

Treatment of menorrhagia with a novel “frameless” intrauterine levonorgestrelreleasing drug delivery system: a pilot study

D. Wildemeersch*, E. Schacht**

*Control Research, Technology Park Zwijnaarde, Ghent, Belgium

**Polymer Research Group, University of Ghent, Department of Chemistry, Ghent, Belgium

Abstract

Objective

To evaluate the effect on menstrual blood loss of a novel “frameless” intrauterine drug delivery system (IUS), FibroPlant-levonorgestrel (LNG), releasing 14µg of LNG/d. An ancillary objective being to evaluate the contraceptive performance.

Study design

An open label, non-comparative ongoing pilot study. Thirty-two insertions were performed in fertile women between 31 and 51 years of age for the treatment of menorrhagia as well as for contraceptive purposes. Fifteen women were fitted with the FibroPlant-LNG IUS immediately following removal of a copper-bearing IUD, the GyneFix IUD, who developed excessive bleeding. To discriminate between menorrhagia and normal menstrual blood loss, women were evaluated using a simple visual assessment technique. The trial covers a period from a minimum of 1 month up to 23 months.

Results

At the time of study analysis the total number of women-months was 361. Fourteen women having the FibroPlant-LNG IUS in place for periods in excess of one year and twenty-nine women for 6 months or more. All women reported greatly reduced bleeding. However, no cases of amenorrhea resulting from endometrial suppression were encountered. The reduction of bleeding was appreciable after one month of treatment and decreased further over the next months to remain stable afterwards. The mean bleeding score before treatment was 338 (185-740) in the group with no prior IUD use and 368 (185-890) in the group with prior IUD use, respectively, and dropped to a mean score of 70 (range 5-210) in the 'no prior IUD use' group and to a mean score of 52 (3-150) in the 'prior IUD use' group, respectively after 1 to 23 months follow-up which is highly statistically significant ($p < 0.001$). There was no statistical difference in bleeding scores before and during treatment between the two groups of women with or without prior copper IUD.