

## **Observational evaluation of the effect of a combiphasic oral contraceptive on cycle control and acne**

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**Objective:** To assess the efficacy, tolerability, and the effect on facial acne of a combiphasic desogestrel (DSG) containing oral contraceptive (OC) (Gracial®). **Design & Methods** An open-labeled, multi-center clinical trial was performed in Hungary. Six hundred female volunteers were included in this interim-analysis and all were switching from another OC. The women received the combiphasic, DSG-containing OC (7/15 days of 25/125 µg DSG and 40/30 µg ethinylestradiol) for at least 6 months. Cycle-control parameters, severity of acne and the patients' satisfaction were assessed at baseline and after 6 treatment months. Statistical analyses included the Student's paired t-test for continuous variables and Wilcoxon's matched pairs signed rank test for categorical variables.

**Results:** The mean age of the female volunteers was 26.0 years (SD 6.2). The main reasons for switching OCs were menstrual problems (34.3%), acne (32.8%), and headache (17.0%). Duration of menstrual bleed decreased significantly from 4.7 days at baseline to 4.0 days after 6 treatment months. The proportion of regular cycles increased to almost 100% at the end of the study-treatment period. The intensity of menstrual bleed shifted more towards normal, with only 0.2% of the women experiencing more than normal bleed after 6 treatment months. The proportion of women with spotting (27.0%) or breakthrough bleeding (18.5%) at baseline decreased with 96% and 95%, respectively. There was a significant relative reduction of women with facial acne of 50% compared to baseline, and the women with continuous acne (22.6%) showed a decrease in the number of pustules. There were no clinically relevant changes in bodyweight or blood pressure. Nearly all women (98.5%) were either satisfied or very satisfied with the combiphasic DSG-containing OC.

**Conclusions:** Gracial® is well tolerated by the women. The combiphasic DSG-containing OC has a significantly positive effect on cycle control and it decreases the severity of acne significantly.