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**AVIATORS' URINE COLLECTION DEVICES: PRELIMINARY
LABORATORY TRIALS**

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ABSTRACT

Female aircrew personnel identified a lack of adequate, gender-specific urine relief facilities and gender-specific urine collection devices in a previous naval aviation survey effort, Aircrew Modified Equipment Leading to Increased Accommodation (AMELIA). The Naval Aerospace Medical Research Laboratory conducted four laboratory trials of various commercially available, off-the-shelf urine collection devices (UCDs) as part of a reimbursable project for Naval Air Warfare Center-Aircraft Division, Warminster, Pennsylvania to evaluate (1) the maximal fluid capacity of various constant-wear UCDs and disposable/reusable UCDs; (2) the comfort, fit, and compatibility of constant-wear UCDs with specific personal aviator's flight equipment; (3) the effect of a simulated +3G_z environment on the constant-wear UCDs with and without a simulated weight of 80 lbs; and (4) the effect of a rapid-decompression/ high-altitude (simulated aircraft environment) profile in the hypobaric (low pressure) chamber. Upon completion of these trials, we recommended five constant-wear UCDs and six disposable/reusable UCDs for use by aircrew personnel in the fleet assessment phase of the Naval Air Systems Command sponsored, interim UCD project.

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INTRODUCTION

A literature search revealed a limited amount of research concerning urine collection devices (UCDs) for aircrew personnel. As early as 1943, Jacqueline Cochran recognized that urine collection systems for women who fly prolonged missions must be designed differently.¹ The United States Air Force (USAF) and the National Aeronautics and Space Administration (NASA) adopted a UCD, the Disposable Absorption Containment Trunk (DACT), which is a diaper-like device for high-altitude, pressure suit ensembles.² Female and male NASA astronauts use the DACT during launch and reentry on space shuttle missions, and USAF female aviators who flew the U-2 and TR-1 reconnaissance aircraft used the DACT.² The DACT absorbed a maximum of 950 cc of menstrual blood and urine without leakage during 10.75-hour sessions in a USAF study. A higher urinary output resulted in minimal leakage.² One disadvantage of the DACT is its cost: \$500 for each diaper that can be worn once, then discarded even if not used to collect urine.³

Under normal conditions, a woman has a certain bladder volume threshold for micturition (urination). The female's bladder volume is determined by age and life situation (e.g., history of multiple pregnancies or history of bladder infections). Additionally, the bladder threshold may vary considerably with psychogenic factors (e.g., emotional considerations, medical or psychologic trauma), resulting in a small volume and increased frequency in some situations, and an increase in bladder volume and retention in other situations.⁴ The bladder volume for women who experience postpartum urinary retention can vary between 700 and 1000 ml of fluid. The nonpregnant woman has a bladder capacity between 350 and 450 ml. A woman usually experiences a desire to urinate when the bladder contains between 150 and 200 ml of fluid. The maximum urge for urination occurs with a bladder volume of 450 to 550 ml.⁵

Another potential urinary problem for some females is urinary urgency and frequency because the incidence and prevalence of these symptoms increase with age. The symptoms are a result of a diverse group of etiologic bases (e.g., pathologic, iatrogenic or psychologic). Urinary urgency is referred to as a powerful sensation to void, regardless of bladder volume. Urge incontinence, the involuntary loss of urine associated with a strong desire to void, may be related to both urinary urgency and urinary frequency in females. Urinary frequency may result in voiding at intervals of 2 h or less, sometimes more than seven times per day.⁶

Female aircrew personnel could experience a debilitating in-flight physiological episode; ureteral spasm akin to a sensation of passing a kidney stone occurs because of voluntary extended urine retention and an overfull bladder. A male naval aviator experienced this problem during a helicopter mission because of voluntary extended urine retention. Six and one-half hours after consuming one can of cola and about a quart of water, he attempted to relieve himself using his piddle pack in flight. He experienced severe pain, nausea, and dizziness. He also felt faint. The aviator had experienced ureteral spasm during urination due to a bladder over its maximum capacity, causing severe flank pain that lasted for several minutes. There is no way to predict who (female or male) may experience a similar situation, even if an individual has never had a problem before.⁷

A fiscal year 1993 survey of female aircrew personnel, conducted under the Aircrew Modified Equipment Leading to Increased Accommodation (AMELIA) program by the Naval Aerospace Medical Research Laboratory (NAMRL), identified a lack of UCDs for females onboard aircraft.⁸ Female aircrew personnel identified various methods of coping with the lack of compatible/suitable UCDs. They also indicated that they would like to see some type of UCD incorporated into their aircraft or as part of issued Aviation Life Support Systems (ALSS).⁸ In this technical report, the term "aircrew personnel" will include naval aviators, naval flight officers, naval aircrewmembers, naval flight surgeons, naval aerospace physiologists, and naval aerospace experimental psychologists.

Based on the AMELIA survey's results, Naval Air Warfare Center - Aircraft Division, Warminster (NAWC) began investigating interim and long-term solutions for the lack of adequate urine relief facilities and devices for females aboard USN/USMC aircraft. The UCD project is a two-phase effort consisting of a nondevelopmental item (NDI) effort and a longer research and development effort that, if necessary, will develop a female-compatible UCD specifically for the aircraft environment. As part of the first phase of this effort, NAWC

constant-wear UCDs and 3 disposable/reusable UCDs) for the laboratory trials prior to a fleet assessment by aircrew personnel. These products were purchased by NAWC based solely on the product's commercial availability. At this point, no performance requirements were instituted in order to allow all available products to be evaluated. All products were evaluated without the manufacturers' input, excluding information given on the products' packaging. This situation permitted testing to be done without influence from the commercial market. During the project, NAWC added additional UCDs (one generic constant-wear UCD, two generic disposable/reusable UCDs, and one male-only disposable/reusable UCD) to increase the options for aircrew personnel. Information concerning these products was not available at the time of the product search. Due to the personal preference nature of the evaluation, all feasible "off-the-shelf" UCDs were included to increase the number of options for aircrew personnel.

