

The External Urethral Barrier for Stress Incontinence: A Multicenter Trial of Safety and Efficacy

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Objective: To assess the efficacy and safety of an external urethral barrier for the management of mild to moderate stress urinary incontinence in adult women.

Methods: Four hundred eleven women with the symptom of stress urinary incontinence in 12 United States centers participated. Additional inclusion and exclusion criteria were applied before protocol device use, and ultimately 390 subjects began device use. Outcome measures for efficacy and safety were assessed. Efficacy was evaluated by the number of leakage episodes using a voiding diary, subjective urinary leakage severity, incontinence impact scores, and pad testing. Safety was evaluated by symptom assessment, urinalysis, urine culture, measurement of postvoid residual urine volume, vulvar cytology, vaginal culture, and ($n = 81$) cystometric testing.

Results: Efficacy was indicated by statistically significant reductions in the number of leakage episodes, subjective leakage severity scores, incontinence impact scores, and pad-test loss during device use. The data also indicated that the device was safe, as evidenced by the lack of statistically significant changes in the percentage of subjects with urinary tract infections during device use or in postvoid residual urine volume and cystometric indices. Symptoms of

vulvar irritation or lower urinary tract discomfort occurred in a small percentage of subjects but were generally transient, and only three women discontinued using the device.

Conclusion: The external urethral barrier appears to be a safe nonsurgical alternative to absorbent products for the management of mild to moderate stress urinary incontinence in adult women. (*Obstet Gynecol* 1999;93:932-7. © 1999 by The American College of Obstetricians and Gynecologists.)

Stress urinary incontinence is the most common type of incontinence in women and affects the daily lives of millions of individuals.¹ Although many effective treatments are available through health care professionals, options for self-management of mild to moderate stress urinary incontinence have been limited largely to absorbent products, with several drawbacks including bulk, odor, and inadequate urine absorption.

A urethral barrier device has been developed to prevent rather than absorb urine loss in women with mild to moderate stress incontinence. The purpose of this study was to evaluate the safety and efficacy of this device.

Materials and Methods

The urethral barrier device (Figure 1) is a small, single-use disposable foam shield that is worn externally over the urethral meatus (Figure 2). It is held in place by an adhesive hydrogel and is easily removed for voiding.

After appropriate institutional or regional review board approval, 12 centers enrolled patients for study participation using verbal and written consent. The primary investigator at each site was a urogynecologist (seven), urologist (two), nurse practitioner (two), or family practice physician (one). The protocol was de-

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Figure 1. The external urethral barrier.

signed to self-select potentially eligible women because the product was planned for nonprescription use. The 21-week study period consisted of a 1-week qualifying period, a 4-week baseline assessment period, 12 weeks of device use, and 4 weeks of follow-up after discontinuation of device use. An initial sample of 648 subjects was recruited through advertisements in local media and from patients already seeking care at the study centers. Four hundred eleven were ultimately enrolled. Women with symptoms of mild to moderate stress incontinence were sought as subjects. Additionally, women with symptoms of mixed incontinence (stress and urge incontinence) were allowed to participate if they reported that stress incontinence was the dominant incontinence symptom.

Throughout the study, we tried to minimize the need for clinician instruction. At the first visit, the subjects completed history and symptom questionnaires and

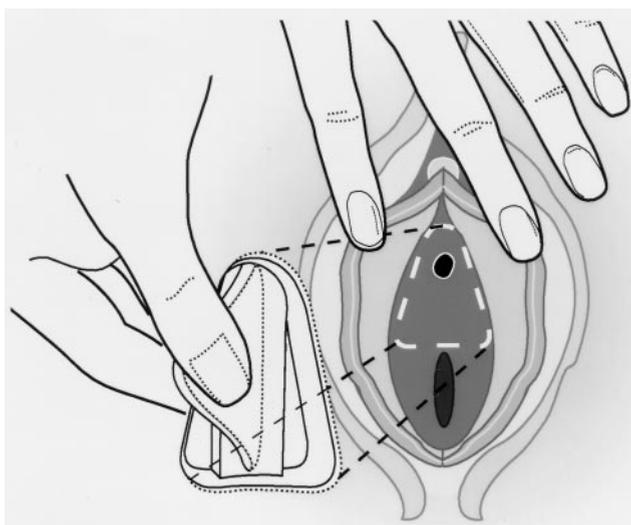


Figure 2. Proper placement of the external urethral barrier.

