

## **Endometrial suppression with a new “frameless” levonorgestrel releasing intrauterine system in perimenopausal and postmenopausal women: a pilot study**

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### **Abstract**

A novel intrauterine drug delivery system, FibroPlant-levonorgestrel (LNG), derived from the frameless GyneFix intrauterine device (IUD) is described and the preliminary results in 30 symptomatic climacteric and postmenopausal women are discussed. The treatment with the FibroPlant-LNG intrauterine system (IUS) was instituted to suppress the endometrium during estrogen substitution therapy (EST) to prevent endometrial proliferation and bleeding. The purpose of the study was to evaluate the clinical and ultrasonographic effect of this new intrauterine progestin delivery system. Two dosage forms were tested: the first 11 women received a 3-cm long coaxial fibrous delivery system, delivering approximately 10 µg/day of LNG; the remaining 19 women in the study received a 4-cm long delivery system, delivering approximately 14 µg/day. The calculated duration of release of the two systems is approximately 5 years. Twenty-two women were perimenopausal at the start of the treatment. Women in this study were observed during at least one year. Most postmenopausal women received percutaneous 17β-estradiol (Oestrogen), 1.5 mg daily on a continuous basis.

### *Results*

All postmenopausal women in the 2 groups reported amenorrhea during the entire study period (up to 2 ½ years follow-up). Endometrial atrophy in these women was confirmed by vaginal ultrasound examination. Seventeen of 22 perimenopausal women reported amenorrhea at the first or second follow-up visit at 1 and 3 months following insertion of the IUS, respectively. The remaining had infrequent scanty bloody discharge needing a panty liner, at the most, for protection. There were no complications in this study (e.g., infection, expulsion or perforation). The FibroPlant-LNG IUS is very well tolerated by all women and no systemic hormonal side effects were reported. There were no removals for medical reasons.

### *Conclusion*

The results of this pilot study suggest that the frameless FibroPlant-LNG IUS is safe, well tolerated and effective in suppressing the endometrium during EST. No differences could be clinically distinguished between the 2 dosages. Compliance was optimal. The fact that the IUS also acts as a potent contraceptive is of added importance.