In the interim, NAMRL coordinated the evaluation of several off-the-shelf UCDs for both female and male aircrew personnel. This effort may lead to a long-term solution depending on fleet acceptance in each aircraft community (prop, jet, and helo). All interim UCDs were commercially available, off-the-shelf products widely used for urinary relief while camping/hiking or for incontinence. Two factors, the time constraint posed by the starting date for the fleet assessment of the interim UCDs and the potential risk to human subjects using/wearing the UCDs in a simulated aircraft environment, influenced the design of the four laboratory trials. We present the methods, procedures, results, discussion, conclusions, summary, and recommendations for four laboratory trials of various off-the-shelf UCDs in this report. The four laboratory trials of the UCDs included: (1) the maximal fluid capacity of various constant-wear UCDs and disposable/reusable UCDs; (2) the comfort, fit, and compatibility of constant-wear UCDs only with specific personal aviator's flight equipment of six female aerospace physiologists; (3) the effect of a +3G_z environment (simulated aviation environment) on the constant-wear UCDs with and without a simulated weight of 80 lbs; and (4) the effect of a rapid-decompression/high-altitude profile (simulated aviation environment) on both the constant-wear UCDs and the disposable/reusable UCDs in the hypobaric (low-pressure) chamber.

We established criteria that the constant-wear UCDs and the disposable/reusable UCDs had to meet prior to our recommendation of their use in a subsequent fleet assessment by female and male naval aircrew personnel. The first criterion was that the constant-wear UCDs and the disposable/reusable UCDs hold a minimal amount of urine (e.g., 150 - 200 ml), which approximates the nonpregnant female's first desire to urinate. The second criterion was that the constant-wear UCDs must be comfortable and compatible with the female aviator's ALSS (e.g., flight suit, torso harness, and anti-G suit). The third criterion for the constant-wear UCDs in a simulated aircraft environment (+3G_z) of the Coriolis Acceleration Platform (CAP) was (1) no bead/gel bleed-through or displacement through the top layer of the constant-wear UCD's absorbent material, and (2) no excessive fluid leakage out of the constant-wear UCD's absorbent materials to the paper toweling placed under the constant-wear UCDs when a simulated weight of 80 lbs was placed on top of it. Theoretically, bead or gel displacement through the top layer of the constant-wear UCD's absorbent material could lodge on or near the female's urethral opening and contribute to a urinary tract infection (UTI). Furthermore, any significant fluid leakage from a constant-wear UCD due to pulling Gs may be deemed unacceptable by the female and male aircrew personnel in the tactical jet community. The final criterion for both the constant-wear UCDs and the disposable/reusable UCDs was any observable configuration changes due to a simulated aircraft environment (rapid-decompression and high-altitude profile) in the hypobaric chamber that may be deemed unacceptable by the female or male aviator. The criteria for constant-wear UCDs in the hypobaric chamber (LPC) trials were (1) no bead/gel displacement through the top absorbent layer of the UCD, or (2) no excessive fluid leakage onto the paper toweling placed under the constant-wear UCDs. The criteria for the disposable/reusable UCDs in the hypobaric chamber were twofold: (1) no backflow of fluid via the extension tubes from the collection bags, or (2) no structural failure of the collection bag or extension tube due to expanding trapped gases during a rapid decompression and subsequent ascent to a simulated altitude of 40,000 ft.

MATERIALS AND METHODS

SUBJECTS

Six aerospace physiologists, ranging from ages 23 to 35 served as subjects. They evaluated the comfort, fit, and compatibility of 14 constant-wear UCDs (#1-14) with their personal Aviation Life Support System (ALSS) before the laboratory trials in the hypobaric chamber and the CAP.

MATERIALS

Subjects evaluated two categories of commercially-available, off-the-shelf UCDs: constant-wear UCDs and disposable/reusable UCDs. Product names for the two categories of UCDs are listed in Appendix 1. The constant-wear UCDs were worn in the individual's undergarment, and the disposable/reusable UCDs were stored until needed for urination. Initially, NAWC provided samples of 14 constant-wear UCDs and 1 disposable/reusable UCD. Later, NAWC approved the use of one additional constant-wear UCD and five more disposable/reusable UCDs for this study. The NAWC categorized the constant-wear UCDs and disposable/reusable UCDs in one of three maximal fluid capacity categories based on the manufacturers' product information on the package: light to moderate voiding UCD, moderate to heavy voiding UCD, and complete voiding UCD. Descriptive information for each UCD was obtained from the product's package, and is summarized below.

Light-to-Moderate UCD. When using a UCD in this range, urine must be intermittently released. Although it is impossible to judge the amount of urine released each time, it is necessary to void in small quantities to avoid leakage. Eight pads, one belted undergarment, and one undergarment fall in this category of the constant-wear UCDs. The off-the-shelf, constant-wear UCDs in this category are described on the subsequent pages:

1) UCD #1-Pad. Baking soda inside the pad absorbs odors; extra protection zone that is thicker in the middle for protection and has tapered ends for comfort; extra length to protect against end leakage; and a flow-through cover that draws fluid inside the pad away from the body.

2) UCD #2-Extra-Absorbency Long Pad. Absorbent material safely locks liquid into a gel to help prevent leaks; dryness layer that pulls liquid away from body; elastic gathers curve the pad for a better body fit and leak prevention.

3) UCD #3-Belted Undergarment. Flexible leg-gathers and cupped shape design with contour pad helps provide close, comfortable fit; thin core absorbs moisture away from skin.

4) UCD #4-Pad. Absorbs wetness quickly, and keeps it away from skin; soft, elastic gathers help provide a snug fit in the crotch area to prevent leakage.

5) UCD #5-Pad. Pad fibers have molecular structure that absorbs fluid away from skin; pad is much thinner than a maxi-pad; elastic gathers and channels provide leakage protection; cover on top of pad keeps wetness from skin; longer back provides more leakage protection.

6) UCD #6-Pad. Covering pulls wetness into the core; side gathers curve the pad to help fit pad to body and prevent side leakage; contouring lines help shape the pad for fit.

7) UCD #7-Pad. Manufacturer's package did not provide product specific information for UCD.

