Original research article

A randomized trial on the clinical performance of Nova T®380 and Gyne T®380 Slimline copper IUDs☆

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Abstract

Purpose: The objective of this open randomized study was to compare the clinical performance of Nova T®380 and Gyne T®380 Slimline copper intrauterine devices (IUDs).

Materials and Methods: Eligible for analyses were 957 Norwegian parous women aged 18–45 years. Clinical performance was measured upon the removal of IUD due to contraceptive failure, expulsion, bleeding, pain, pelvic inflammatory disease and other medical reasons during a 5-year study period.

Results: The discontinuation rate due to contraceptive failure was significantly higher in the first year for Nova T®380 users than for Gyne T®380 Slimline users, whereas no differences were observed thereafter (the 5-year cumulative failure rates were 4.4% and 2.2%, respectively, per 100 women). However, the partial expulsion rate was significantly higher in the first year for Gyne T®380 Slimline users than for Nova T®380 users (the 5-year cumulative rates were 3.4% and 1.1% respectively, per 100 women). No other major differences in reasons for discontinuation were found between the study groups. There was a slight nonsignificant increase in hemoglobin levels for both study groups over the course of the study.

Conclusion: Clinical performance was considered satisfactorily high for both devices.

Keywords: Nova T®380; Gyne T®380 Slimline; Copper IUD; Clinical performance; Bleeding; Pain; Contraceptive failures; Partial expulsion; Total expulsion

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