Clinical Evaluation of the URINCare® System

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Abstract – A clinical evaluation of the URINCare® external urine collection system (Omni Medical Products) was preformed on male and female fighter pilots by the U.S Air Force. A total of 45 subjects trialed the system to evaluate the systems performance during long duration (8-16 hour) missions. The system was rated for its ability to keep the user dry, its overall comfort and ease of use. Both male and female external urine collection devices were evaluated. Overall 44 out of the 45 subjects rated the system with an acceptable or completely acceptable rating, with no adverse events being reported. The results of the trial led to a Safe-to-Fly certification for use on all USAF aircraft.

(Key Words: External urine collection)

Introduction

There are no acceptable commercially-available, bladder relief systems for female or male aircrew members flying extended flight operations in single or dual-seat fighter and reconnaissance aircraft. Male aircrew members use two types of bladder relief bag systems such as the piddle pack, and external condom catheters with tubing. While using the current available devices, a pilot has to unbuckle and partially undress to relieve their bladder. During this time, the pilot is not in control of the aircraft and is vulnerable to external events such as weather and other aircraft, thereby compromising his safety and that of the aircraft. When circumstances do not allow the pilot to take several minutes to use the urine collection bag, the pilot has to urinate on himself to relieve bladder pain, leaving the pilot wet with urine throughout the duration of the flight compromising his physical comfort.

Catheter systems can cause serious skin irritation or erosion due to hygiene issues. Condom catheters have a tendency greater than twice in an 8 hour period, making it an unreliable solution for long duration missions. The catheter relies on gravity to drain urine away from the penis. Due to the positioning of the pilot in the ejection seat, the flow of urine is restricted from moving downward; therefore the penis remains wet for the duration of the mission, causing irritation and redness.

These current bag or catheter systems can be dangerous to use if the pilot needs to eject from the aircraft while urinating. The optimum bladder relief system would allow the pilot to eject from the aircraft even while urinating, requiring it to be hands-free and at least semi-automatic.

Female aircrew members cannot use the bag systems or catheter assemblies designed for males. Instead, most use commercially available adult diapers such as Depends. These diapers have the following drawbacks:

1. The diapers do not have the capacity to hold the 1000 cc of urine produced during some

long duration flights. This requires female pilots to use multiple diapers during a mission.

2. High g maneuvers force the female aircrew member downward into the seat, displacing urine from the diaper and leaving the female to sit in a wet diaper for the duration of the flight.

3. Prolonged exposure to urine can cause skin irritation and may develop into more serious conditions such as pressure ulcers.

A new external extracorporeal urine collection device was developed to solve this problem. The device consists of four basic parts. The first component used for males, is a soft polyethylene collection cup with liquid sensors. (**See Figure 1**) The collection cup is similar to ones used by professional athletes and resides in a specially designed undergarment. The flexible medical urethane cup contains urine sensors and serves as a reservoir for urine as it escapes from the bladder. The cup fits comfortably over the penis letting the shape contour to the body. Attached to the cup is a medical grade foam ring to create a seal between the body and the device. The first component used for females is a soft semi-inflated female pad with urinary sensors. The inflated pad sits inside a female undergarment, allowing it to contour to the shape of the body. **(See Figure 2)** The pad has multiple collection holes containing urine sensors. This area serves as a reservoir for urine as it escapes from the bladder.

Figure 1.
External male cup with sensors: Shown with collsaple medical grade foam ring.