8) UCD #8-Pad. Cover directs moisture into pad to keep skin dry and maintain pad softness; layer draws liquid from surface of pad; quilted layer disperses fluid for rapid absorption; fluid is locked into gel to prevent leakage; deodorant neutralizes odor; foam backing provides containment, softness, and comfort.

9) UCD #9-Shield Pad. Absorbent material for protection and odor control; protects against leakage from stress or overflow incontinence; comfortable fit; usable by both men and women.

10) UCD #10-Undergarment/Diaper. Panties must be worn with this product; no other product specific information provided by manufacturer on UCD's package.

Moderate-to-Heavy UCD. As with the light-to-moderate UCDs, voiding must occur in stages to avoid leakage. However, these items will collect more fluid than light-to-moderate UCDs. Voiding in stages should be attempted to ensure sufficient absorbency. One pad and two undergarment/diapers fall in this category of constant-wear UCDs. The following off-the-shelf, constant-wear UCDs are described below:

1) UCD #11-Pad. Absorbent core locks liquid into a gel to prevent leakage; dry layer with channels helps pull liquid away from the surface and into the core; odor-absorbent material helps prevent the formation of ammonia -- a primary cause of odor; soft, comfortable shell with contoured shape and foam backing in a cup shape for leakage protection.

2) UCD #12-Undergarment/Diaper. Secured to body with tape on corners of UCD for testing purposes; normally a belt with Velcro straps or elastic straps holds UCD to body. Reusable straps are adjustable for secure fit up to 54" hips. Liner keeps moisture away from skin. Leakage control zone with absorbent center area absorbs and locks fluid away from body. Elastic leg gathers reduce leakage.

3) UCD #13-Belted Undergarment-Diaper. Absorbent gel-lock system keeps individual dry; moisture barrier prevents leaks; strong elastic belts and multiple elastic leg for optimum fit; no-tear buttonholes and buttons for elastic straps; fits women and men with hip sizes to 60".

Complete-Voiding UCD. These UCDs are made to hold complete voiding of the bladder. We tested two undergarment/diapers (constant-wear UCDs) and seven disposable/reusable UCDs in this category of UCDs. The following off-the-shelf, constant-wear and disposable/reusable UCDs are described below:

1) UCD #14-Undergarment Diaper. Nonwoven fabric against skin; absorbent center; moisture-proof backing; elastic leg gathers provide snug fit for leakage prevention; absorbent material within core locks in liquid and neutralizes odor-causing acids in urine; elastic waist straps adjust to waist sizes up to 54"; UCD gradually tapered to body shape; reusable straps attach to buttonholes.

2) UCD #15-Belted Undergarment/Diaper. Several layers of absorbent materials that cover a gel-lock system. Tape tabs attach the back of the diaper to the front part. An elastic band and waistband can be wrapped around front to secure the diaper in place.

3) UCD #16-Plastic Pouch-type Disposable/Reusable Receptacle. A plastic bag with V-shaped contoured edge/pouch for easy use and a zipper lock seal. Absorbent powder in the lower part of plastic bag turns to gel when liquid is added. The UCD is disposed of when powder is completely saturated into a gel.

4) UCD #17-Plastic Container and Female Adapter/Reusable Receptacle. Sure-grip handle and funnel design make it easy to use by males. A plastic cap screws on the funnel and ensures that fluid does not leak from the container. Sanitary plastic bottle rinses clean. A female adapter attaches to funnel of plastic container placed next to female perineum for use. The adapter is removed and placed in plastic pouch, and cap is screwed on the funnel of the container after use. The adapter is sanitized for reuse.

5) UCD #18-Condom Catheter/Disposable Receptacle. This UCD is for males-only, condom (three sizes) is placed over the penis and empties, via a tube, into a disposable/reusable bag. A drain is located on the bottom of the bag, and plastic bands on bag hold it in place on the leg.

6) UCD #19-Plastic Funnel with Extension Tube/Reusable Receptacle. This UCD is for females only. The UCD is used by pulling extension tube outward from funnel until it locks; opening of funnel fits snugly against the female perineum for ease of use and allows an individual to completely relieve the bladder while standing. Extension tubes of varying lengths can be used with this UCD, and the extension tube can be emptied into a bag, urinal, toilet, or can.

7) UCD #20-Disposable Urinal Kit/Disposable Receptacle. Kit contains a bag with plastic slide seal tube, absorbent powder, and moist towelette (for personal hygiene after urination). Absorbent powder turns into liquid gel and deodorizes urine. Funnel design in collection bag prevents spills. After use, replace "slide seal tube" over top of the bag to close it. Dispose UCD in garbage receptacle after use.

8) UCD #21-Portable Restroom Kit/Disposable Receptacle. Kit contains a gray plastic bag (collection device) with plastic tie, two small absorbent powder packets, one moist towelette for personal hygiene, and a small amount of toilet paper. Kit can be used for both liquid and solid waste. Plastic bag can be placed over rim and into receptacle of portable commode, wastebasket, empty toilet, or other support object. We recommend that two absorbent powder packets are emptied into bag prior to urination, even though directions on package indicate sprinkling powder into plastic bag after use. Liner bag must be removed from support mechanism after use, and twist top of bag closed. Use twist tie to seal plastic bag. Dispose of UCD in garbage receptacle after use.

9) UCD #22-Disposable Receptacle. A small biodegradable paper funnel flips open for relief while standing. Urine collection device fits snugly against female's body for easy use. Nothing to wear or empty. Urine collection device is disposed of after use.

APPARATUS

Coriolis Acceleration Platform (CAP)

A large, man-rated motion research device was used to provide qualitative information on fluid leakage and/or gel/bead displacement (bead bleed-through out of top layer of UCD's absorbent material) from constant-wear UCDs only in a simulated +3 G_z environment. The constant-wear UCDs were placed on a chair mounted in a box at a maximum distance from the CAP's center of rotation. The gimballed chair swung freely and aligned the UCD's G_z (head to foot) axis with the resultant gravito-inertial force as the box was accelerated up to a maximum of +3 G_z force for 1 min.

