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A Prototype Urine Collection Device for Female Aircrew.

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ABSTRACT

INTRODUCTION: Women are gaining increased access to small military cockpits. This shift has stimulated the search for practical urine containment and disposal methods for female aircrew. There are no external urine collection devices (UCD) for women that are comfortable, convenient and leak free. We describe a prototype UCD that begins to meet this need. **METHODS:** Materials used to make custom aviator masks were adapted to mold a perineal mask. First, a perineal cast (negative) was used to make a mold (positive). Next, a perineal mask made of wax was formed to fit the positive mold. Finally, a soft, pliable perineal mask was fabricated using the wax model as a guide. The prototype was tested for comfort, fit and leakage. **RESULTS:** In the sitting position, less than 5 cc of urine leakage occurred with each 600 cc of urine collected. Comfort was mostly satisfactory, but ambulation was limited and the outlet design could lead to kinking and obstruction. **CONCLUSIONS:** A perineal mask may serve as a comfortable and functional external UCD acceptable for use by females in confined environments. Changes are needed to improve comfort, fit, and urine drainage. Integration into cockpits, pressure suits, chemical defense gear, and environments where access to relief facilities is restricted is planned

INTRODUCTION

Changes in the perceived military threat in Europe, military downsizing, budget cuts and other political realities increase the emphasis on long duration and rapid deployment. Global Reach - Global Power espouses a new vision for power projection over global distances. Something as simple and banal as urine containment and disposal contribute to the human factors that can make human endurance limiting in plans for supporting long duration missions.

Congressional action to remove combat restrictions has increased the number of women gaining access to military cockpits. The size of high performance cockpits and personal protective gear can severely restrict opportunities for relief from the physiological need to pass urine. Condom catheters or "piddle packs" have been an acceptable solution for males, but even these solutions encourage some crew members to adopt fluid restriction and other unsatisfactory strategies to avoid urinating inflight. The problem is magnified for the female crew member. There are no external urine collection devices (UCD) for women that are comfortable, convenient and leak free. This shift of women into combat roles that can restrict access to convenient urine relief facilities has stimulated the search for a practical external urine containment and disposal method for female aircrew of high performance aircraft. Solving urine disposal problems for women aviators would be of great benefit to the military and has clinical and non-clinical commercial applications. We describe a prototype UCD that begins to met this need for the female aviator.

METHODS

A female subject volunteered to have a mold made of her perineal area in order to obtain a form for modeling and molding a prototype mask. The subject was placed in the lithotomy position with the thighs only slightly abducted. Hydrophilic vinyl polysiloxan with a hardened acrylic backing was used to make a negative cast of the perineum. This process was similar to the methods used to obtain facial impressions for custom fitting aviator masks. Using the negative cast, a synthetic stone positive impression was poured. The positive impression was used to mold several wax prototype perineal mask forms. After several design trials, we selected a wax prototype from which to model a custom perineal mask. The materials were sent to the Life Support function at Wright-Patterson AFB where a custom latex perineal mask was molded and returned for testing. The prototype mask was worn by the subject for seven continuous hours during each of five days. The mask was held in place by cotton briefs modified to accommodate the outlet tube and an adult diaper. Routine daily activities were carried out limited to ambulation around a small apartment. When urgency occurred a collection bag was attached to the outflow tubing and the subject urinated in sitting or standing positions. Urine flow was gravity dependent for this trial. The diaper and briefs were weighed to quantify the small amount of leakage. The subject commented on comfort and functionality.

RESULTS

Placement of the device was well maintained in the sitting position and with light ambulation. In the sitting position less than 5 cc of leakage occurred with each 600 cc of urine collected. Comfort was satisfactory while sitting, but the prototype was too deep and wide for comfortable ambulation. Central placement of the outlet tube allowed some pooling of urine inferiorly when used in the sitting position. The latex material at the outlet was too pliable. This could lead to kinking of the outlet tube and flow restriction under more severe test conditions. Comfort could be improved during ambulation without sacrificing function if the device could be molded slightly more narrow and with less depth.

