

Submitted

Three-year efficacy and acceptability of the GyneFix[®] 200 intrauterine system (IUS)

Xiaoming Cao,* Wenhao Zhang,* Xun Zhao,* Nong Lin,* Limei Wang,* Chunhua Li,*
Lijuan Song,* Weijia Zhang,* Zhihong Zhang,* Dirk Wildemeersch*

**Tianjin Municipal Institute for Family Planning, Tianjin, China*

***Control Research, Ghent, Belgium*

Abstract

Objective

This study was conducted to evaluate the efficacy of a 'mini' version of the frameless IUS (GyneFix[®]) which has a copper surface area of approximately 200 mm². The small GyneFix version consists of 4 copper cylinders instead of 6 and is only 2 cm long.

Materials and methods

A total of 392 insertions were performed in an open non-randomized study in parous (76%) and nulligravid/nulliparous (24%) women in Belgium and China. This interim analysis reports on 13,699 women-months of use. All women were followed-up for a minimum of 12 months, up to three years and more.

Results

Four pregnancies occurred with the GyneFix 200 IUS in this study of which one occurred after unnoticed expulsion of the device, yielding a cumulative failure rate of 0.48 at three years. The cumulative removal rate for medical reasons was 1.65 at three years and the expulsion rate was 0.39. These low event rates resulted in a high continuation of use (93.92 at three years). Neither perforations nor PID cases were encountered in this study.

Conclusion

The present study suggests that the GyneFix 200 IUS is highly effective and probably as effective as the standard GyneFix IUS. This is attributed to the anchoring of the device to the fundus of the uterus promoting its contraceptive action. The fact that the total surface area of the device, releasing a maximum amount of copper ions, is a fundamental difference with conventional IUDs and probably essential in obtaining the high contraceptive efficacy seen in this study. The small total surface area of the GyneFix 200 IUS also minimizes menstrual bleeding and is an improvement over larger types of conventional IUDs, as indicated by the low removal rate for abnormal bleeding with the small GyneFix.