9A9 Hypobaric/Low-Pressure Chamber (LPC)

We used the LPC to observe any changes firsthand. Changes we observed consisted of excessive fluid leakage or bead bleed-through the top absorbent layer of material in the constant-wear UCDs, or structural failures due to expanding trapped gas in partially-filled disposable/reusable UCDs in the constant-wear and disposable/reusable UCDs in both dry and saturated configurations during a rapid decompression and ascent to altitudes of 25,000 to 40,000 ft.

PROCEDURES

Comfort/Fit Trial of Constant-wear UCDs

Six female aerospace physiologists (Aeromedical Safety Officers) wore 14 constant wear UCDs (#1-14) under their flight suit and MA-2 torso harness. They evaluated overall comfort, fit, and acceptability of these UCDs. Urine collection device #15, a constant-wear UCD, was not evaluated because it was added after this trial. Urine collection device #18, a condom catheter/bag for male personnel was added after this trial, but an evaluation

was deemed unnecessary since it is already available in the Navy supply system. The disposable/reusable UCDs (#16, 17, and 19-22) were not evaluated because they are stored until needed for urination.

Fluid Saturation/Maximal Capacity Trial

We evaluated each UCD one time (e.g., constant-wear or disposable/reusable) for maximal fluid capacity in this laboratory trial. A total of 15 off-the-shelf, constant-wear UCDs (e.g., pads and undergarments) and 6 disposable/reusable UCDs were saturated with the maximum amount of tap water. We added the tap water in 25-ml increments for all 15 constant-wear UCDs and 3 disposable/reusable UCDs (#16, 18, and 19). For three UCDs (#17, 20, and 21) in the complete-voiding category, we added the tap water in 100-ml increments due to the UCDs' large capacity. The total amount of fluid absorbed was recorded for each UCD, and observations were made about approximate absorption rate, dryness, and gel formation. Two UCDs (#19 and #22) were funnels that are used for complete relief of the bladder into any available receptacle (complete-voiding category) while standing, and an evaluation of fluid capacity was deemed unnecessary.

Coriolis Acceleration Platform (CAP) Trial

Six constant-wear UCDs (#3-5, 8, 11, and 14) were subjected to acceleration forces ($+G_z$) in the CAP to check for any fluid leakage, or displacement/bleed-through of beads, absorbent powder, or gel through the top layer of the UCDs' absorbent material. Urine collection device #15 was obtained after the CAP trials; therefore, data are unavailable for this UCD because the CAP was reconfigured for other studies. We did not test the disposable/reusable UCDs (#16, 17, and 19-22) in the CAP because they are stored until used by the aviator. Due to the configuration of UCD #18 (storage bag is attached to leg, and valve prevents fluid backflow via the extension tube to condom), it was not tested in the CAP trial. We videotaped the procedure and the condition of the UCDs after completion of each CAP run. The procedure involved UCD placement, in a saturated condition, on a gimballed chair mounted inside a box at the maximum distance (17.41 ft) from the CAP center of rotation. The UCD was exposed to simultaneous rotation about two axes to $+3 G$ s at the acceleration rate and deceleration rate of 15 deg/s^2 . A $+3 G_z$ force was maintained for 1 min during each run.

Two CAP runs were conducted for each constant-wear UCD at 70% of maximal fluid capacity: the first run with no weight on top of the constant-wear UCD, and the second run with two sandbags on top of the constant-wear UCD (for a total weight of 80 lbs) to simulate the approximate torso weight of a female. The sandbag weights were arranged on the seat to approximate the buttocks seated on top of the constant-wear UCD. Colored tap water (red and blue) was used to detect fluid leakage during the CAP trial. The constant-wear UCDs were saturated with a volume of tap water equivalent to 70% of the UCDs' maximum fluid capacity prior to the UCDs placement in CAP during the two runs with and without the 80-lb simulated weight. One additional run was conducted for UCD #3 at 100% fluid capacity (100 cc) with the 80-lb weight on top of the UCD. Two additional runs were conducted for UCD #14 at 100% and 80% fluid capacity (175 cc and 140 cc, respectively) with the 80-lb weight.

To ascertain any fluid leakage or gel/bead displacement through the top layer of the constant-wear UCD's absorbent material, several layers of materials were placed from bottom to top on the seat pan of the gimballed chair. The bottom layer was a sheet of colored, waxed paper, waxed side up. The second layer was a double thickness of absorbent white paper towels. These two layers were secured in the seat with tape. The UCD was placed on top of these two layers, then a second sheet of colored waxed paper, waxed side down, was placed on top of the UCD. The absorbent paper below the UCD and the waxed paper on top of the UCD would show any traces of fluid leakage and gel/bead displacement.

Rapid Decompression (RD)/High Altitude Trial in 9A9 Hypobaric/Low Pressure Chamber (LPC)

Two trials were conducted in the altitude chamber to observe any changes (e.g., excessive fluid leakage or bleed-through of absorbent powder, gel or beads through the top layer of the constant-wear UCD's absorbent material, or structural failure of disposable/reusable UCDs due to significant air volume changes) in seven

constant-wear UCDs (#3-5, 8, 11, 14, and 15) and three disposable/reusable UCDs (#16, 18, and 19) without human subjects in a simulated aircraft environment (a rapid-decompression and high-altitude profile). The UCDs were tested in a dry configuration for the first trial (no tap water added to the constant-wear UCDs, and the disposable/reusable UCDs removed from the packages and not inflated with any air), and a partially saturated configuration during the second trial. The rapid decompression (RD) profile was immediately followed by chamber ascent to chamber altitudes of 25,000 through 40,000 ft for detection of any noticeable changes in the UCDs' integrity, any significant fluid leakage, or gel/bead displacement or bleed-through the top layer of the constant-wear UCD's absorbent material. The last paragraph of this section discusses the amount of tap water added to each of the UCDs in the partially saturated configuration.

Four disposable/reusable UCDs (#17, 20-22) were obtained after completion of the LPC trial and were not evaluated in the LPC trial. Urine collection device #17 was a plastic container that is stored until used. UCDs #20 and 21 have a configuration and function similar to UCD #16. Urine collection device #22 was not evaluated because of its configuration as a paper funnel that is stored until used for complete voiding of the bladder. These UCDs are compatible for use in the prop and helo communities, but not the tactical jet community where the individual is strapped to an ejection seat.

