

Long Term Nonhormonal Treatment of Vaginal Dryness

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Abstract

Long term use of nonhormonal vaginal therapy consisting of a product whose main ingredient is polycarbophil is effective in treating both sexual and nonsexual complaints of women whose symptoms are related to vaginal dryness.

Introduction

The safety and efficacy of nonhormonal therapy utilizing the main ingredient of polycarbophil has already been documented.¹ This paper deals with the one year follow up of women who used the vaginal moisturizer (Replens) for one continuous year at a frequency of three times per week. Of an initial group of 89 subjects, 46 women completed the one year study. Data shows that improvement in vaginal health as measured by a vaginal health index is maintained with long term use of the nonhormonal product regarding vaginal moisture (coating the surface), vaginal fluid volume, pH, tissue integrity and tissue elasticity.

Background

A more vocal and an increasing number of

women entering the menopausal and postmenopausal years has brought many of the problems associated with estrogen deprivation to the forefront.² Also as many women near the menopause, the problems of estrogen deficiency to the mucosal lining is a common presenting problem to many physicians.^{3,4} Both the long term consequences of estrogen deprivation to the vagina, including cystocele, rectocele, urinary stress incontinence, uterine prolapse and chronic vaginal discharge (atrophic vaginitis), as well as short term problems of inadequate moisture with sexual arousal and painful intercourse are frequent complaints of the aging female.⁵⁻⁷ With prior generations, although physicians were aware of the vaginal problems of older women, they were not as inclined to offer treatment if the women were not sexually active. Today the problems associated with vaginal dryness are vocalized both by sexually active as well as sexually inactive women as more and more women are looking at ways to affect quality of life and do not feel that chronologic age limits expectations of feeling well.⁸

Estrogens are effective in reversing the vagi-

Table I

Vaginal Health Index					
	1	2	3	4	5
Elasticity	none	poor	fair	good	excellent
Fluid Volume (Pooling of Secretions)	none	scant amount, vault not entirely covered	superficial amount, vault entirely covered	moderate amount of dryness (small areas of dryness on cotton tip applicator)	normal amount (fully saturates) on cotton top applicator)
pH	6.1 or above	5.6 - 6.0	5.1 - 5.5	4.7 - 5.0	4.6 or below
Epithelial Integrity	petechiae noted before contact	bleeds with light contact	bleeds with scraping	not friable - thin epithelium	normal
Moisture (Coating)	none, surface inflamed	none, surface not inflamed	minimal	moderate	normal

nal atrophy changes that begin in the early menopausal years and progress throughout a woman's life, but many women cannot or will not take estrogens because of medical problems, side effects (breast tenderness, resumption of menstrual cycles), or personal preferences.⁹ In addition, for women who have a uterus and require a progestin to insure endometrial maturation, the PMS-like symptoms can have a tremendous negative impact on overall well being. For women who choose to use systemic hormone replacement therapy, the dose of estrogen necessary for control of vasomotor symptoms, osteoporosis and cardiovascular disease prophylaxis may not be sufficient to prevent symptoms related to vaginal atrophy.^{1,9-11} Lastly, there are a group of women who have transient estrogen deprivation to their vaginas and need a preparation that will afford them adequate vaginal moisturization during this period of time. For these types of patients, alternatives to estrogen have long been sought for vaginal symptoms. The use of a vaginal moisturizer which has a polycarbophil base has been shown to be effective in short term studies.¹ This was the first long term study looking at efficacy and safety of this polycarbophil vaginal moisturizer.

Materials and Methods

Ninety-three perimenopausal and postmenopausal women were recruited in stage one of the protocol. Eighty-nine women completed stage one of the protocol and of these fifty-four women chose to continue in the stage 2 protocol which was an extension of the stage one protocol. In the stage 2 protocol, the study was open label and there was no cross-over. Subjects used the bioadhesive vaginal moisturizer three times a week and were evaluated at 3, 6, 9 and 12 months. At three months intervals patients' were asked questions regarding product satisfaction and at the same time the study physicians completed a vaginal health index¹ which evaluated vaginal elasticity, vaginal fluid volume, pH, vaginal epithelial integrity and vaginal moisture. (See Table 1)

