# ADVANTAGES OF FRAMELESS INTRAUTERINE DEVICE AND SYSTEM IN **NULLIPAROUS AND ADOLESCENT WOMEN**

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#### **Abstract**

Background: The use of long-acting reversible contraceptives (LARC), particularly the intrauterine device (IUD) and implant, are advocated in young nulliparous and adolescent women as they don't require daily adherence.

Objective: To provide expert advice on the use of IUDs in these women based on clinical experience in order to maximize continuation of use of the method.

Results: The clinical study results presented in this poster suggest that high continuation of use of an IUD can be achieved by giving attention to the geometric relationship between the IUD and the host uterine cavity. Frameless IUDs virtually eliminate pain complaints and embedment seen with too large IUDs.

Conclusion: Appropriate intrauterine devices could enhance continuation of use and result in high continuation of use and, as a consequence, result in fewer unintended pregnancies and induced abortions.

## Introduction

When considering the size of the uterine cavity in young women and the size of the available IUDs, most IUDs are too large for the majority of these young women.

Almost 50 years ago, researchers stressed the importance of an optimal interrelationship between the IUD and the uterine cavity as fewer side effects and greater acceptability would thereby be promoted. Clinical shows experience that geometric incompatibility between the rigid or semi-rigid IUD and the uterine cavity can lead to partial or total expulsion, embedment, pain, unintended pregnancy, and abnormal or heavy uterine bleeding, resulting in removal of the device. Discontinuation rates after 6 months or one year of 40 to 50% are not unusual. Early discontinuation places these young women at risk of unintended pregnancy as many among them move to less effective methods or to no protection at all. Early discontinuation undermines the potential of the IUD to reduce unintended pregnancy. In addition, the wasted expense of the IUD and the burden of insertion provokes bad publicity for this method.

This presentation reports on the use of frameless copper and LNG-releasing IUD/IUS in nulliparous and adolescent women.

## **Materials and Methods**

The data for the current multicenter study were extracted from an earlier study12 with the frameless copper IUD (small version) and supplemented with data recently collected from a currently ongoing post-marketing study. Data for the frameless LNG-IUS in nulliparous women younger than 25 years of age and adolescent women were taken from previous contraceptive studies13 with this system. All participants in the study were screened as to their clinical suitability for IUD insertion and compliance with the World Health Organization eligibility criteria.

#### Results

One hundred and fifty-four nulliparous and adolescent women were followed up in this study for at least 2 years. Age and duration of use distribution is given below (Table 1 and 2).

Table I Age distribution of the GyneFix® and FibroPlant®-LNG contraceptive users (all women ≤25 years)

Age (years)	GyneFix n=104	FibroPlant n=50
Mean (SD)	20.8 (2.8)	19.8 (3.2)
Range	(14, 25)	(15, 25)

Note: GyneFix, Contrel Research (Ghent, Belgium). FibroPlant, Contrel Research. eviation: LNG, levonorgestre

Table 2 Distribution of the duration of usage of the GyneFix® and FibroPlant®-LNG

Duration (months)	GyneFix n=104	FibroPlant n=50
Mean (SD)	22.5 (12.9)	37.9 (19.7)
Range	(1, 90)	(2, 85)

Notes: Mann-Whitney U-test: P<0.001. GyneFix, Control Research (Ghent,

One pregnancy occurred with the GyneFix 200 IUD after unnoticed early expulsion of the device. Two further expulsions were reported, one with the GyneFix 200 IUD and the other with the FibroPlant LNG-IUS. The total discontinuation rate at one year was low (3.3 and 4.3 with the copper IUD and LNG-IUS, respectively) and resulted in a high rate of continuation of use at one year (96.7 with the copper IUD and 95.7 with the LNG-IUS, respectively). Continuation rates for both frameless copper IUD and frameless LNG-IUS remained high at 3 years (.90%). There were no cases of perforations or pelvic inflammatory disease reported during or following insertion.

Table 3 Event and cumulative gross discontinuation rates per 100 women/year in 104 GyneFix® users and 50 levonorgestrel-releasing FibroPlant® contraceptive users

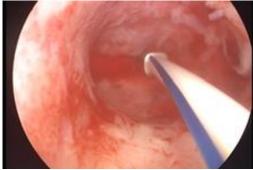
	Gyr	GyneFix		FibroPlant		
	n	Rate (SE) 95% CI		n	Rate (SE) 95% CI	
		At one year	At 2 years		At one year	At 2 years
Accidental pregnancy	- 1	1.1 (1.08) [0.027-6.09]	1.1 (1.08) [0.027-6.09]		-	-
Expulsion	2	1.1 (0.76) [0.13-3.91]	2.8 (1.98) [0.34-10.24]	- 1	2.2 (2.15) [0.054-12.17]	2.2 (2.15) [0.054-12.17]
Planned pregnancy	1	1.1 (1.13) [0.028-6.37]	1.1 (1.13) [0.028-6.37]	- 1	2.2 (2.15) [0.054-12.17]	2.2 (2.15) [0.054-12.17]
Total use-related	4	3.3 (1.63) [0.89-8.44]	5.1 (2.47) [1.37-12.93]	2	4.3 (3.01) [0.52-15.65]	4.3 (3.01) [0.52-15.65]
discontinuation						
				(	GyneFix	FibroPlant
Women recruited					104	50
Continuing users				9	97	47
Lost to follow-up				3	3	1
Woman-months of use	(total p	period)		(	6,304	4,635
Cumulative continuation rate per 100 women at one year		9	96.7	95.7		
Cumulative continuation rate per 100 women at 2 years				94.9	95.7	
	n mto r	per 100 women at 3 years		( ,	94.9	95.7

#### **Discussion**

Intrauterine devices (IUD) are long-acting reversible contraceptive methods that are independent from daily attention. Unlike methods that need daily motivation, IUDs are 'forgettable' methods that are also highly effective. They are, therefore, advocated by all major organization to prevent unintended pregnancy. However, current IUD use often leads to early discontinuation, even within 3 or 6 months following insertion. It is known for many years that IUDs perform best, leading to high continuation of use, if attention is given to geometric factors such as size and shape of the host uterine cavity prior to inserting an IUD. Continuation of use, for the full claimed duration of action, will usually remain low if the relationship between IUD and uterine cavity is out of proportion.







Frameless LNG-IUS