The RD profile consisted of ascent to a chamber altitude of 29,150 ft in the main chamber and ascent of the intermediate chamber with the UCDs to a chamber altitude of 8,000 ft at an ascent rate of 5,000 ft/min. The chief engineer initiated the rapid decompression sequence by pressing a switch at the chief engineer's console so that the decompression of the intermediate chamber was completed within 2 sec. The two chambers equalized at an altitude of approximately 22,000 ft. After the RD, the two chambers were ascended at 5,000 ft/min to chamber altitudes of 25,000, 30,000, 35,000, and 40,000 ft with a 15-sec level-off at each altitude for observation of any changes in the UCDs. Upon completion of the first run, the two chambers were descended at 5,000 ft/min to 29,150 ft where the main chamber was leveled off, and the intermediate chamber continued descent to site level. The second RD/high-altitude profile was conducted in the same manner with the constant-wear UCDs in a 100% saturated configuration, and the disposable/reusable UCDs in a partially saturated configuration as described in the next paragraph.

The seven constant-wear UCDs and the three disposable/reusable UCDs were placed on top of white art paper taped to a gurney in the intermediate chamber of the LPC in a dry configuration for the first RD/high-altitude profile. During the second RD and high-altitude profile, the seven constant-wear UCDs (100% saturated with tap water containing green food colorant) were taped to the top of the white art paper on the gurney. The three disposable/reusable UCDs were filled with the following amounts of fluid (tap water with green food colorant) and hung from the ceiling: 400 ml in UCD #1, 300 ml of a 700-ml capacity in UCD #19, and 400 ml of a 1,000-ml capacity in UCD #18. Disposable bags attached to the end of the extension tubes for UCDs #18 and 19 were partially filled with fluid (see previous sentence for amount of fluid) and trapped air to observe any air volume changes inside the bags due to the lower pressure encountered as a result of the RD and high-altitude profile. The RD/high-altitude profile in the LPC was videotaped from outside the intermediate chamber's window. Changes in UCD configuration, fluid leakage for all UCDs, and bead/gel displacement through top layer of seven constant-wear UCDs' absorbent material were noted.

RESULTS

Comfort/Fit Trial of Constant-Wear UCDs

The field of off-the-shelf, constant-wear UCDs was narrowed to six (UCDs #3-5, 8, 11, and 4). The six female aerospace physiologists eliminated eight of the constant-wear UCDs (#1, 2, 6, 7, 9, 10, 12, and 13) because they were not comfortable or were incompatible with the ALSS worn in this trial. Urine collection device #15 was not available.

Maximal Fluid Capacity Trial

The maximum fluid capacity (tap water) of the 15 constant-wear and 7 disposable/reusable UCDs varied: light-to-moderate category of UCDs from 50 ml to 275 ml; moderate-to-heavy category of UCDs from 150 ml to 175 ml; and complete-voiding category of UCDs from 175 ml to 1,500 ml. Quantitative results are listed in Table 1 and qualitative observations are listed in Appendix 2.

Table 1. Quantitative Evaluation of Maximum Fluid Capacity of Candidate Urine Collection Devices (UCDs).

UCD Number	Type of UCD	Vol. (ml)
Light-to-Moderate Voiding Category of UCDs		
1	Pad	75
2	Pad	100
3	Belted Undergarment	100
4	Pad	200
5	Pad	275
6	Pad	50
7	Pad	200
8	Pad	175
9	Pad	75
10	Diaper	75
Moderate-to-Heavy Voiding Category of UCDs		
11	Pad	175
12	Diaper	175
13	Diaper	150
Complete Voiding Category of UCDs		
14	Diaper	175
15	Diaper	500
16	Disposable Receptacle	400
17	Reusable Receptacle	800
18	Disposable Receptacle	1000
19	Reusable Receptacle	N/A
20	Disposable Receptacle	800
21	Disposable Receptacle	1,500
22	Disposable Receptacle	N/A

COROLIS ACCELERATION PLATFORM (CAP) LABORATORY TRIAL

Observations of any fluid leakage or bead/gel displacement for the six constant-wear UCDs (#3-5, 8, 11, and 14) from the CAP trial are discussed in Appendix 3. Urine collection device #3 exhibited the least amount of fluid leakage of all of the constant-wear UCDs evaluated during this trial. Three UCDs (#5, 11, and 14) exhibited bead/gel bleed-through the top layer of the UCD's absorbent material. Due to the satisfactory results observed during the first two CAP runs for UCDs #3 and 14, we conducted one additional run at 100% capacity for UCD #3 and two additional runs at 80% capacity and 100% capacity for UCD #14. Some bead bleed-through occurred for UCD #14 at 80% capacity, but not at 100% capacity. Urine collection device #14 exhibited significant fluid leakage during these two additional runs. A slight leakage of fluid occurred for UCD #3 at 100% capacity. Urine collection device #15 was obtained after CAP reconfiguration.

RAPID-DECOMPRESSION (RD)/HIGH-ALTITUDE LABORATORY TRIAL IN 9A9 ALTITUDE/LOW PRESSURE CHAMBER (LPC)

During the first trial with the UCDs in the dry configuration, no noticeable changes were noted in the seven constant-wear UCDs (#3-5, 8, 11, 14, and 15) and the three disposable/reusable UCDs (#16, 18, and 19). The absorbent powder/gel/beads did not bleed through the top layer of absorbent material for any of the constant-wear UCDs. The disposable/reusable UCDs were removed from the packages that they were stored in and not inflated with any air because most aircrew personnel store these items in a small, compact shape in a pocket of their flight suit or anti-G suit. All UCDs passed the RD/high-altitude test in the dry configuration.