Of the 54 women who entered the one year study period, the average age was 55 years. 43 patients were married. Most patients were sexually active and had been for an average of 25 years. 26 (48%) patients were on estrogen therapy, having taken the hormone for an average of 26 months, and complained of vaginal dryness. A large percentage of patients, 59%, had not undergone hysterectomy. 46 patients completed the

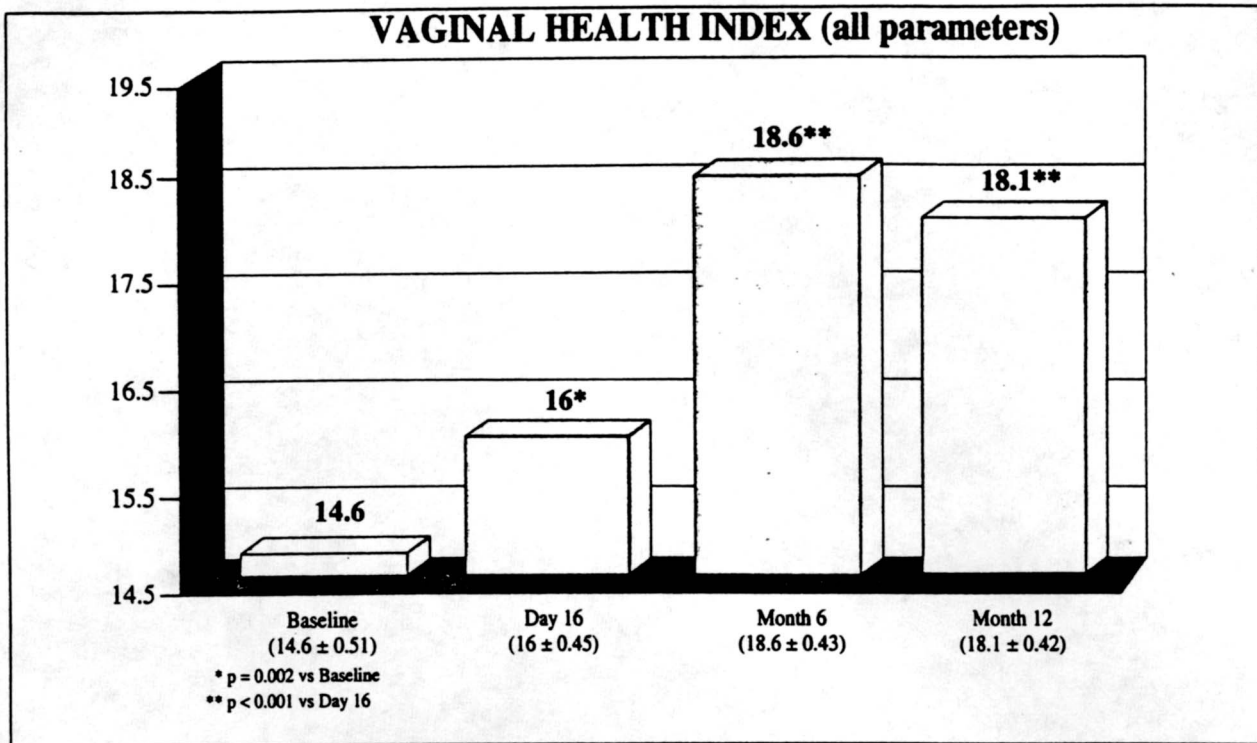


Figure 1. Nonhormonal bioadhesive moisturizer in peri/postmenopausal women

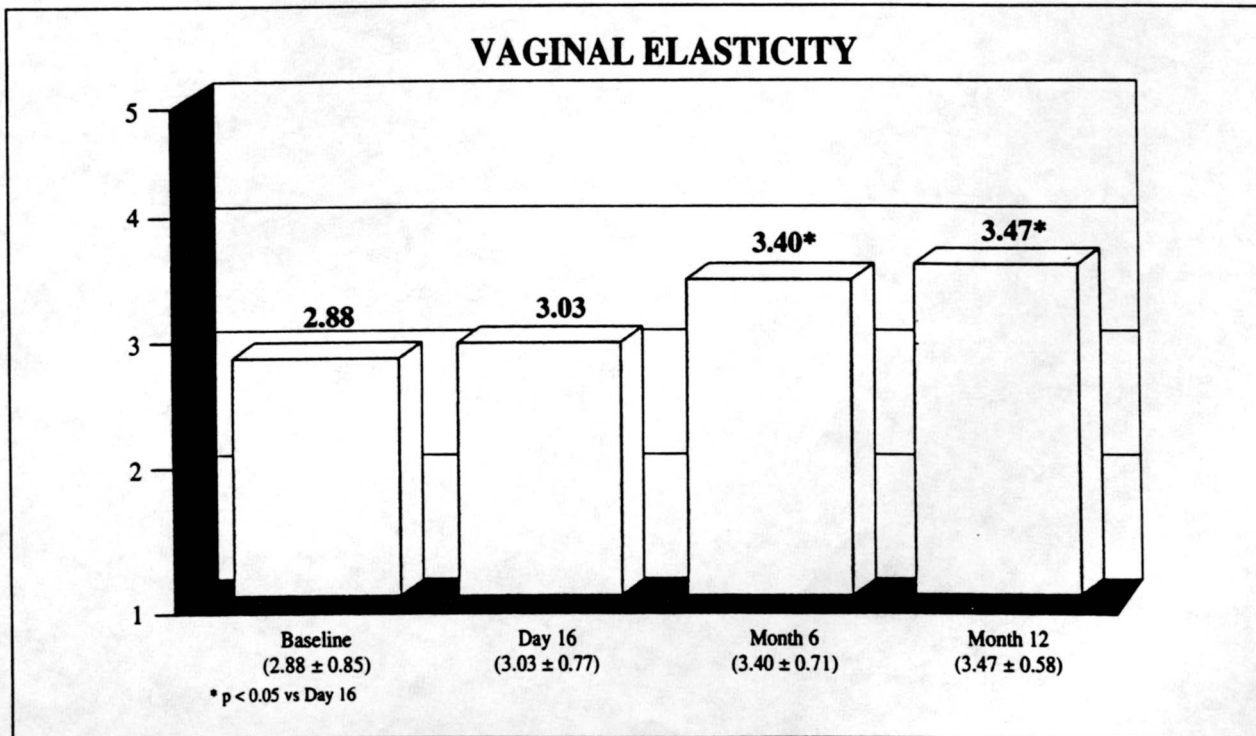


Figure 2. Nonhormonal bioadhesive moisturizer in peri/postmenopausal women.

