

CLINICAL REPORT

Clinical Evaluation of the Easy-Flow Catheter

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Abstract—A clinical evaluation of the Easy-Flow External Condom Catheter (Delphi Medical Products) was performed on incontinent patients of the Salt Lake City VA Medical Center. All 20 subjects were experienced users of condom catheters prior to entering the study. Use of the experimental device reduced frequency of change for 10 patients, increased daytime dryness for 13 patients, and improved nighttime dryness for 10 patients. All except one of the 20 subjects found the Easy-Flow Catheter easier to apply and all rated it easiest to remove. Overall, 13 of the 20 patients indicated that they preferred the Easy-Flow Catheter to all others used in the past. Although obesity and presence of a small penile shaft were observed to reduce satisfaction with the new device, the Easy-Flow Catheter may improve patient satisfaction for many patients who experience problems with other external condom catheters.

Key words: *external condom catheter, urinary incontinence.*

INTRODUCTION

Urinary incontinence is an increasingly prevalent problem as the population ages. Gradual leakage of urine with occasional sudden heavy flow is a common complaint of older men that severely restricts daily activities and adversely affects life satisfaction. The basic treatment approaches include both internal and external catheter systems to drain and convey urine to a receptacle.

Indwelling devices have proven the most effective as a means of maintaining dryness but because they increase risk and incidence of bladder and urinary infections (1), including pyelonephritis (2), their use is typically restricted to short periods of time. External catheters, which include a sheath surrounding the penis and connection to a drain line, have been associated with penile and urethral complications (3). However, the complications associated with their use have usually been insignificant abrasions or rashes from the sheath or adhesive. The National Institute on Disability and Rehabilitation Research Consensus Statement found little evidence that condom catheters caused urinary tract infections (3). Condom catheters have proven especially useful where a slow, steady urine flow occurs. However, these can be troublesome for individuals with irregular urine flow, or in cases where the sheath is not tight and seepage occurs. Tight sheaths have been reported to cause pain during involuntary erections, be forced off the penis when there is a sudden large flow, or leak when the short-term capacity of the drain line is exceeded. In addition, the straps or adhesives used to hold the sheath in place are often uncomfortable, likely to fail, and can cause skin abrasions. Accordingly, there is a need for improved design of external catheters.

A new external device has been described as extremely resistant to seepage of urine or to being forced off the penis by a sudden large flow of urine. In addition, rather than using straps or adhesives, the sheath of this catheter system is attached to an undergarment that resembles conventional mens' briefs (**Figure 1**).

The device consists of three basic parts. The first is a tubular sheath of rubbery or plastic urine-impervious

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material with a drainage tube connection at one end and a ring at the other. This sheath fits over the penis with the ring at the base of the penis. Located within the ring at the base of the sheath is a reinforcing seal connected to the reinforcing ring at the outer edge of the sheath. The second component (A in **Figure 1**) is a garment that surrounds the lower torso with a frontal opening through which the penis is extended. The opening serves as a receiving hole surrounded by a pair of collars separated by a flange (B in **Figure 1**). The first collar extends outside the garment and the second is positioned adjacent to the base of the penis. The final component is a ring-like collar with inner and outer lips used to secure the sheath to the garment with the penis extending through the seal (C in **Figure 1**).

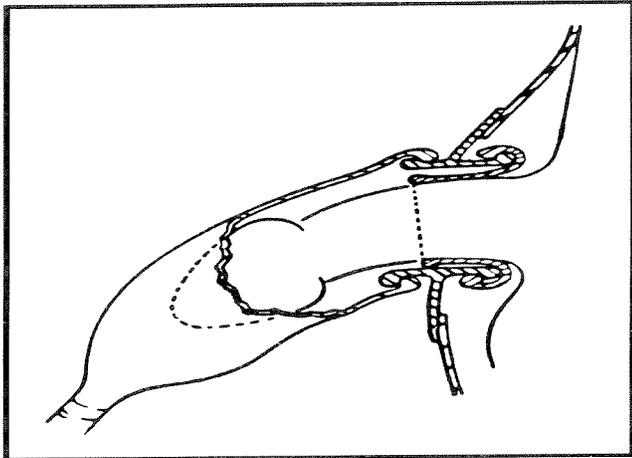


Figure 1.

