



OB23 BufferGel® Duet: Safety and Acceptability Study of a Novel Product Combining a Mechanical and Chemical Barrier in the Vagina

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ABSTRACT TEXT

Background:

BufferGel® is a spermicidal/microbicidal gel containing Carbopol 974P, a cross-linked, polyacrylic acid, osmotically balanced with salts to a pH of 3.9. It is meant to be used alone or with a cervical barrier.

The BufferGel® Duet combines BufferGel® with a cervical barrier to enhance protection against STIs/HIV and pregnancy. The device is a single-use disposable intravaginal product 70mm in diameter made of clear polyurethane in the shape of a sombrero and preloaded with BufferGel®. The novel design is intended for minimum loss of gel to the packaging and delivery of approximately 6mL of BufferGel® on the vagina and 4 mL of gel to the cervix. Six (6) mL of BufferGel® will acidify more than three times the volume of an average ejaculate, keeping the pH at <5.0 to maintain protective vaginal acidity during and after intercourse.

Methodology:

This first clinical trial of the BufferGel® Duet was designed to assess function (ease of insertion and removal, correctness of position after insertion, and frequency of dislodgments), safety, effect on vaginal pH, and acceptability. It was a Phase I, non-comparative study in 30 couples not at risk for pregnancy in the Dominican Republic and Norfolk, VA. Following a test of fit and insertion, the device was assessed during two acts of intercourse over one week.

Results:

Thirty couples completed the study in November 2005. Preliminary results show that the device fit 29 of 30 women, was easy to insert and remove, and appeared safe and acceptable. In a subset of 15 users, 12 were able to insert the device using written instructions without clinician assistance. Weighing the packaging after the device was removed by these 15 users demonstrated that 95% of the packaged gel ended up on the device. Colposcopy findings and more detailed results will be presented at the meeting.

Conclusions:

The BufferGel® Duet fit most women and was easy to insert and remove. The device appeared to be safe and women liked the alternative of the device as a gel applicator. This trial validates the concept of a cervical barrier prepackaged with microbicide.

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