During the second trial with the constant-wear UCDs in a 100% saturated configuration and the disposable/reusable UCDs partially filled with fluids (400 ml in UCD #16; 300 ml of a 700-ml capacity in UCD #19; and 400 ml of a 1,000-ml capacity in UCD #18), we noted the following changes upon return to site level from the RD/high-altitude profile. None of the constant-wear UCDs leaked any fluid on the white art paper during the RD or high-altitude portion of the laboratory trial. We did notice significant bleed-through of beads from the top absorbent layer of UCD #5, and a small number of beads (less than 10-15) on top of the absorbent layer of UCD #11. Urine collection device #15 was very dry to the touch with no bead/gel bleed-through. The following observations were noted for the disposable/reusable UCDs on the second run. Urine collection device #16, a sealed plastic bag with an absorbent powder/gel, did not expand due to lowered air pressure associated with the RD or high-altitude profile. However, the weight of the fluid/gel/absorbent powder exerted a downward gravitational pull on UCD #16 as it was hanging from the ceiling and prevented full closure of the UCD's ziplock. Trapped air inside the partially fluid/gel-filled collection bags of UCDs #18 and 19 expanded slightly during the RD, but did not pop off the masking tape that was lightly attached to the openings of the condom of UCD #18 and the collection cup of UCD #19 at the end of the two UCDs' extension tubes. Expanding air in the collection bags should not flow back up the extension tubes of either UCDs #18 (male UCD) or #19 (female UCD) during a RD and affect the aviator. No structural failures due to expanding trapped air occurred for the disposable/reusable UCDs during either of the two LPC runs. No other changes were observed in the three disposable/reusable UCDs.

DISCUSSION AND CONCLUSIONS

Due to our concern for fleet acceptance of the constant-wear UCDs (pads, diapers, or belted undergarments), six female aerospace physiologists wore the various constant-wear UCDs under a flight suit, torso harness, and anti-G suit (ALSS items) to evaluate overall comfort and compatibility (except UCD #15) with ALSS. Based on the aerospace physiologists' assessment of the comfort/fit/compatibility of the constant-wear UCDs, we narrowed the field of selected constant-wear UCDs to seven (UCDs #3-5, 8, 11, 13, and 14) for the CAP trial and the RD/high-altitude LPC trial.

A laboratory trial for maximal fluid capacity demonstrated a wide variation in total volume of tap water absorbed by the various constant-wear and disposable/reusable UCDs. The constant-wear UCDs (pads) varied

between 75 and 275-ml capacity. The constant-wear UCDs (diapers/belted undergarments) varied between 75 and 500-ml capacity. The disposable/reusable UCDs varied between 400 and 1,500-ml capacity. Two disposable/reusable UCDs (#19 and 22) allowed complete voiding of the bladder in a standing position; therefore, maximal fluid capacity for these UCDs was not a concern. Based on the literature search, a candidate UCD should have a minimal fluid capacity of 150 to 200 ml. This amount is the bladder volume that initiates the nonpregnant females' desire to urinate. However, the constant-wear UCDs' thresholds may have to be higher because a nonpregnant female's bladder capacity is normally between 350 to 450 ml. Nine of the fifteen constant-wear UCDs (#4, 5, 7, 8, and 11-15) met the minimal capacity of 150 to 200 ml, but only one constant-wear UCD (#15) met the normal female's bladder capacity of 350 to 450 ml. All of the disposable/reusable UCDs (#16-22) met the normal female bladder capacity of 350 to 450 ml. Urine collection device #18 for males should meet the male's bladder capacity because the bag can hold up to 1000 ml of fluid. Based on the results of this laboratory trial, 10 constant-wear UCDs and 6 disposable/reusable UCDs would absorb an amount of fluid (150-250 ml) equal to the bladder volume at which a nonpregnant female generally experiences the first desire for urination, providing temporary relief until the individual can land the aircraft.

We evaluated the selected constant-wear UCDs (except #15) for fluid leakage and bead/gel bleed-through (bead or gel displacement through the UCD's top layer of absorbent material) during the CAP trials. Urine collection device #15 was received after the CAP device was reconfigured for other studies and was not evaluated in a simulated G environment. Based on the CAP trial, three constant-wear UCDs (#5, 11, and 14) had bead displacement through the UCDs' top layer of absorbent material. Urine collection device #5 exhibited bead displacement during both CAP runs (with and without 80-lb weight). Some gel displacement occurred for UCD #11 during the first CAP run (without 80-lb weight), and a small number of beads were attached to the top layer of wax paper after the second CAP run. Urine collection device #14 exhibited a small amount of bead displacement at 80% fluid capacity with the 80-lb simulated weight, but no bead displacement occurred at 70% fluid capacity (with and without 80-lb weight) or at 100% fluid capacity (with 80-lb weight) for UCD #14. This unusual finding for UCD #14 may have been due to the 80-lb weight shifting in the seat of the CAP during the 3-G_z run at 80% fluid capacity. Urine collection device #11 exhibited significant fluid leakage during both CAP runs (with and without the 80-lb weight on top of UCD). Urine collection device #11 leaked fluid as evidenced by dampness on art paper during the first CAP run, and saturation of absorbent paper toweling under the UCD and saturation of the top layer of the art paper on both sides during the second CAP run.

Even though four of the constant-wear UCDs exhibited fluid leakage in the CAP trials, we recommended these constant-wear UCDs for the prop and helicopter communities in which the total G load is considered minimal (less than 2 Gs). Four UCDs (#3, 4, 8, and 14) exhibited significant fluid leakage during the second through fourth CAP runs (with 80-lb weight). Urine collection device #3 leaked a small amount of tap water during the second CAP run (70% maximal fluid capacity) and the third CAP run (100% maximal fluid capacity), resulting in a slight dampness on a small area of the top layer of waxed paper on top of the UCD during both runs. Urine collection device #4 had significant fluid leakage, saturating a large area (approximately 5 x 6 in) of the layer of absorbent toweling under the UCD and saturation of both sides of the art paper (approximately 2 x 4 in patch) above the UCD. Urine collection device #8 leaked fluid, saturating the layer of absorbent toweling under the UCD (both areas approximately less than 2 in. in width or length, and both sides of the art paper above the UCD a patch approximately 2½ x 3 in). Urine collection device #14 had a small amount of leakage during the second CAP run (70% maximal fluid capacity) as evidenced by a damp area (less than 2½ in. in wide or long) on one side of the art paper on top of the UCD. However UCD #14 exhibited significant fluid leakage during the third CAP run (100 % fluid capacity) and fourth CAP run (80% maximal fluid capacity). Fluid saturated the layer of absorbent toweling under UCD#14 and a large patch on the art paper above the UCD during both CAP runs. Based on results of the CAP trials, UCD #3 performed the best under simulated +G_z conditions because it did not exhibit any bead/gel displacement and only had a small amount of fluid leakage. Urine collection device #8 was considered adequate because it did not exhibit any bead gel bleed-through or displacement and a small amount of fluid leakage. Urine collection device #4 may be used for the fleet assessment in the prop and helo communities due to a lack of bead/gel displacement or bleed-through; however, fluid leakage under Gs may prove unsatisfactory for the tactical jet community. Urine collection device #14 might also be used in the prop, jet (nonejection seat), and helo communities.

