

A Nonhormonal Bioadhesive Vaginal Moisturizer

I. Effect on Sperm Motility and Ova Penetration

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Introduction

It is estimated that 25 million peri- and post-menopausal women suffer from vaginal dryness. The condition in this population of women is most commonly caused by a decline in estrogen. An additional group of younger reproductive aged women, however, may suffer from vaginal dryness as well. For these women in their childbearing years, certain drug therapies may result in vaginal dryness as a secondary condition (i.e. Danocrine* for endometriosis and fertility drugs such as Pergonal**).

In recent studies (1,2) a nonhormonal bioadhesive vaginal moisturizer, Replens† has shown to be an effective addition or alternative to estrogen therapy in relieving vaginal dryness symptoms. When recommending the use of a vaginal moisturizer, however, physicians are often concerned about the effects this therapy may have on sperm motility and ova penetration.

Therefore, the following studies were conducted to provide useful information to physicians treating vaginal dryness symptoms. The results indicated that the nonhormonal bioadhesive vaginal moisturizer did not adversely affect sperm motility and ova penetration.

CASE	SPERM COUNT (Millions/ml)	MOTILITY (%)	PENETRATION RATE (%)	
1	58.0	89.6	Control	50.0
			Moisturizer	54.5
2	7.6	52.6	Control	50.0
			Moisturizer	50.0
3	23.0	58.7	Control	66.7
			Moisturizer	42.9
4	62.0	83.9	Control	43.8
			Moisturizer	38.5
5	64.0	79.6	Control	47.0
			Moisturizer	35.7

* Danocrine®, Winthrop Pharmaceuticals, New York, NY

** Pergonal®, Serono Laboratories, Inc., Randolph, MA

† Replens®, Parke-Davis, Morris Plains, NJ

TABLE 2				
Expanded Study Penetration Rates				
CASE	SPERM COUNT (Millions/ml)	MOTILITY (%)	PENETRATION RATE (%)	
1	58.0	89.8	Control	50.0
			Moisturizer	54.5
2	7.6	52.8	Control	50.0
			Moisturizer	50.0
3	23.0	58.7	Control	66.7
			Moisturizer	42.9
4	62.0	83.9	Control	43.8
			Moisturizer	38.5
5	64.0	79.6	Control	47.0
			Moisturizer	35.7
6	55.0	60.	Control	66.7
			Moisturizer	63.6
7	33.0	54.5	Control	0.0
			Moisturizer	0.0
8	81.0	40.7	Control	54.5
			Moisturizer	72.7
9	71.0	79.6	Control	54.5
			Moisturizer	60.0
10	54.0	58.8	Control	69.2
			Moisturizer	55.6
11	62.0	51.6	Control	22.2
			Moisturizer	12.5
12	69.0	81.2	Control	25.0
			Moisturizer	25.0
13	82.0	51.2	Control	27.3
			Moisturizer	14.3
14	64.0	79.8	Control	47.0
			Moisturizer	35.7
15	66.0	45.5	Control	25.0
			Moisturizer	25.0
16	55.0	58.2	Control	37.5
			Moisturizer	10.0
17	49.0	51.0	Control	25.0
			Moisturizer	31.3
18	88.0	86.4	Control	18.2
			Moisturizer	25.0
19	36.0	44.4	Control	37.5
			Moisturizer	44.4
20	94.0	78.7	Control	27.3
			Moisturizer	45.5
21	106.0	71.7	Control	33.3
			Moisturizer	30.0
		TOTAL	Control	41.7
			Moisturizer	39.3

Methods and Results

To determine the effects of the nonhormonal bioadhesive vaginal moisturizer on sperm motility and ova penetration, a preliminary test using fresh semen samples of eight men with proven fertility were mixed with the same volume of a 1:1 dilution of the moisturizer with mBWW (modified Biggers, Wittingham and Whitter) media. The mixture was centrifuged and resuspended; 2 ml of mBWW was then layered over the resuspended mixture and after one hour, the sperm which were able to swim up were incubated with hamster ova. Following the completion of the preliminary test, an expanded study was conducted using fresh semen samples of 26 men with proven fertility.

These tests represent a modification of standard laboratory procedures used to determine sperm motility (3,4) and ova penetration (5,6,7). Since the bioadhesive moisturizer with medium was viscous and opaque, sperm motility could not be checked microscopically. By using a swim-up technique by layering the buffered solution over the mixture, only the motile sperm swam up into the buffered layer.

The results shown in Table 1 reflect the eight samples in the pilot study. In three of the cases, there was little or no penetration on the control samples: poor or no penetration of hamster ova using fresh semen specimen is common. The five cases reported are definitely samples from patients with proven fertility.

The expanded study yielded results from 21 of the 26 samples collected (Table 2). Of the 21 cases, only Case 7 had zero percent penetration for both control and moisturizer. The remaining 20 cases had varies penetration rates, with a low of 10 percent for the moisturizer in Case 16. Average penetration rates for all remaining samples was 36.8 percent. Cases 1, 8, 9, 17, 18, 19, and 20 had higher penetration rates with the lubricant. The remaining 5 samples were not tested because of poor motility (<20%).

Conclusion

The results of the preliminary and expanded study indicate the Replens had no effect on sperm motility and does not affect sperm ability to penetrate hamster ova. This may provide a level of confidence for physicians and patients, assuring that this formulation may be used by women during fertility programs.

References

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