Components of the Easy-Flow Catheter system. A: Undergarment with components B and C in place. B: Detail of collar, which extends outside the garment. C: Detail of collar, which attaches to B and secures the sheath to the garment. *Reproduced with permission of patent holder, J.J. Giacalone.*

The catheter system may be made in several different diameters to accommodate penises of different diameters, but in most cases the ring at the base of the sheath has an inside diameter of about 3.683 cm (1.45 in). The diameter of the inner and outer lips would then be about 4.318 cm (1.7 in) to allow the sheath and seal rings to snap securely into place. Theoretically, a sudden flow of urine will tend to expand the sheath and the resulting pressure will press the wall of the inner seal and ring more tightly against the penis, preventing leakage. Even with a large volume, sudden urine flow, the sheath should remain secure due to the way in which the collar system attaches it to the garment (**Figure 2**).

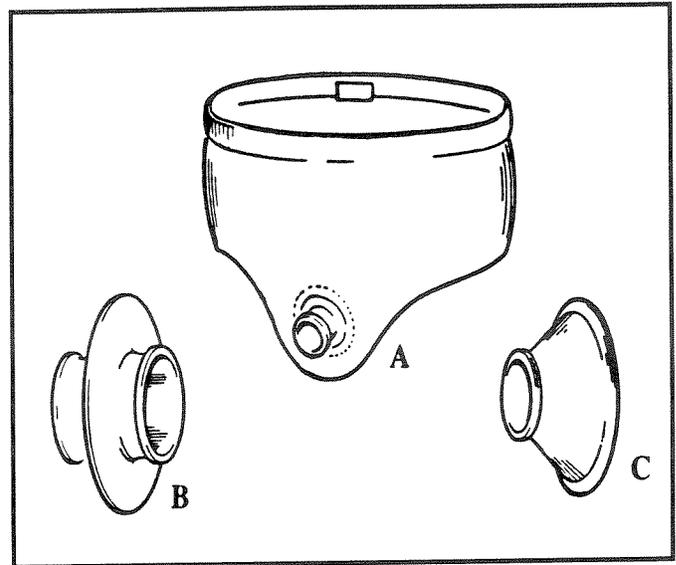


Figure 2.

Cutaway detail of Easy-Flow Catheter system in place. Arrow indicates inner seal, which responds to pressure and prevents leakage. *Reproduced with permission of patent holder, J.J. Giacalone.*

The proposed advantages of this device are that it is easy to apply and remove, and will accommodate large intermittent flows of urine as well as permit drainage of a constant, low flow of urine. However, a device of this type has not been previously subjected to clinical evaluation. In the present study, this new external device was tested by patients experienced in the use of external catheters. (**Figures 3** and **4** are photographs of the device as it was constructed for this study.)

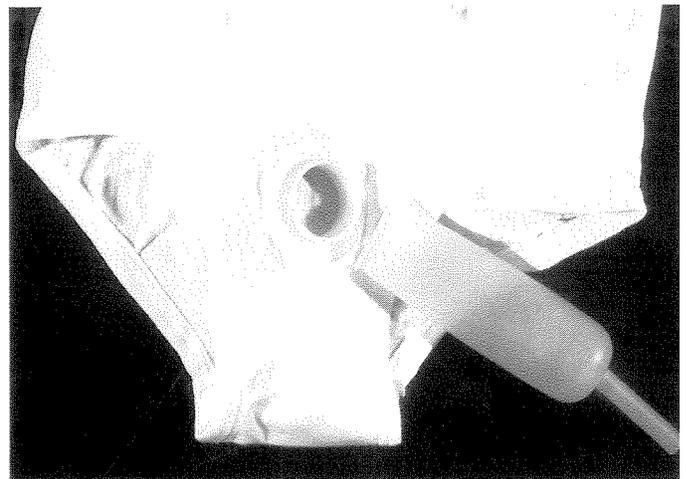


Figure 3.

Easy-Flow Catheter system attached to men's briefs (front view). *Reproduced with permission of patent holder, J.J. Giacalone.*

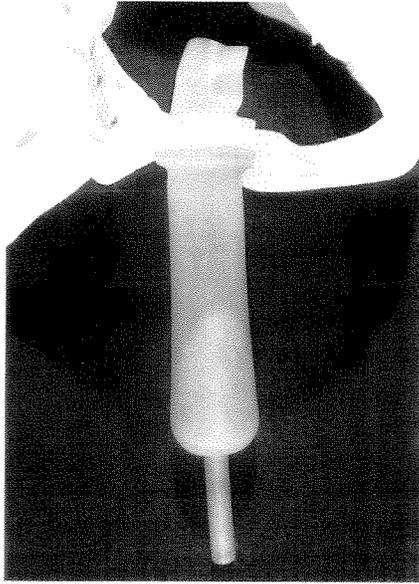


Figure 4. Easy-Flow Catheter system, from the side, illustrating method of attachment to penis. *Reproduced with permission of patent holder, J.J. Giacalone.*