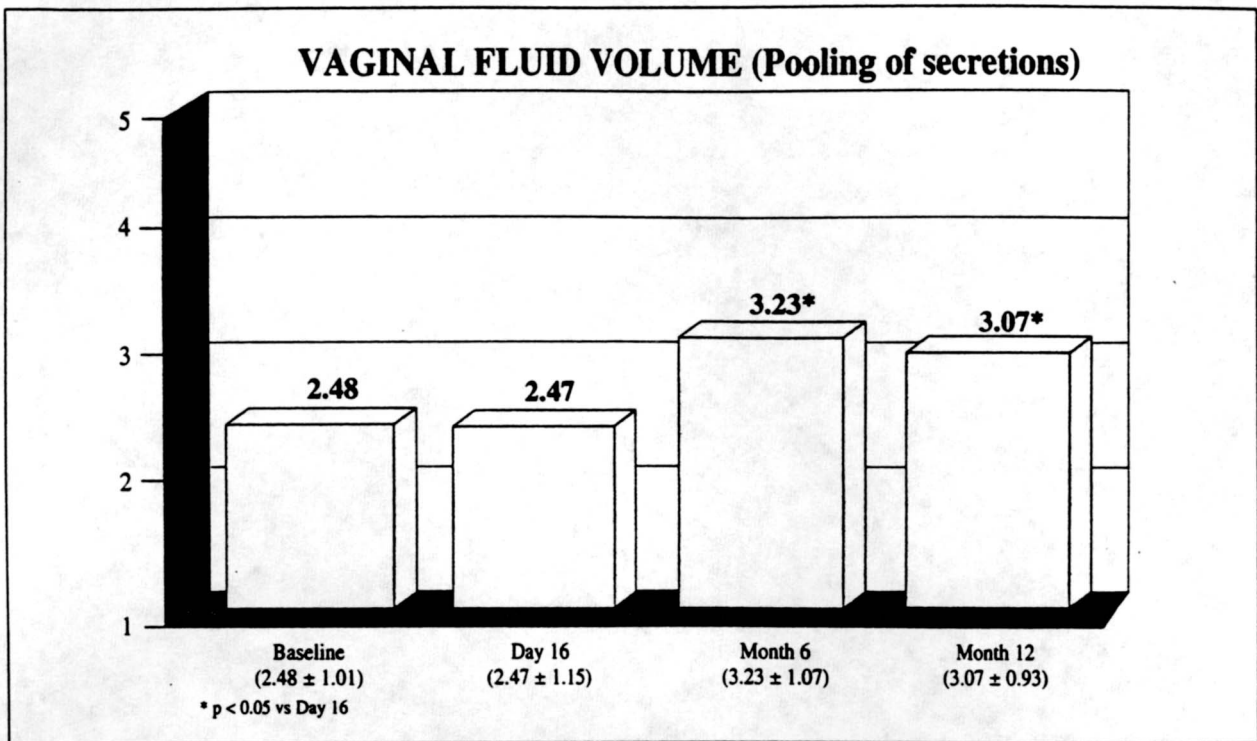


Figure 3. Nonhormonal bioadhesive moisturizer in peri/postmenopausal women

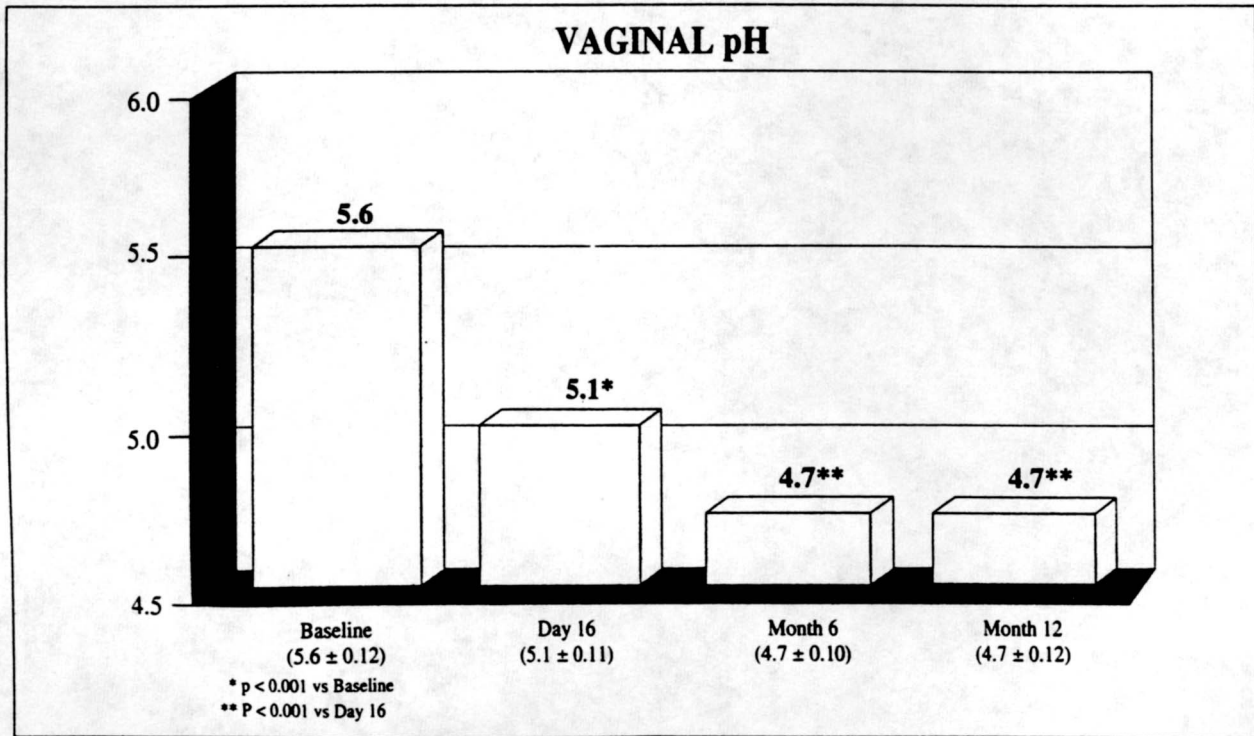


Figure 4. Nonhormonal bioadhesive moisturizer in peri/postmenopausal women

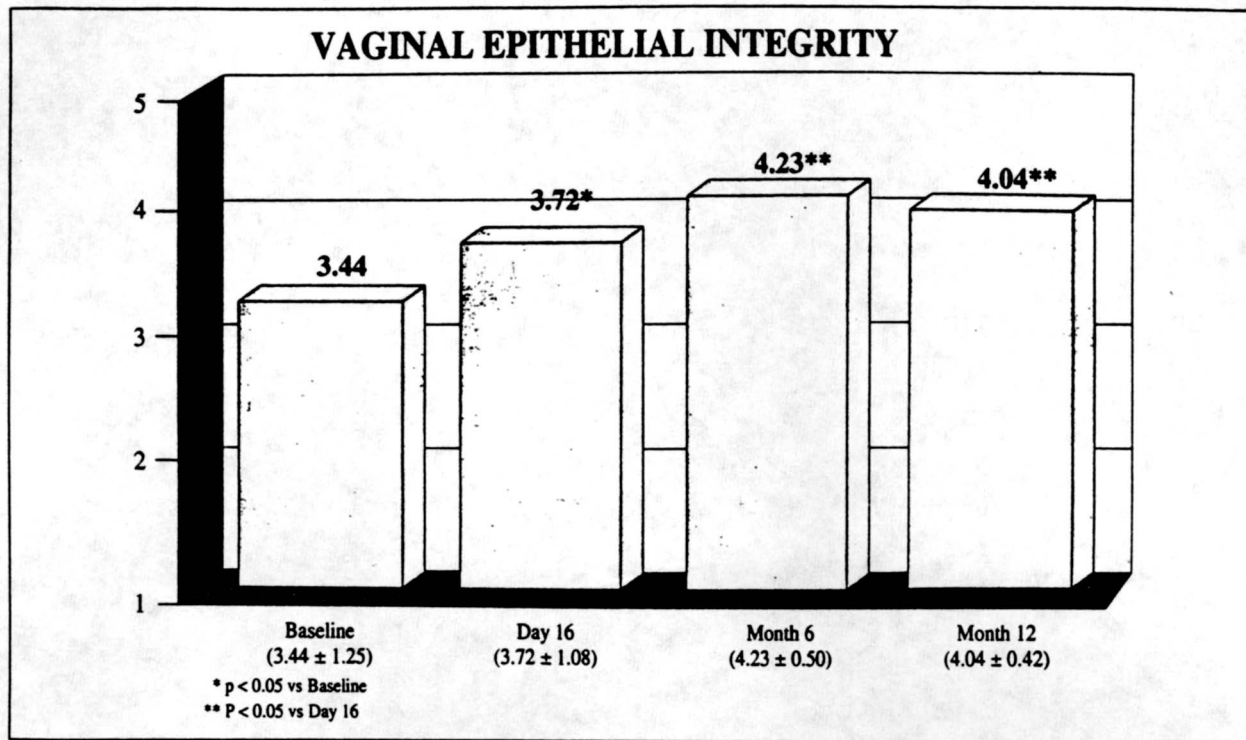


Figure 5. Nonhormonal bioadhesive moisturizer in peri/postmenopausal women

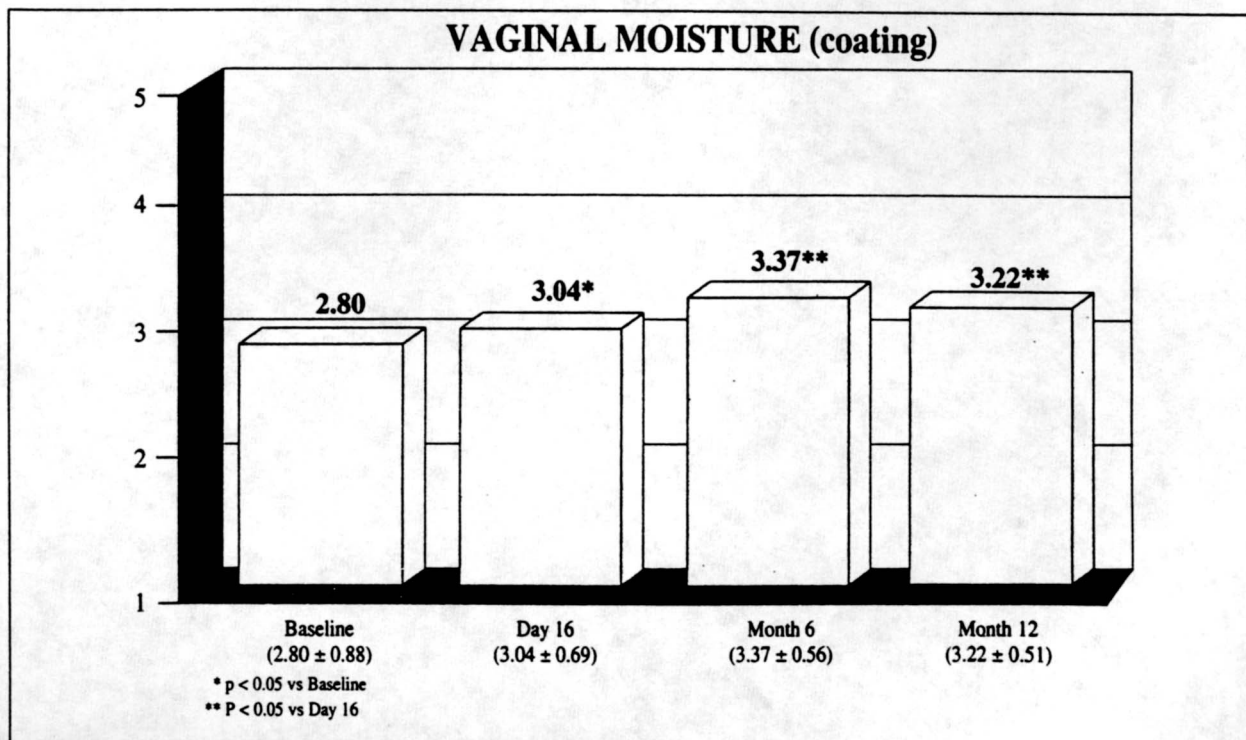


Figure 6. Nonhormonal bioadhesive moisturizer in peri/postmenopausal women

entire study period with 8 patients lost to follow up at 6 months. There were no patients who dropped out due to adverse effects.

Results

Over the course of the study the vaginal health index continued to show that not only had vaginal health improved but this improvement was maintained as long as subjects were using the product (See Figure 1). In fact all parameters of the vaginal health index showed improvement including vaginal moisture, vaginal fluid volume, vaginal pH, vaginal epithelial integrity and vaginal elasticity (See Figures 2,3,4,5 and 6). The figures show vaginal health index parameters for 6 & 12 months; 3 & 9 months data are not shown because of no statistically significant