Table 1. Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
1) Eighteen years of age or older.	1) Presents with symptoms of urinary tract infection.
2) Not currently pregnant.	2) Presents with symptoms or physical signs of vaginal infection.
3) Physically able to complete and comply with all study requirements.	3) Presents with symptoms or physical signs of intralabial irritation.
4) Mentally competent and able to understand all study requirements.	4) Reports that her skin is easily irritated by the use of soaps, lotions, or feminine products.
5) Able and willing to consent to study participation.	5) Physical examination reveals that her urethral meatus is clearly inside the vaginal opening.
6) Has access to transportation and is not transient.	6) Postvoid residual urine volume, as measured by bladder ultrasound, is ≥ 200 mL.
7) Indicates in the symptom questionnaire that her primary symptom is mild to moderate stress incontinence.	7) Patient has undergone any surgical procedure to treat incontinence, or pelvic surgery, within the last 6 months.
8) Objectively demonstrates a minimum of three episodes of incontinence in her baseline voiding diary.	8) Began/discontinued taking medication to treat incontinence within the last month.
	9) Began noninvasive therapy within the last 5 months, or discontinued within the last 1 month.
	10) Unable to understand instructions for use or unable to properly place the external urethral barrier.

self-assessed their appropriateness for device use. Strict inclusion and exclusion criteria were used for study participation (Table 1). Once they gave informed consent, the subjects received an instruction sheet for device placement. Using the enclosed information sheet and a toll-free telephone number for assistance, the subjects were required to independently place the device appropriately (ie, complete coverage of the external meatus) within three attempts. The investigators confirmed proper placement by verifying that the device completely covered the urethra. If this did not occur, the subject was excluded from further participation.

Once enrolled, the subjects were provided with a daily journal, a 7-day voiding diary, and materials for a home pad test (12 waking hours) to be completed before the second visit (1 week later). At the second visit, inclusion and exclusion criteria were rechecked, and compliance with data collection was assessed. Subjects

were then given voiding diaries for the 4-week baseline assessment period. After this baseline period, the subjects began 12 weeks of device use. The subjects received barriers every 4 weeks and were instructed to use the device as their normal incontinence protection. There were no limitations on the number of devices that subjects could use during the investigation. No additional instructions were given regarding proper placement or use of the device, but an instruction sheet was provided with each box of devices. Study visits during device use were scheduled at 4-week intervals. Subjects completed home tests at each 4-week interval and completed questionnaires and laboratory assessments at each office visit. At the end of the device-use period, unused urethral barriers were collected. The final 4 weeks of the study consisted of follow-up after discontinuation of device use.

Efficacy was evaluated subjectively and objectively using questionnaires, voiding diaries, and pad testing. Data before and during device use for all four efficacy indices were required for inclusion in the efficacy analysis. All subjects kept a daily journal throughout the study, recording menses and the number of devices used. The urinary leakage severity questionnaire, completed at every visit, rated the severity of leakage experienced during various activities.² Thirteen activities commonly associated with stress urine loss were rated on a scale of 0 to 3, yielding a maximum score of 39.

An incontinence impact questionnaire was completed at each visit after the baseline assessment period.³ Subjects were asked to rate the degree to which urine leakage had a negative effect on their daily lives. Twenty-six specific activities were rated, and the activity ratings were combined to yield a total incontinence impact score ranging from 0 to 300. Higher scores indicated a greater impact of incontinence on daily activities. A 7-day voiding diary, adapted from the clinical practice guidelines,⁴ was completed in the week before each study visit. In addition, a 12-hour home pad test was performed the day before each study visit.

Safety monitoring was designed to detect urinary tract infection, vulvar irritation and vaginitis, urine retention, and detrusor overactivity. When urinary tract infections were present, urine was cultured to identify the causative organism. All patients enrolled at five designated study sites ($n = 81$) underwent testing to detect urine retention and detrusor overactivity. The centers were selected based on availability of equipment and urodynamic expertise.