METHODS

Patients who were long-term users of external condom catheters for urine collection were identified from the Pharmacy medication files of the Salt Lake City Department of Veterans Affairs (VA) Medical Center. Recruitment from this list proceeded until 20 patients agreed to participate in a clinical trial of the new external catheter device, the Easy-Flow External Condom Catheter (Delphi Medical Products, Inc., Escondido, CA). Overall, 32 individuals were invited to participate, but 12 of these patients declined, indicating that they were reluctant to try anything on an experimental basis or were extremely satisfied with their current choice and did not care to look at any other options. All patients who were successfully recruited completed the study as described.

Each patient, or his guardian, gave informed consent to participate in the study after a presentation was made explaining the goals, potential benefits, and risks of the study. Either the patient or primary caregiver completed the same survey before and after using the Easy-Flow Catheter. Patients who completed the trial ranged from 26 to 83 years of age and were diagnosed with conditions associated with incontinence as described in **Table 1**.

Prior to using the new device, subjects or their caregivers were asked to complete a questionnaire regarding their previous experience with external catheters. For each type of device, they reported frequency of changes, whether or not the patient required assistance, the number of weeks used, whether or not the patient experienced

Table 1.
Diagnosis responsible for urinary incontinence.

Diagnosis	Number of Subjects
Spinal Cord Injury (SCI)	11
TransUrethral Resection of the Prostate (TURP)	2
Multiple Sclerosis	2
Dementia	1
Diabetes	3
Traumatic Brain Injury	1

urinary tract infections with use of that device, and the degree to which the device kept the patient dry during the day and during the night. They were also asked to indicate their current preference of devices with regard to ease of application, quality of adherence, ease of removal, freedom from skin breakdowns, incidence of odor, and finally, to indicate the device preferred for overall satisfaction. All patients and caregivers were invited to submit comments regarding their prior experience with external catheters. All patients were then given the experimental device, carefully instructed, and asked to evaluate their observations during at least one week of use. The patient or his caregiver then completed the questionnaire again. Length of previous use of external catheters and length of use of the Easy-Flow Catheter are summarized in **Table 2**.

Table 2.
Length and duration of use of urinary continence devices.

Duration	Number of Subjects
Length of Previous Experience	
4 to 12 weeks	3
12 to 26 weeks	2
26 to 52 weeks	4
more than 52 weeks	11
Duration of use of the Easy-Flow Catheter	
1 week	7
2 weeks	10
3 weeks	1
4 weeks	2

RESULTS

Prior to using the Easy-Flow Catheter, seven of the patients indicated a frequency of changes greater than

two times per day. With the Easy-Flow Catheter, only two patients needed to change more than two times a day. The main reasons for changes included "condom came off" (14 patients), "other scheduled or care needs" (11 patients), and "intermittent catheterization" (2 patients) before using the Easy-Flow Catheter. (Six patients reported at least two of these reasons for frequent changes.) Main reasons for changes with the experimental device were "other scheduled medical or care needs" (16 patients), "condom came off" (6 patients), and intermittent catheterization (1 patient)—3 patients indicated 2 reasons for changes. Eleven patients reported needing assistance with other devices. Only one of these indicated that no assistance was needed with the Easy-Flow Catheter. Half of the subjects reported recurrent urinary tract infections regardless of the type of device used. Daytime and nighttime dryness reports are shown in **Table 3**.

Table 3.
Reported "Dryness."

	Performance of Preferred Device (pre)	Performance of Easy-Flow Catheter (post)
Daytime Dryness:		
Always	1	13
Sometimes	15	5
Never	3	1
Not applicable*	1	1
Nighttime Dryness:		
Always	3	10
Sometimes	15	6
Never	2	3
Not applicable*	1	1

*One patient used external catheters only at night, and another used them only to go out during the day.

For ease of application, four patients preferred VA, seven preferred Freedom, four preferred Mentor, two preferred Hollister, two preferred Bard, and one reported "all the same." After using the Easy-Flow Catheter, only one of the patients remained loyal to Mentor. All others preferred the ease of application with the experimental device. Asked which device stayed on the best, four patients indicated VA, nine indicated Freedom, two indicated Hollister, one indicated Mentor, one indicated Urinary Pouch, three indicated Bard. After using the Easy-Flow Catheter, one patient who previously favored Freedom and one who previously favored Urinary Pouch

indicated that the experimental device stayed on better. All patients reported that the Easy-Flow Catheter was easier to remove than any of the previously used devices.