difference from the 6 month data. None of the women reported serious side effects and all women reported continued improvement in their original symptoms, i.e., vaginal dryness, irritation, burning, itching, and painful intercourse.

Discussion

Although vaginal symptoms during the perimenopausal-menopausal years are due to declining estrogen levels, nonhormonal therapy using a bioadhesive moisturizer was shown to be a well tolerated vaginal product without any serious side effects and it improved overall vaginal well being as measured by the vaginal health index over the course of the one year trial. This is not only an important finding for postmenopausal women who either will not or can not use estrogen

or who are on estrogen and still have symptoms of estrogen deficiency but for those women who for several years before the actual menopause have early vaginal atrophy symptoms.^{1,12-15} For transition women who may still be menstruating and prefer not to use hormonal therapy, use of a nonhormonal vaginal moisturizer with polycarbophil has been shown to be effective and well tolerated and can be used during the transition period without concern about serious side effects. This is especially important for younger women who are more sexually active than older women and therefore are engaging in more sexual activity. Further studies should look at whether the use of a vaginal preparation such as Replens during the perimenopausal years will actually retard vaginal atrophy because of continued moisturization effect. If a moisturizer with polycarbophil is used by transition women, further fall off in frequency of sexual exchange may also diminish. That is, if coitus remains comfortable women will be more willing to engage in sexual activity than if intercourse is painful. Lastly, further research should explore if there is an additive effect in women who use hormone replacement with a nonhormonal vaginal preparation in terms of maintaining vaginal health. Possibly, the amount of estrogens that are needed to maintain vaginal health may be decreased in women who are also using a nonhormonal vaginal preparation with polycarbophil. Overall the product studied was found to be well tolerated and effective in improving overall vaginal health for one year of continuous use.

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