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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.

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.<sup>2</sup>

### 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<sup>1,3</sup> consists of six copper sleeves threaded on a length of polypropylene thread, giving a total exposed copper surface area of 330 mm<sup>2</sup>. 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<sup>4</sup> 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<sup>2</sup>. The device includes a monofilament polyethylene tail, which aids in removal of the IUD.

### 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.<sup>1</sup> It has been marketed in the UK since early 1998, and is currently licensed for 5-year use.

### Admission procedure

Women had previously been self-selected from among the patients attending an open-access specialist National Health Service (NHS) contraception service in central London for emergency contraception. Of those requesting the IUD method, 192 women had consented in writing to be randomly assigned to receive either the GyneFix or the Gyne-T380S or the Nova-T200<sup>®</sup>, taking into account their intentions regarding short- or long-term use. Details of the eligibility criteria, randomisation and blinding have been described elsewhere.<sup>2</sup>

### Removal of the IUD

We asked each woman requesting removal of the IUD at the end of the 6-week observation period to complete visual analogue scales (VAS) to document her perception of pain experienced. We showed each woman how 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 the worst pain she could imagine.

Immediately prior to IUD removal we took a VAS measurement of each woman's anticipated pain of removal. We then clamped straight Spencer Wells forceps to the string(s) of the IUD. We removed the IUD by pulling on a calibrated Newton dynamometer hooked to one handle of the forceps. By use of a peak force indicator we were able to measure the maximum force used in removal. The force was calculated to the nearest fifth decimal figure. A stopwatch was started, and 5 minutes after removal each woman completed a VAS of the actual pain of removal, and also of the pain at 5 minutes. The doctors used a similar VAS to record their own assessment of the woman's pain of removal.

The type of device fitted was not revealed to the woman until completion of removal. Because the string(s) of the IUDs are different in colour and quantity, it was not possible for the physician to be blinded as to which device he/she was removing.

### Statistical considerations and data analyses

**Outcome measures.** Our primary outcome measure was the force of IUD removal. Our secondary outcome measure was pain at removal.

**Power calculations.** These were based on the pain of insertion.<sup>2</sup>

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 force required for removal of the GyneFix and the Gyne-T380S. We compared the VAS scores relating to anticipated and actual pain of the removal procedure, and pain 5 minutes after the removal. We also

**Table 3** Removal force and visual analogue scores

Removal force and VAS	GyneFix <sup>®</sup> (n = 7)		Gyne-T380S <sup>®</sup> (n = 13)		Difference in means (95% CI)	p
	Mean	SD	Mean	SD		
Force of removal (Newtons)	5.2	2.08	2.2	1.46	3.0 (1.1–4.9)	0.004 (S)
Missing data	2		1			
Mean VAS (mm)						
Anticipated pain (pre-removal)	54	19.8	38	19.9	16 (–3.6–35.6)	0.10 (NS)
Pain during removal (recall at 5 minutes)	22	12.3	20	18.4	2 (–14.4–18.4)	0.81 (NS)
Pain at 5 minutes after removal	8	7.6	7	8.2	1 (–6.9–8.9)	0.77 (NS)
Doctor's perception of removal	29	19.4	39	56.3	10 (–56.7–36.6)	0.67 (NS)

NS, not significant; S, significant; VAS, visual analogue score (data complete).

**Table 1** Reasons for request for removal of an IUD by women in the study

Reasons	GyneFix <sup>®</sup> (n = 7)		Gyne-T380S <sup>®</sup> (n = 13)	
	n	%	n	%
Bleeding	2	29	3	23
Pain	0	0	6	46
Other: method-related	1	14	2	15
Other: personal	4	57	2	15

**Table 2** Demographics of women in the long-term arm undergoing IUD removal

Demographics	GyneFix <sup>®</sup> (n = 7)		Gyne-T380S <sup>®</sup> (n = 13)	
	n	%	n	%
Age at insertion (years)				
18–19	1	14	1	8
20–29	3	43	6	46
30–39	2	29	4	31
40+	1	14	2	15
Parity <sup>a</sup>				
Nulliparous	7	100	8	62
Parous	0	0	5	38
Previous TOP/miscarriage	5	71	5	38
No previous pregnancy	2	14	6	46
IUD use previously	1	14	0	0

<sup>a</sup>Some women with previous TOP/miscarriage were also parous. IUD, intrauterine device; TOP, termination of pregnancy.

compared the investigator's VAS scores with the woman's VAS scores relating to the pain experienced during the removal. In comparisons of categorical data, Chi-squared analysis was performed, whereas continuous data were compared using two sample *t*-tests. For all statistical analyses  $p < 0.05$  is considered significant, and confidence intervals (CI) are quoted at the 95% level.