In addition to the symptom questionnaire, dipstick urinalysis (Ames Multistix 7; Ames, Elkhart, IN) was performed at each visit after enrollment to detect leukocytes or nitrites and microhematuria. A dipstick test

was considered positive if leukocytes (greater than trace amounts) or nitrites were present. Midstream urine cultures were obtained at study onset, initiation and completion of device use, and study termination. Additional cultures were obtained if a subject reported symptoms or had a suspicious urinalysis. In asymptomatic patients, a culture was considered positive when a single uropathogen had a colony count of greater than 10^5 colony-forming units per milliliter. A colony count of greater than 10^2 was considered positive for symptomatic patients.

Postvoid residual urine volumes were determined at each study visit after enrollment. Volumes were assessed by ultrasound (Bladder Scan; Diagnostic Ultrasound, Seattle, WA) within 10 minutes of voiding.

A total of 81 subjects (from five centers) underwent complete cystometrogram testing before device use and during device use at week 17. The standardized cystometry protocol specified retrograde saline (medium fill) with the subject in the sitting position. Abdominal pressure was recorded by a rectal or vaginal pressure transducer and intravesical pressure by a transurethral catheter. First sensation, volume at fullness, maximum capacity, and presence of detrusor activity were recorded.

Symptoms of vulvar irritation were assessed at each visit. In addition to physical examination of the vulvar tissues, cytology smears were collected from the periurethral area where the urethral barrier was worn. Vulvar cytology was performed before the baseline assessment period, immediately before device use, at the conclusion of device use, and at study termination. Smears were classified as normal, inflammatory, or abnormal at a single centralized laboratory.

Vaginal Gram stains were obtained at all study visits except the initial visit. A standardized scoring system was used to detect bacterial vaginosis.⁵ Yeast hyphae were evaluated separately on a 0–4 scale. Yeast infection was diagnosed if the rating was 3+ or greater. All patients at selected centers ($n = 125$) were tested with vaginal cultures twice before device use, immediately after device use, and at study termination. These cultures were analyzed at the central laboratory for pathogenic changes in the following vaginal flora: *Lactobacillus*, *Gardnerella vaginalis*, group B streptococcus, enterococcus, *Staphylococcus aureus*, coliforms, yeast, and *Bacteroides*.

As expected, most of the data were skewed to the right or were otherwise statistically non-normal. For this reason, nonparametric statistical methods were used for most analyses. The nonparametric Friedman test for repeated measures was done to compare data for three or more time periods, and the paired sign test was used to compare data from two time periods. The paired t test was done to compare cystometric indices

before and during device use (week 17) because the distributions of the differences between the pre-use and during-use indices were approximately normal. The McNemar test was used to compare percentages from two different time periods. Because many statistical tests were done, a .01 significance level was used instead of .05 to reduce the multiplicity problem (an increased risk of a type I error). Data are presented as mean \pm standard deviation. Medians are given as well as means when the mean and median differ substantially.

Results

Four hundred eleven women were enrolled in this study. All study participants placed the device correctly. The majority (62%) placed it correctly on the first attempt; 25% required a second attempt and 13% required three attempts. The subjects were generally parous (89%), with an average weight of 162 ± 35 lb (range 95–290) and an average age of 49 ± 11 years (range 18–78). Fifty-four percent of the 169 postmenopausal subjects were using estrogen supplementation. All subjects reported symptoms of stress urinary incontinence. Three hundred ninety subjects began device use, and 346 women completed the entire 21-week protocol.

Of the 65 subjects who did not complete the trial, 21 withdrew before device use. Of the remaining 44 dropouts, 17 were lost to follow-up, 12 withdrew for device-related reasons, nine developed an unrelated condition, and six were dropped by the investigator for protocol-related reasons.

The study subjects used an average of 4.3 ± 2.3 barriers each day at week 9, 4.1 ± 2.1 barriers at week 13, and 4.0 ± 2.4 barriers at week 17. Although subjects tended to use fewer barriers per day at week 17 than at week 9 ($P = .006$) or week 13 ($P = .008$), these differences were statistically but not clinically significant. The device was worn an average of 9.2 ± 5.1 hours per day at week 9, 9.2 ± 5.0 hours at week 13, and 9.0 ± 5.3 hours at week 17, with no statistically significant difference at the .01 level ($P = .037$). Sixty-three percent of the subjects reported using the device during the night at some point during the study. The device was considered easy to remove by almost all of the subjects: 97% at week 9, 98% at week 13, and 95% at week 17 ($P = .022$ –.63). Most of the subjects also reported that the device was comfortable: 89% at week 9, 90% at week 13, and 93% at week 17 ($P = .015$ –.44). Sixteen percent of the subjects reported reusing the device at some point during the study.