that do not exceed 2-2½ Gs, but fluid leakage and a small amount of bead bleed-through (80% maximal fluid capacity only) are unsatisfactory for the tactical jet (ejection seat) community.

The last laboratory trial exposed eight constant-wear UCDs (#3-5, 8, 11, and 13 -15) and three disposable/reusable UCDs (#16, 18, and 19) to the pressure changes associated with a rapid decompression followed immediately by ascent to chamber altitudes up to 40,000 ft. Both UCDs #20 and 21 were obtained after completion of the LPC trials and were not tested because they are similar in design, configuration, and function to UCD #16. Based on UCD #16's performance in these laboratory trials, UCDs #20 and 21 would most likely yield the same result in a LPC trial. We did not notice any changes in configuration for all of the UCDs (dry configuration) during the first RD/high altitude run, thus we can assume that they will not pose any problem to aircrew in a dry configuration at altitude. Only two constant-wear UCDs (#5 and 11) had a noticeable change in the "saturated" configuration (100% fluid capacity); a small number of beads were displaced through the top layer of UCDs' absorbent material and could possibly pose a hazard for female aircrew personnel as foci for urinary tract infections (UTIs). No changes in configuration were observed for the disposable/reusable UCDs (#16-19) during the first RD/LPC profile in a "dry" configuration (trapped gas expansion with ascent to altitude), but a slight expansion in overall volume due to expanding trapped air in UCDs #18 and 19 (not UCD #16) occurred during the second run (approximately 50% fluid capacity). Finally, the structural integrity of the four disposable/reusable UCDs was not affected by trapped gas expansion during both RD/high-altitude runs in the LPC. We did not test UCD #17 because it is a sanitary plastic container (can be rinsed/sanitized for reuse) that is incompatible for use onboard tactical jet aircraft where the individual is strapped to an ejection seat; however, it can be used on most prop and helo aircraft where the individual can unstrap from the seat and use the facilities available.

SUMMARY

Due to the time constraints dictated by the fleet assessment of these interim UCDs, the experimental design for the laboratory trials provided some preliminary information on commercially available, off-the-shelf UCDs prior to the fleet assessment by female and male aircrew personnel. Due to periodic product innovations and improvements, new constant-wear UCDs routinely replace current products in the market. As a result, the constant-wear UCDs evaluated by the investigators may have been replaced by newer, improved products. Our goal was to ensure that the candidate UCDs would absorb an adequate amount of fluid and be accepted by female and male personnel before procuring the candidate UCDs for a fleet assessment. Furthermore, we wanted to eliminate those UCDs which might be negatively affected by the adverse conditions of a simulated G environment (CAP trials) and the rapid decompression/high altitude environment (LPC chamber) without exposing human subjects to potential risks.

As a result of the maximal fluid capacity laboratory trial and the comfort/fit trial, we eliminated eight UCDs (#1, 2, 6, 7, 9, 10, 12, and 13) of the original 14 constant-wear UCDs prior to the CAP and LPC trials. Based on the results of the CAP and LPC trials, we eliminated two constant-wear UCDs (#5 and 11) for the fleet assessment by female and male aircrew personnel onboard naval aircraft. We recommended five constant-wear UCDs (#3, 4, 8, 14 and 15) and three disposable/reusable UCDs (#16, 18 and 19) for a fleet assessment by female and male aircrew personnel based on the results of these four trials. Four disposable/reusable UCDs (#17, and 20-22) will be included in the fleet assessment, even though they were not evaluated in the LPC trial. Urine collection device #17 is incompatible for use onboard tactical jet aircraft (ejection seat); however, it can be used on some jets (nonejection seat), and most prop and helo aircraft where the individual can unstrap from the seat and use the device. UCDs #20 and 21 have a configuration (plastic bag which can be sealed) and function similar to UCD #16 which was evaluated in the LPC trial. Urine collection device #22 is a disposable paper funnel that allows complete relief while standing. Based on UCD #22's configuration and intended use onboard naval aircraft (prop and helo communities), it was not necessary to evaluate it in these four trials.

RECOMMENDATIONS

The next phase of this project will be the fleet assessment in the actual aircraft environment by male and female aircrew personnel, resulting in a final technical report on its results. We recommended five constant-wear UCDs (#3, 4, 8, 14 and 15) and three disposable/reusable UCDs (#16, 18 and 19) for a fleet assessment by female and male aircrew personnel based on the results of these four trials. Four disposable/reusable UCDs (#17, and 20-22) will be also be included in the fleet assessment.

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Appendix 1. Product Names of Candidate Urine Collection Devices (UCDs)

UCD Number	Type of UCD	Product Name of UCD
Light-to-Moderate Voiding Category of UCDs		
1	Pad	Stayfree Super Maxi
2	Pad	Depend "Poise"
3	Belted Undergarment	Attends Guards
4	Pad	Attends
5	Pad	Entrust Plus Guards
6	Pad	Always Curves Maxi
7	Pad	Free & Active
8	Pad	Surety-S Ultra Plus Guard
9	Pad	Entrust Plus
10	Diaper	Dignity System
Moderate-to-Heavy Voiding Category of UCDs		
11	Pad	Serenity with Drylayer Plus Guard
12	Diaper	Depend Easy Fit
13	Diaper	Drug Emporium Extra Absorbency
Complete Voiding Category of UCDs		
14	Diaper	Entrust Plus
15	Diaper	Ultra Attends "Super Plus"
16	Disposable Receptacle	Flight Extender II
17	Reusable Receptacle	Little John & Lady Jane Adapter
18	Disposable Receptacle	MMG External Catheter
19	Reusable Receptacle	Freshette
20	Disposable Receptacle	Brief Relief
21	Disposable Receptacle	Disposa-John
22	Disposable Receptacle	Disposable Freshette

Appendix 2. Qualitative Evaluation of Maximum Fluid Capacity of Urine Collection Devices.