The incidence of skin breakdown with external catheter use was decreased with use of the Easy-Flow Catheter for seven of the patients who reported past problems. One patient for whom Mentor was associated with the least skin breakdown continued to prefer Mentor after using the experimental device. All other patients reported that skin breakdown had not been a problem for them. Five patients reported less incidence of odor associated with the Easy-Flow Catheter, although four patients indicated no odor associated with any of the devices used. The remaining patients indicated no preference or maintained the preference listed prior to their use of the experimental device for controlling urinary odor.

Of the 20 patients, 17 reported problems with urine flow sometimes forcing the condoms of previous devices off the penis. Only four patients reported having this problem with the Easy-Flow Catheter. Six of the 20 reported that catheters previously used caused skin irritation. Only one patient reported skin irritation with the experimental device. Eight patients had experienced skin irritation with adhesives used to attach previous external catheters. No skin irritation was reported while using the Easy-Flow Catheter. Seven patients reported noticeable odor with previously used devices. Three reported odor while using the Easy-Flow Catheter and one other patient noticed some odor only during nighttime use of the experimental device.

Finally, **Table 4** summarizes use history, overall preference before using the Easy-Flow Catheter, and overall preference after using the experimental device. All three patients who previously preferred Bard, one who previously preferred Hollister, three who preferred Freedom, three who preferred VA, and three who had not indicated a preference named the Easy-Flow Catheter their overall favorite following the clinical trial.

DISCUSSION

Although patients used the Easy-Flow Catheter for only a short time relative to their prior experience with external catheters, they appeared to adapt well and quickly. While the short exposure may have limited chances to experience difficulties, most patients reported overall satisfaction with the experimental device and more than half preferred it to all others used in the past.

Table 4.

Types of devices used by patients and their overall preference prior to using the Easy-Flow Catheter.

Device Type	Number of patients reporting previous use	Number of patients reporting preference (pre)**	Number of patients reporting preference (post)***
VA*	9	3(2)	—
Texas	2	—	—
Freedom	13	7(1)	2
Mentor	5	1(1)	2
Hollister	5	2(0)	1
Bard	4	3(0)	—
Urinary Pouch	1	—	—
Easy-Flow Catheter	—	—	13

*"VA" was used when patients could not remember the name of the external catheter, but reported that it was supplied by the Pharmacy service of the VA Medical Center. Eleven subjects had used 2 types of external catheters prior to the clinical trial; 4 had used 3 other devices.

**Numbers in parentheses indicate number of patients who previously had used only the preferred device. Two patients whose prior use included VA, Freedom, Texas, Mentor, and Urinary Pouch, did not indicate a preference; one patient who previously used VA indicated a preference for diapers; and one patient who had used VA and Bard indicated that neither was satisfactory.

***Two patients indicated diapers as their overall preference following the clinical trial. One of these indicated a preference for Freedom prior to the clinical trial.

In particular, ease of application and removal was noted to be an improvement over other condom systems in all but one patient. The experimental system also improved both day and nighttime dryness for a majority of the patients in the study.

Physical characteristics that made the device inappropriate were a short, small penile shaft that would retract from the condom with movement of the patient. Obesity, with a pendulous abdomen, which would force the under-shorts (and the catheter) away from the body, and therefore withdraw the penis from the catheter, was also a contraindication to the use of this device. The only episode of skin breakdown was in a young brain-injured patient who suffered superficial skin abrasions when he became agitated during twice daily range of motion therapy.

SUMMARY

The Easy-Flow External Condom Catheter was rated by the patients in the trial as superior to existing systems in a number of areas. It was the easiest device to position and remove for the majority, and more than half indicated that they preferred this external catheter system to all others used in the past. Although our small, nonrandom sample of patients and the absence of a control group preclude statistical inferences and generalization to all external catheter users, these results suggest that the Easy-

Flow External Condom Catheter may provide greater patient satisfaction for many patients who have problems with other external catheter systems.

ACKNOWLEDGMENTS

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Figures 1 and 2 and photographs of the device used in this study were reproduced with permission of the patent holder, J.J. Giacalone. Original figures appear in United States Patent Document #4,588,397, dated May 13, 1986.

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