

P112. Physical tests of the Levosert T-frame and its inserter provide objective parameters that confirm their safety and easiness at insertion

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OBJECTIVE

To better characterize the physical properties of the Levosert T-frame (viscoelastic property) and its inserter (flexibility and tipping of the inserter) in comparison with two other long acting reversible contraceptives (LARCs) releasing small doses of levonorgestrel (Mirena and Jaydess).

METHODS

The results of the three tests (Memory, Buckling and Puncture Test) were evaluated by a statistical comparison (student t-test with a confidence interval of 5%) to determine the equivalence of the physical properties ($p > 0.05$) of the studied products.

MAIN OUTCOME MEASURE(S)

Physiological uterine contractions observed during menstrual cycle are capable of generating up to 50 N of myometrial force depending on internal pressure and surface area. Therefore is desirable to insert LARCs with a flexible T-frame that can easily accommodate such contractions. A rigid T-frame can cause painful penetration of the tips of the horizontal arms during contractions causing endometrial trauma and bleeding. The viscoelastic property determines the deformability and capacity to adjust to the uterine wall.

Perforation at insertion is a rare but serious complication of IUD use. The forces required to perforate the myometrium (>30 N) are greater than the forces needed to insert an IUD if the inserter tube is flexible, because it will simply "bow" if it comes up against the myometrial wall.

Sharpness of the inserter extremity is also an important component of insertion easiness, pain and perforation. The Puncture Test, commonly used in medical applications for determining the sharpness of a device, consists in measuring the strength needed to rupture an aluminum foil.

RESULT(S)

Levosert demonstrated significantly better viscoelastic properties. Its horizontal arms recovered their initial position faster than the two other LARCs.

The strength required to kink the Levosert inserter tube was similar or slightly higher than Mirena and Jaydess, but well below 30 N.

The force required to puncture the foil was significantly higher for Levosert than for the two other LARCs, demonstrating a mark reduction in sharpness of the Levosert inserter tube.

CONCLUSIONS

Intrauterine contraception is a first-line option for parous and nulliparous women. The physical tests of the Levosert T-frame and its inserter confirm that they are well designed to avoid most side effects and pitfalls observed during LARCs insertion (failure, pain, endometrial trauma and bleeding or perforation).

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