

Submitted

Menstrual blood loss with a miniature, “frameless”, copper-releasing intrauterine system

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Abstract

Objective

To evaluate the effect on menstrual blood loss of a novel “frameless” copper-releasing intrauterine system (IUS), GyneFix[®]200, having an effective copper surface area of 200 mm².

Study design

An open label, non-comparative menstrual blood loss study. Menstrual blood loss was assessed in 60 parous (n=23) and nulliparous women (n=37) with age between 17-46 years of age (mean 30.4) using a visual assessment scoring technique. Menstrual scores were calculated at different time intervals following insertion of the IUS. The menstrual period prior to insertion of the IUS and the menstruation most recent to the last follow-up visit were assessed. The trial covers a period from 3 months to more than 4 years (average 31 months).

Results

Women reported similar menstruations with the GyneFix 200 IUS when compared with menstrual blood loss before insertion. This corresponds closely with the menstrual scores. The median bleeding score before treatment was 110.5 (range 28-265) and 110 (range 28-260) after 3 to 51 months follow-up which is not statistically different (P = 0.596).

Conclusion

This study suggests that the GyneFix[®]200 intrauterine system does not increase menstrual blood loss. The small size of the IUS is the main explanation for the reduced effect of the device on menstrual bleeding.