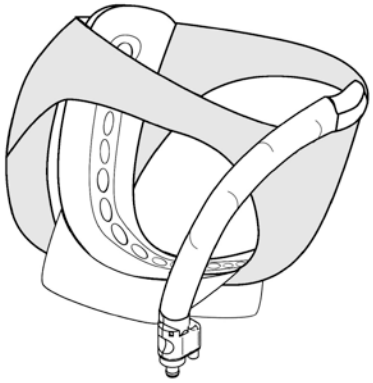
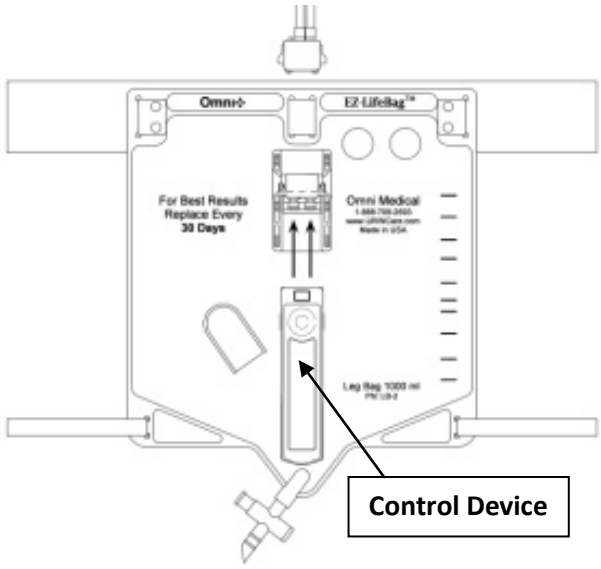


Figure 2.
External Inflatable Female suspensory with liquid sensors shown with collection holes inside garment.

The second component is a specially designed urinary drainage bag . The bag is similar to other commercially available bags on the market, with the exception that the hose connector is designed to interface with the cup or pad and control device.

Figure 4:
Drainage bag with control device attachment



The third part is a garment similar to commercially available boxer briefs, jockstrap, or female cotton briefs, which help keep the cup or pad in place. **(See Figure 3**)

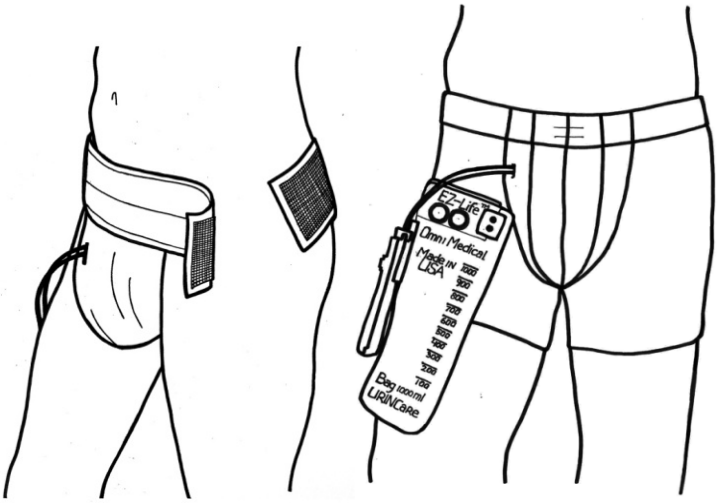


Figure 3:

Male Garments
The final component is a self priming impeller pump, used to evacuate and expel urine and moisture from the cup. The pump slides on and connects to the drainage bag **(See Figure 4).** The largest advantage of this device is keeping individuals dry, potentially minimizing and/or eliminating maceration, excoriation, ulcerations, erosions, fungal and bacterial infections associated with absorbent pads and Texas/condom catheters.

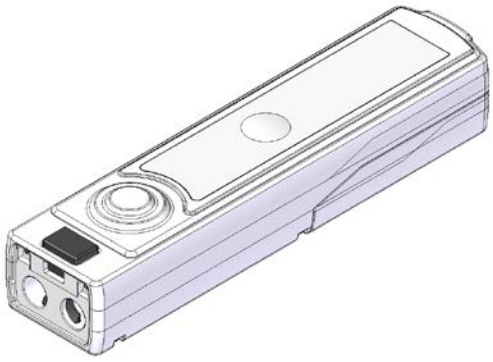


Figure 5:
Control Device Pump

Methods
The trial contained three phases: Phase one, comprised of in house clinical trials under the approval of the Essex Institutional Review Board, Inc. This trial consisted of 7 ambulatory male and female subjects. Each user completed six 8-hour trial period uses. Phase two, comprised of five 8-hour ground trials under the approval of the Air Force at Wright-Patterson Institutional Review Board. This trial incorporated 11 Female and 6 male subjects who were users of Piddle Packs, external condom catheters and Depends® briefs for bladder relief. Phase three comprised of ten flight trials each of 8 male and 6 female pilots. This phase was also conducted under the approval of the Air Force at Wright-Patterson Institutional Review Board. All subjects who were successfully recruited completed the study as described.

