The Gyne-T380S[4] is a T-shaped IUD that has a polyethylene frame wound with 176 mg of copper wire on the stem, and collars each containing 66.5 mg of copper on its transverse arms. The total exposed surface area of copper is approximately 380 mm^2. The device includes a monofilament polyethylene tail, which aids in removal of the IUD.