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INSTRUMENT REVIEW

A Three-Dimensional Way to Prevent Pregnancy: The IUB Intra Uterine Ball—A Newly Introduced IUD in Clinical Trials

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Introduction

The intrauterine device (IUD) is the most frequently used reversible family planning method in the world. The earlier IUDs made of inert plastic materials have largely been superseded in modern medical practice by improved designs which release copper or levonorgestrel (LNG-IUS). These modifications considerably enhanced the efficacy of the IUD. However, the modern copper IUDs in their different shapes exist already over 40 years in clinical use and the levonorgestrel IUDs for more than 20. While highly effective, IUDs are associated with complications, including fundal perforation, malposition, and expulsion. Aggregated prevalence of these issues is estimated at 7–12 %. Most innovations in this field in the last years were mostly in trying to improve insertion safety by minor changes in IUD shapes (most of them T-shaped or a copper-coated thread known as "frameless") and remodeling of the insertion kits. These innovations, however, have not changed the complication rates.

We report on a newly developed IUD with a three-dimensional structure—the IUB—the intra uterine ball.

IUB General Description

The SCu300A IUB™ is a copper IUD which upon insertion in the uterus takes a three-dimensional spherical "ball" form. The IUB™ is deployed and removed in the same manner as standard IUDs and is expected to have the same efficacy. Due to its form and deployment process the IUB™ is expected to reduce risks of perforation, malposition, and expulsion and as came up from early studies may also reduce patient discomfort and menorrhea.

Device Specifications and Technical Information

The IUB™ is made of a NiTinol alloy wire, with characteristics to keep its preset shape. The wire is covered with a thin white polymer coating. The 17 pure copper spheres are threaded over the wire (see Fig. 1 below). The distal sphere is attached at one end to reduce sharpness and the proximal sphere is attached together with the thread. The total copper surface area is 300 mm^2. A 20-cm-long double-tailed uncolored nylon monofilament thread is attached for removal. Once deployed, the IUB™ is ~12 mm in diameter, however, it is likely to accommodate its shape to the

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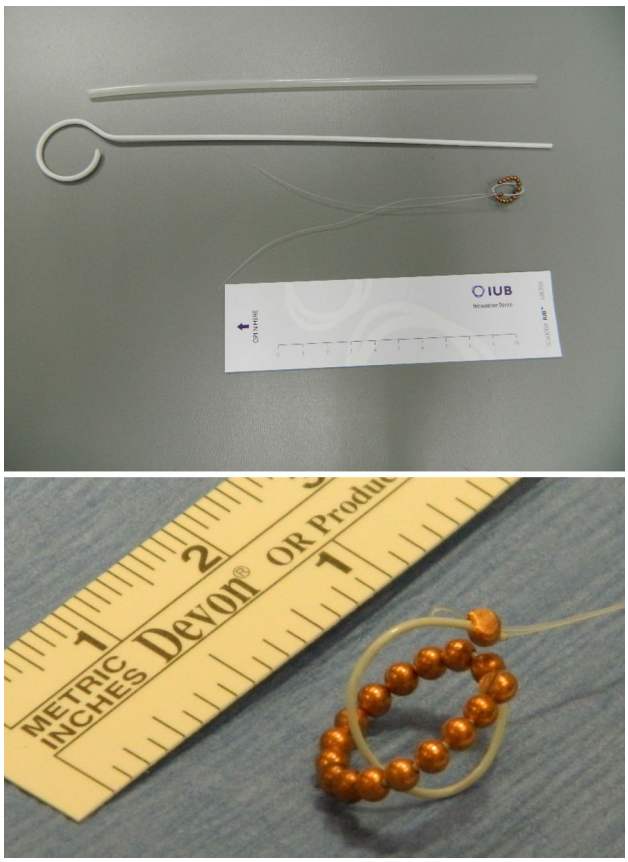

Fig. 1 The IUB™ with insertion kit (*upper*) and released (*lower*)

uterine cavity. The IUB™ is intended to have a lifetime of 5 years.

