An open randomized trial of two copper-IUDs, nova Tâ 380 versus gyne Tâ 380 slimline: three-year results

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Objective: To compare user effectiveness of two copper-IUDs; NOVA T®380 versus GyneT®380 Slimline (GyneT), in a prospective open randomised trial.
Methods: The study was carried out among 30 general practitioners at 13 medical centres in the city of Trondheim, Norway, from May 1993 through June 2000. Included were parous women, 18 to 45 years of age at insertion, and who had completed most recent pregnancy at least 7 weeks prior to insertion. 957 women fulfilled inclusion criteria, 470 were randomised to the NOVA T®380 group and 487 to the GyneT group. At insertion there were no differences between the randomised groups related to demographic data nor contraceptive history. Survival analyses were used for comparison of IUD related outcomes between the devices. Totally 4.2% of the women were lost-to-follow-up.
Results: At 12 months there was a statistically significant difference in favour of GyneT in preventing pregnancy ($p<0.05$). After 12 months there was no difference in efficacy between the devices. On the contrary, significantly more GyneT users experienced a partial expulsion than NOVA T®380 users ($p<0.05$). No other removal related differences were observed among the study groups. 52% of the NOVA T®380 users and 47% of the GyneT users completed 36 months of follow-up.
Conclusion: During the first year of use GyneT users had statistically significantly better efficacy than NOVA T®380 users, but not thereafter. Except for partial expulsion, the study showed no other significant differences in IUD related outcomes between the study groups.