

## **Contraception and treatment in the perimenopause with a novel “frameless” intrauterine levonorgestrel-releasing drug delivery system: an extended pilot study**

D. Wildemeersch (1), E. Schacht (2), P. Wildemeersch (1)

(1) Contrel Research, Technology Park Zwijnaarde, Ghent, Belgium

(2) Polymer Research Group, University of Ghent, Department of Chemistry, Ghent, Belgium

The objective of the study is to evaluate the contraceptive performance, acceptability, side effects and adverse events of a novel “frameless” intrauterine drug delivery system (IUS), FibroPlant-levonorgestrel (LNG), releasing 14µg of LNG/d, in perimenopausal women. An ancillary objective is to evaluate the effect of the new IUS on menstrual blood loss in women with or without fibroids.

The study conducted in one-hundred-nine women suggests that FibroPlant-LNG IUS is an effective contraceptive. No pregnancies occurred with the FibroPlant-LNG IUS. The total use-related discontinuation rate at one year is low (1.9) and results in a high rate of continuation of use (98.1). In addition the FibroPlant-LNG IUS demonstrated a high level of effectiveness in reducing bleeding in women with excessive menstrual flow even when medium or large fibroids were present. An effect, however, on the size of the fibroids could not be demonstrated.

Patient satisfaction with the method is high, which is a prerequisite for continuance of the method, and may be linked with the advantageous design characteristics of the FibroPlant-LNG IUS, the virtual absence of hormonal side effects and the low incidence of irregular bleeding and spotting even during the first three months following insertion of the FibroPlant IUS. Counseling remains important though to explain women about the possible occurrence of changes in their menstrual pattern which may sometimes be annoying but harmless.

It is concluded that many women over 40 could substantially benefit from the advantages of intrauterine drug delivery which provides contraception and treatment of a possible associated condition such as menorrhagia. The treatment also creates the opportunity to pass through the transitional perimenopausal period smoothly and to benefit fully from the advantages hormone replacement therapy offers in terms of treatment of short-term symptoms and long-term prevention by gradually replacing the waning estrogens.

Further reading: Wildemeersch D. Development of a miniature, frameless intrauterine levonorgestrel-releasing intrauterine system for contraception and treatment: a review of clinical experience. *Reproductive BioMedicine* 2001; vol. 4,1:69-80 ([www.rbmonline.com](http://www.rbmonline.com)).