Insertion Technique

The IUB is inserted to the uterus, using the same simple insertion kit of plastic tube and a push rode. This very simple inserter (Fig. 2) nullifies the need for doctor's insertion training and as a matter of fact, any health care provider, including community nurses, can easily be trained to insert IUBs.

Fig. 2 IUB loaded in an insertion tube

After introduction of the loaded tube into the uterine cavity, the health provider releases the IUB by pushing the rope forward into the tube. The IUB is emerging from the tube in a 180° angle counter the uterine fundus (Fig. 3)—thus decreasing the risk of perforation.

The ball structure and absence of sharp edges are pillars for preventing mal-position and uterine wall irritation and the final 12 mm outer diameter of the IUB reduces the chance of expulsion through the utero-cervical canal.

Proof of Concept Clinical Trial

The results of the first human clinical trial were published recently [1]. Fifteen healthy women aged 25–42 were recruited to assess the initial safety and efficacy of the IUB and were followed for 1 year, with follow-up visits at 1, 3, 6, 9, and 12 months. Women satisfaction, as well as menstrual pain and discomfort level were recorded and compared to the time before insertion. Physician rate for ease of insertion and removal was reported on 1–5 scale (1 easy, 5 difficult). All devices were inserted by the same

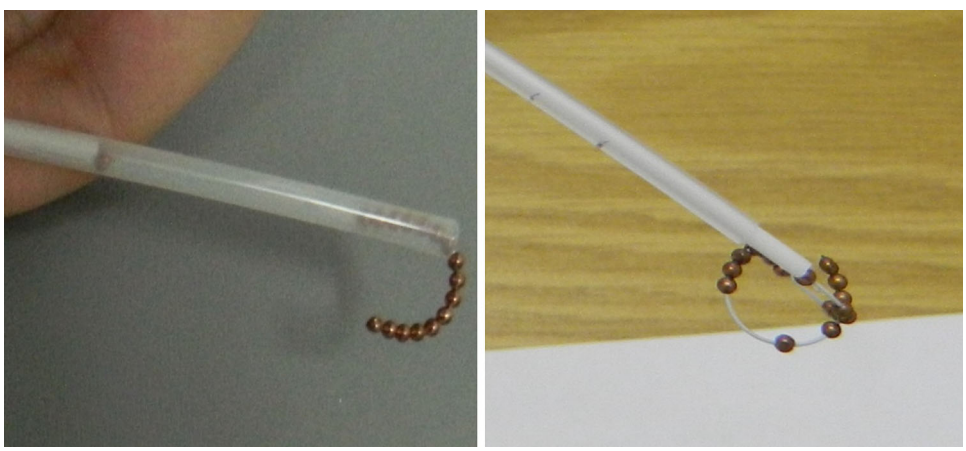

Fig. 3 IUB release partially (*left*) and to a fully ball shape (*right*)

procedure; the lead author, the IUB inventor, supervised the PI for the first patient.

Results

Of 15 women participating in the study, one subject discontinued the study before the 6 month visit because of excessive bleeding. A D&C pathology result revealed simple endometrial hyperplasia (A non IUB related event). No perforations, expulsions, mal-positions, pregnancies, or complications were recorded. Abdominal pain was reported by 1 woman 1 month after insertion, and then by 2 women at 3 months and 1 year.

Conclusions

The safety profile of the IUB™ device appears similar or better than that reported in the literature, with no perforations, expulsions, mal-positions, or complications and a discontinuation rate of 7.14 %. The participating women reported high satisfaction rate and there was a tendency toward improving dysmenorrhea. The small study size was appropriate only for proof of concept. A large-scale prospective comparative study is on the way.

References

1. Baram I, Weinstein A, Trussell J. The IUB, a newly invented IUD: a brief report. Contraception. 2014;89:139–41.