Efficacy was assessed in the 356 women who completed pre-device and device-use data for all four

efficacy measures. Thirty-four (9%) of the 390 women who began device use were excluded from the efficacy analysis because of failure to complete the required efficacy testing.

The barrier was effective in reducing urine loss as measured by the urinary leakage severity questionnaire. The subjective report of urinary leakage severity fell during device use, from a baseline mean of 10.1 ± 5.1 (median 9.0) to 3.3 ± 4.0 (median 2.0) during week 9, to 3.5 ± 4.3 (median 2.0) during week 13, and to 3.5 ± 4.3 (median 2.0) during week 17 ($P < .001$ for all three comparisons). Leakage severity scores increased to 7.0 ± 4.6 (median 6.0) after device use was discontinued, a statistically significant increase over the leakage scores for all three device-use periods ($P < .001$ for all three comparisons). However, the leakage severity scores after discontinuation were significantly lower than the baseline scores ($P < .001$).

The results for the total incontinence impact scores were similar. The impact scores decreased from a mean of 41.0 ± 39.4 (median 29.7) immediately before device use to 11.9 ± 20.1 (median 3.3) at 9 weeks, 11.4 ± 25.6 (median 3.0) at 13 weeks, and 10.5 ± 20.3 (median 0.0) at 17 weeks ($P < .001$ for all three comparisons). After device use was discontinued, the impact scores increased to 28.4 ± 37.4 (median 16.2), a statistically significant increase over the impact scores for all three device-use periods ($P < .001$ for all three comparisons). The impact scores after discontinuation were lower than the pre-use scores ($P < .001$).

The average 12-hour pad-test urine loss was reduced from 15.8 ± 26.5 mL (median 6.9) before device use to 6.9 ± 11.5 mL (median 3.7) during device use ($P < .001$).

The number of daily incontinence episodes recorded in the 7-day voiding diary decreased during device use, from a baseline mean of 14.2 ± 12.3 episodes (median 10.0) to 6.9 ± 8.7 (median 4.0) during week 9, to 5.2 ± 7.3 (median 3.0) during week 13, and to 4.9 ± 6.9 (median 3.0) during week 17 ($P < .001$ for all three comparisons). After device-use discontinuation, the mean number of incontinence episodes rose to 9.4 ± 10.4 (median 6.0), a statistically significant increase over all of the device-use periods ($P < .001$ for all three comparisons). The number of incontinence episodes was lower after device-use discontinuation than at baseline ($P < .001$).

The average daily frequency of voiding recorded in the diary was 8.2 ± 2.8 immediately before device use and remained similar during device use (7.8 ± 2.6 at each of the weeks 9, 13, and 17) and after discontinuation of device use (8.0 ± 2.6). Although there was a statistically significant reduction in voiding frequency at week 17 compared with the voiding frequency immediately before device use ($P = .009$), this difference

was not clinically important. There were no other statistically significant differences at the .01 level between these study periods with respect to voiding frequency ($P = .014-.65$).

Twenty-six women reported symptoms suggestive of urinary tract infection at some point during the study. However, there were no statistically significant changes in the percentage of subjects with positive urine cultures during the study. These percentages were 2.8% during the baseline assessment period, 2.8% immediately before beginning device use, 4.1% during device use (week 17), and 2.3% after discontinuation of device use.

There were no statistically significant changes in the percentage of subjects with leukocytes or nitrites on urinalysis: 5.4% at baseline; 4.7% at week 9, 4.8% at week 13, and 7.2% at week 17 during device use; and 5.5% after discontinuation of device use. Similarly, there were no statistically significant changes in the percentage of subjects with at least a trace of blood in the urine: 24% at baseline; 20% at week 9, 21% at week 13, and 19% at week 17 during device use; and 19% after discontinuation of device use.