DISCUSSION

We have designed a perineal mask that fits against the perineum as a customized UCD for females. It is very similar in principle to a male athletic supporter and cup used to prevent athletic injuries and should have equal comfort and utility. It should be possible to fit 95 percent of all women using 6-10 sizes. Like the present male UCD used in the U-2/TR-1, the device should be reusable and relatively inexpensive. Other external UCDs designed for female use include the Disposable Absorption Containment Trunk (DACT), the Maximal Absorptive Garment (MAG), the Hollister device and similar custom made vaginal seals, and devices modified from ostomy appliances used in clinical medicine.

The DACT is a highly absorbable diaper used in pressure suits by the Air Force. This device is worn throughout the mission until the pressure suit is removed. The DACT is designed to hold up to 900 cc of urine and be used once for a period of seven hours. Problems with the DACT include leakage, dermal irritation, cost and discomfort due to its impermeable construction and the large surface area covered(1). NASA uses a similar device called the Maximal Absorptive Garment (MAG) designed to hold up to 1500 cc of urine. NASA originated a patent for a custom fitted urethral outlet held in place by a soft pliable vaginal seal and an undergarment(2). A similar urethral funnel and vaginal seal is marketed commercially by Hollister Incorporated. The Hollister device is particularly well designed for integration into the pressure suit or cockpit environments. However, its comfort is likened to riding a bicycle seat. Preliminary discussion with female U-2 pilots suggests that it may not be suitable. Some women may find it intolerable for flight of very long durations or flights encountering high G loads(3). Other investigations into the area of female urinary collection devices has been in the field of clinical medicine. Urine collection devices for incontinent women and nursing home patients have utilized adhesives developed for ostomy appliances(4, 5). Use of such devices is not common. To our surprise, we have been unable to find references to a device similar to our perineal mask.

Additional features of our design for female aviator use include adding superabsorbent chemicals to the urine storage bags to simplify disposal and minimize risk of inadvertent contamination of the cockpit from leakage. Specifications for a reusable undergarment to hold the device in place will incorporate a super absorbent pad to retain the small amount of leakage that is probably inevitable in many applications. Future trials for possible use in the U-2/TR-1 pressure suit will incorporate airflow similar to the flow achieved through cabin/suit pressure differentials in the male UCD system. Airflow may assist with flow and improve hygiene. If these tests go well, we will need to locate a manufacturer who is able to incorporate design recommendations related to the depth of the device and increased stiffness at the outlet port.

The development of a comfortable, external UCD for females would be of great benefit. Military applications include cockpit relief during long duration flights, pressure suit environments, and incorporation into chemical warfare defense clothing. Commercial applications include use in any environment where access to a relief facility is limited. Clinical uses in both ambulatory and non-ambulatory incontinent patients could be an attractive benefit of this design. Initial findings have been rewarding. We are looking forward to testing a second generation device which corrects some of the design deficiencies noted in the preliminary test reported here.

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REFERENCES

1. Barlow, J.F., and S.E. Richardson. "Evaluation of the disposable absorption containment trunk for female U-2 and TR-1 pilots." Aviation, Space and Environmental Medicine. 1991, 62(6):577-9.

2. Michaud R.B. and R.A. Frosch. Urine Collection Apparatus. United States Patent 4,270,539 (filed Apr 27, 1979). United States Patent Office, June 2, 1981.

3. Crook B. and R.E. Sherman. "Proposal for flight test of Hollister female urinary incontinence system." Personal Communication. Nov 1991.

4. Johnson, D.E., H.L. Muncie, J.L. O'Reilly and J.W. Warren. "An External urine collection device for incontinent women. Evaluation of long term use." Journal of the American Geriatric Society. 1990. 38(9):1016-22.

5. Johnson, D.E., J.L. O'Reilly and J.W. Warren. "Clinical evaluation of an external urine collection device for nonambulatory incontinent women." Journal of Urology. 1989. 141(3):535-7.