## Results

### Numbers recruited and followed up

In the original study, a total of 192 patients were randomised, 175 within the long-term arm of the study (90 to GyneFix and 85 to Gyne-T380S), and 17 within the short-term arm (10 to GyneFix and seven to Nova-T200). The latter arm was discontinued early due to low recruitment. Removal was undertaken in the research unit for 20 long-term users, and for 10 short-term users. (For a further seven long-term users removal was performed

**Table 4** Removal force and visual analogue scores (long- and short-term study arms)

Removal force and VAS	GyneFix® (n = 14)		Gyne-T380S® (n = 13)		NovaT200® (n = 3)		p
	Mean	SD	Mean	SD	Mean	SD	
Force of removal (Newtons)	6.1	1.97	2.2	1.46	1.8	2.80	< 0.0001 (S)
Missing data	2		1				
Mean VAS (mm)							
Anticipated pain (pre-removal)	49	22.6	38	19.9	49	9.0	0.39 (NS)
Pain during removal (recall at 5 minutes)	25	18.2	20	18.4	29	29.3	0.72 (NS)
Pain at 5 minutes after removal	12	21.3	7	8.2	7	5.5	0.73 (NS)
Doctor's perception of removal	30	21.5	39	56.3	14	17.4	0.61 (NS)

NS, not significant; S, significant; VAS, visual analogue score (data complete).

elsewhere.) Since the two groups were randomised separately, we considered it inappropriate to analyse the removal data jointly. Therefore the results below and in the Tables 1–3 relate to long-term users only. However, including in the analysis also the short-term users did not alter our findings significantly, as can be seen in Table 4. The indication for removal is shown in Table 1.

#### Demographics

There was no significant difference between those women randomised to GyneFix and Gyne-T380S in terms of age, parity and previous experience of vaginal examination and IUD use (Table 2).

#### IUD removal

The force required to remove the device was significantly higher for those with GyneFix [mean 5.2 Newtons (N)] as compared with Gyne-T380S (mean 2.2 N),  $p = 0.004$  (Table 3).

Yet there was no significant difference in the pain experienced during removal, either as assessed by the patient or as perceived by the doctor. Interestingly the patients anticipated the pain to be considerably more than they actually experienced. In fact, the pre-removal VAS scores were not dissimilar to the pre-insertion VAS scores at the commencement of the study.<sup>2</sup> The doctors perceived the removal pain to be considerably higher than actually documented by the patients.

#### Discussion

No previous comparison has been published of the difference in the force required to remove an implanted GyneFix as compared with framed IUDs. However, the forces required for IUD removal in our study are comparable to those quoted elsewhere. Wildemeersch et al. quote the average traction force required to remove an implanted GyneFix as 6 N, (I Bátor and D Wildemeersch, personal communication) which is three to four times that required for framed IUDs (1.0–1.7 N).<sup>5</sup> The myometrial tissue reaction at the site of anchorage of the polypropylene knot has been shown in hysterectomy specimens to be minimal.<sup>3</sup>

Importantly, this significantly greater force required to remove an implanted GyneFix as compared with the Gyne-T380S did not translate to any significant difference in

discomfort experienced by the patient, which was minimal for all devices. It should be noted that these findings are based on small numbers, with limited power to detect small differences in the pain of removal experienced.

Moreover, our pre-IUD removal VAS scores suggest that patients expect the removal experience to be as painful as the actual IUD insertion. Our findings confirm that this is not so, including for the GyneFix, and should encourage clinicians to counsel patients reassuringly.

#### Conclusion

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

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**Competing interests.** Professor Guillebaud has received *ad hoc* consultancy payments, lecture fees and research grants from various manufacturers of contraceptives.

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