Each subject was given an informed consent to participate in the study after an explanation was made explaining the goals, potential lbenefits and risks of participating in the study.

Prior to using the new external device, subjects were asked to complete a (questionnaire) regarding their experience and satisfaction using presently available methods for bladder relief. The questionnaire asked the subject to report whether or not the device was easy to use, whether or not it was comfortable, and whether or not it kept them dry and if they had any history of urinary tract infections with the use of the device. All subjects were encouraged to submit comments regarding their prior experience with bladder relief methods.

Table 1. Phase 1: Duration of Study

Duration	Number of Subjects
Male Subjects	
1 to 4 weeks	1
4 to 8 weeks	4
8 to 12 weeks	1
Female Subjects	
1 to 4 weeks	1
4 to 8 weeks	8
8 to 12 weeks	2

Table 2. Phase 2: Duration of Study

Duration	Number of Subjects
Male Subjects	
1 to 4 weeks	1
4 to 8 weeks	4
8 to 12 weeks	1
Female Subjects	
1 to 4 weeks	1
4 to 8 weeks	8
8 to 12 weeks	2

Table 3. Phase 3: Duration of Study

Duration	Number of Subjects
Male Subjects	
1 to 4 weeks	3
4 to 8 weeks	5
8 to 12 weeks	2
Female Subjects	
1 to 4 weeks	2
4 to 8 weeks	2
8 to 12 weeks	2

All subjects were given a new external urine collection device, carefully instructed how to use the device and asked to evaluate their dryness, comfort, and if they experienced any adverse events during each trial of use. Each subject completed a survey after each trial use of the external urine collection system. Duration of each trial period for each male and female subject is reported in **Table. 1,2,3**

Results

45 subjects tested the new external urine collection system. There were 24 female and 21 male subjects who completed the study. **Table 4** summarizes the number of uses each female subject reported with the new external urine collection device. The reported reliability and dryness of the system was rated in four categories. The first, Completely Acceptable (CA) indicated the system keep you completely dry; no leaks) The Second category, Acceptable (A) ratings indicated the system kept you dry, but there was residual urine (<2cc) remained in the collection cup/pad. The third category, Unacceptable (U) indicated the collection system left the subject damp. The last category, Completely Unacceptable (CU) indicated the subject reported wetness after it's use. The summary of results for the surveys are found in **Table 5**.

Table 4.
# of uses per trial

	Phase 1	Phase II	Phase III
Number of uses			
Females	42	52	53
Males	42	27	72

During Phase II one out of the eleven subjects completed 2 of the 6 expected trials. In Phase II one male subject only completed 3 out of the 5 expected trials. During Phase III three female subjects did not complete all 10 expected flight trials. Two females completed only 7flight trials and one female only completed 9 flight trials.

Table 5.
Subjects Report on level of “Dryness

	Subjects Reporting Completely Acceptable (CA)	Subjects Reporting Acceptable (A)	Subjects Reporting Unacceptable (U)	Subjects Reporting Completely Unacceptable (CU)*
Females	57	90	----	-----
Males	86	54	----	1

Completely Acceptable is rated for users that reported complete dryness and no leakage. Acceptable is rated for users that held residual urine left in the collection cup or pad(<2cc) U* One subject indicated he had not charged his batteries prior to using the system. Unacceptable is rated for users who indicated the external collection system left them damp. Completely Unacceptable is rated for users that reported wetness after using the external urine collection device.

There were no incidences of skin break down reporting from any of the 45 subjects, having used the external collection device for a combined amount of 288 trials. No subjects reported experiencing skin breakdown while using other methods. There were no reported incidences of urinary tract infections using the new external urine collection device. Twelve of the female subjects reported they had a history of at least one urinary tract infection within a calendar year using other methods.

Discussion

Although the subjects used the new external urine collection device for only a few times compared to their prior experiences with condom catheters and adult briefs, they all appeared to adapt well and quickly. Most patients reported overall; satisfaction with the experimental device and nearly all preferred this system to others in the past. due to

operating the system with un-charges batteries subject reporting an incident of being wet was