No subject developed urine retention. There were no statistically significant changes in the postvoid residual urine volume determined by ultrasound: 22 ± 38 mL (median 0) at baseline; 20 ± 39 mL (median 0) immediately before beginning device use; 16 ± 37 mL (median 0) at week 9, 18 ± 34 mL (median 0) at week 13, and 18 ± 36 mL (median 0) at week 17 during device use; and 22 ± 45 mL (median 0) after discontinuation of device use ($P = .36$). For the 81 subjects with cystometric measurements, there was a statistically significant decrease in the postvoid residual determined by cystometry, from 37 ± 44 mL before device use to 20 ± 28 mL during device use at week 17 ($P = .001$).

For the 81 subjects who underwent cystometric testing, there were no statistically significant changes in cystometric indices when measurements obtained before device use were compared with those obtained during device use at week 17: volume at first sensation ($P = .54$), volume at fullness ($P = .46$), and volume at maximum capacity ($P = .65$). There was no statistically significant change in the percentage of subjects with detrusor overactivity, which was 15% before device use and 17% during device use at week 17 ($P = .73$).

The percentage of women who reported vulvar irritation was low throughout the study: 0% at baseline; 0.3% immediately before beginning device use; 3.8% at week 9, 1.7% at week 13, and 0.9% at week 17 during device use; and 1.2% after discontinuation of device use. The increase in the percentage of women who reported vulvar irritation at week 9 was statistically significant compared with the percentage at baseline

($P = .001$) and the percentage immediately before device use ($P = .001$). There were no other statistically significant differences at the .01 level between these percentages ($P = .031$). Only two subjects reported vulvar irritation more than once, and only three subjects discontinued the device and withdrew from the study because of vulvar irritation. No patient developed abnormal vulvar cytology during device usage.

The percentage of subjects with bacterial vaginosis did not change appreciably during the study. This percentage was 18% at baseline; 14% immediately before beginning device use; 18% at week 9, 16% at week 13, and 18% at week 17 during device use; and 17% after discontinuation of device use. There were no statistically significant differences at the .01 level in bacterial vaginosis scores for these time points ($P = .030$). For the subgroup of 125 women who had vaginal cultures during the study, there were no statistically significant differences at the .01 level between the baseline, immediately before device use, during device use (week 17), and after discontinuation for *Lactobacillus* ($P = .65$), *G vaginalis* ($P = 1$), group B streptococcus ($P = 1$), enterococcus ($P = .028$), *S aureus* ($P = 1$), coliforms ($P = .99$), yeast ($P = 1$), and *Bacteroides* ($P = .98$).

Discussion

The external urethral barrier used in this study is a simple, easy-to-use device. The women were able to self-select approximately for device use based on their assessment of their individual symptoms of stress urinary incontinence, and almost all of the women placed the device using written instructions. Both subjective and objective measures of efficacy revealed that device use decreased the episodes of urinary incontinence and significantly improved quality of life. This means that the device may be an important alternative to absorbent products and other management strategies.

Some participants experienced persistence of some improvement after device discontinuation. This may have occurred because of the subtle behavioral effects of diary-keeping or caregiver interaction. Alternatively, there may be an independent lingering effect of the device itself, possibly due to bladder training or a neuromuscular effect.

Control of incontinence was not complete in the majority of patients. This is due largely to limitations of the device and the inability of symptoms to completely predict the type of urinary incontinence. The device does not have sufficient adhesive power to prevent urine leakage associated with urge incontinence because the device may be dislodged with a normal voiding effort. Likewise, the device does not have sufficient adherence to control all stress incontinence,

and limited clinical experience suggests that it would be ineffective for severe stress incontinence, such as intrinsic sphincter deficiency. In these clinical situations, the large amount of urine loss would cause device dislocation, as it would in normal voiding.

The results suggest that the device is safe. Irritative symptoms occurred in a minority of the subjects and rarely resulted in discontinuation of the device. Initially, an increase in physical signs of inflammation was noted, and cytology of the vestibular tissues showed an increase in the density of inflammatory cells in subjects in whom these cells were present. This is likely to be a normal response to microtrauma to the area. In this respect, the device is comparable to other external adhesive devices, such as transdermal estrogen patches, which have approximately a 10% incidence of skin irritation.⁶ The incidence of irritation with the external urethral barrier is acceptably low in this self-selected population of study participants, and the symptoms reported in the study resolved easily with ongoing device use or, in unusual cases, with discontinuation of the device.

This external urethral barrier is a new device for women with mild to moderate stress urinary incontinence. The results of this study indicate that it is a safe and effective alternative to absorbent products.

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