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Successful Postcoital Test Results of a Novel Monthly Hormone-Free Vaginal Contraceptive

A. THURMAN[1], J. BAKER[2], J. JENSEN[3], C. SCHREIBER[4], N. ZACK[5], C. MAUCK[5]
[1]Eastern Virginia Medical School, Norfolk, VA, [2]Clinical Research Prime, Idaho Falls, ID, [3]Oregon Health & Science University, Portland, OR
[4]University of Pennsylvania, Philadelphia, PA, [5]Daré Bioscience, Inc., San Diego, CA

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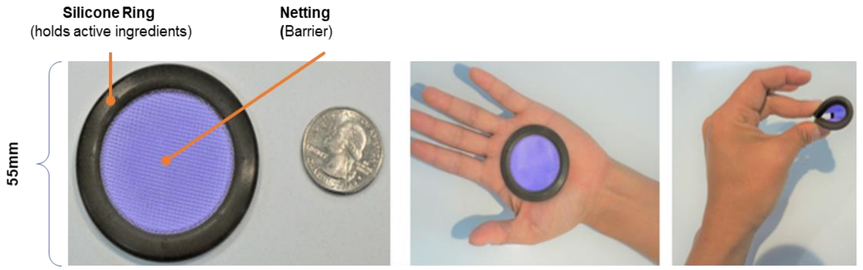
INTRODUCTION

Ovaprene®: a novel **hormone-free** monthly intravaginal contraceptive candidate

- **Once-monthly** use: Inserted at the end of menses and left in place until the next menses
  - **No interruption of intercourse**
- **Two parts** work together to prevent pregnancy:
  - Knitted polymer **barrier** across the opening of the ring to physically block sperm from entering the cervix, while allowing egress of cervicovaginal fluids.
  - Vaginal ring releasing locally acting non-hormonal **ferrous gluconate** to impede sperm motility.



AIM OF STUDY

Determine the **reduction in the number of progressively motile sperm** that enter midcycle cervical mucus when **Ovaprene** is in place compared with when **no device** is in place.

METHODS

Subjects: Premenopausal women with tubal sterilization and regular cycles.
Studied during 3 menstrual cycles:

Baseline cycle (no device)			First Ovaprene cycle				Second Ovaprene cycle			
Mucus check	Sex	Postcoital test	Insert Ovaprene	Mucus check	Sex	Postcoital test	Insert Ovaprene	Mucus check	Sex	Postcoital test

In each cycle, urine ovulation predictor kits were used to determine midcycle.
At the midcycle **mucus check** visit, cervical mucus was examined to confirm midcycle characteristics and absence of sperm.

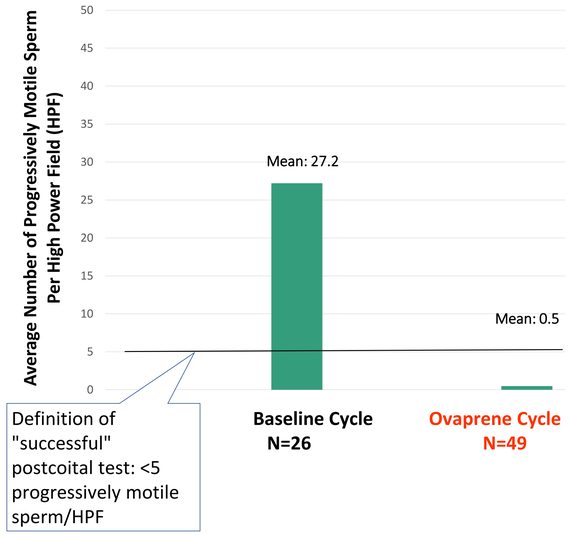
In each cycle, **postcoital tests were** done 2-3 hours after intercourse.
Cervical mucus was examined for midcycle characteristics and number of sperm.

- **To enroll**: During the **baseline cycle**, subjects had to achieve an average of **≥ 5 progressively motile sperm per high power field** during microscopic examination of cervical mucus, per WHO guidelines.
- Definition of a **successful postcoital test with Ovaprene** in place: **<5 progressively motile sperm per high power field**

4 sites: Eastern Virginia Medical School, Norfolk, VA; Clinical Research Prime, Idaho Falls, ID; Oregon Health & Science University, Portland, OR; University of Pennsylvania, Philadelphia, PA

RESULTS

- 26 baseline cycles completed
- 49 Ovaprene cycles completed
- All Ovaprene cycles met criterion for success: average of <5 progressively motile sperm per high power field
- Average # of progressively motile sperm was reduced from 27.2 in baseline cycle to 0.5 in Ovaprene cycle
- Results were not affected by BMI, history of vaginal delivery, or previous vaginal ring use



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CONCLUSIONS

- The criterion for a successful postcoital test was met by all participants in all Ovaprene PCT cycles.
  - This result held true regardless of BMI, history of vaginal delivery or prior vaginal ring use.
- Postcoital test studies of other vaginal methods showed that results like these were associated with 6-month typical use effectiveness rates corresponding to 86%-91% effectiveness.
- A pivotal study is planned in which women at risk of pregnancy will use the device for 6-12 months and actual contraceptive efficacy will be assessed.

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CONTACT INFORMATION

Christine Mauck MD, cmauck@darebioscience.com, 301-325-5439