UCD #	Type of UCD	Brief Observations
1	Pad	Gels in middle. After middle gels, water leaks as pad is pressed.
2	Pad	Gels throughout length. Continues to absorb slowly after 100 ml, but too slow to accept more fluid without leaking.
3	Pad	Has side fluid catches. Slow to absorb, even from start.
4	Belted Undergarment	Gels; capillary action is slow. Slow to absorb at higher loads.
5	Pad	Gels; drier than UCD #4 at 125 ml. Capillary action not as fast as UCD #1, 2, or 3.
6	Pad	Quick to absorb fluid; retains minimal volume of fluid.
7	Pad	After 100 ml of fluid absorbed; absorption rate slowed. Square-shaped UCD.
8	Pad	UCD has top layer and quilting to draw liquid away from surface of pad. Absorbs fluid rapidly until 75-85 ml, then absorption rate slows down. Must add fluid in smaller quantities and allow fluid on top of UCD to be absorbed.
9	Pad	Rapid absorption rate-UCD fills very quickly.
10	Diaper	UCD has no waterproof backing thus, leaks fluid through bottom.
11	Pad	A small, compact UCD that did not increase very much in size when completely saturated with fluid.
12	Diaper	UCD slowly disperses fluid as it is added (slow absorption rate).
13	Diaper	UCD's absorption rate is very slow; and it disperses fluid very slowly as it is added. UCD becomes very mushy when completely saturated.
14	Diaper	UCD's absorption rate is very slow and fluid is slow to distribute over absorption area.
15	Diaper	UCD's absorption rate is very fast due to multiple layers of porous (wicking) materials over a gel/bead layer that absorbs/traps fluid.
16	Disposable Receptacle	UCD has back-flow prevention due to separation of V-shaped area with a zip-lock seal from holding chamber for powder that gels as fluid is added. Do not need to distribute powder by shaking in order to activate all of powder into gel. UCD does not spill when it is completely full due to its configuration. Maximum load determined by volume capacity of zip-locked chamber; some powder was still present at maximum fluid capacity.
17	Reusable Receptacle	Plastic container without adapter for females can hold 800 ml at the bottom of the funnel, and 900 ml, which is approximately 1/2" below the top of the funnel. Sanitary plastic bottle can be rinsed after emptying container in urinal/can/toilet.
18	Disposable Receptacle	UCD's configuration allows urine/fluid to flow through tube and empty into bag quickly. Bag has valve on bottom for emptying in order to rinse/reuse bag, if necessary. Condom is disposed after each wear/use.

Appendix 2. (Cont.)

UCD#	Type of UCD	Brief Observations
19	Reusable Receptacle	UCD was not tested in this trial; no limitation except for capacity of urinal/can/toilet/bag in which urine is emptied via UCD's extension tube.
20	Disposable Receptacle	UCD has back-flow prevention due to funnel-neck design that empties in collection portion of plastic bag. Absorbent powder turns into gel. Fluid added in 100-ml increments to maximal capacity. Absorbent gel was slightly above neck of funnel (less than ½"), and bag was fully distended due to absorbent gel.
21	Disposable Receptacle	UCD can hold urine and/or solid waste. Two packets of absorbent powder were added before filling bag with water in 100-ml increments. Thick, slurry appearance at maximal fluid capacity. Could have probably added another 100 to 300 ml of fluid if necessary.
22	Disposable Receptacle	UCD was not tested in this trial; a paper funnel that can be emptied into any available receptacle/container.

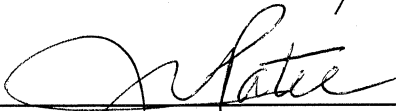
Appendix 3. Evaluation of Fluid Leakage and Bead/Gel Displacement of UCDs in Coriolis Acceleration Platform/Laboratory Trial.

UCD#	Run	Weight	Vol. (ml)	Brief Observations
5	1 of 2	No	190	Some bead migration occurred through the top porous layer of the UCD. No gel or fluid displaced onto the art paper (waxed side facing down) on top of the UCD. No gel or fluid displaced to the white absorbent towels underneath the UCD.
14	1 of 4	No	125	No gel or fluid displaced through the porous top layer of the UCD to the art paper on top of the UCD or on the white absorbent towels underneath the UCD.
3	1 of 3	No	70	No gel/fluid migration occurred through the porous top layer of the UCD onto the art paper on top of the UCD or the white absorbent towels underneath the UCD.
11	1 of 2	No	123	Some migration of gel to the top layer of the fibrous material of the UCD; the gel did not absorb on to the art paper on top of the UCD. the waxy side of the art paper on top of the UCD was damp with fluid from the UCD, and a very small amount of beads were attached to the waxy side of the art paper on top of the UCD. No gel, fluid, or beads reached the absorbent white towels under the UCD.
8	1 of 2	No	70	No gel displacement to top porous layer of UCD; no gel or fluid displaced to the art paper on top of the UCD or the white absorbent towels under the UCD.
4	1 of 2	No	140	No gel displacement occurred through the top porous layer of the UCD; no fluid or gel displacement on the waxy side of the art paper on top of the UCD or on the white absorbent towels under the UCD.
5	2 of 2	Yes	190	A small number of gel/beads was displaced through the top porous layer on one side of the UCD and were attached to the waxy side of the art paper on top of the UCD. No gel or fluid reached the white absorbent towels under the UCD.
14	2 of 4	Yes	125	A small amount of fluid was displaced through the top porous layer of the UCD and a damp area of approximately 2½" (circumference) on the waxy side of the art paper. Top porous layer of UCD was dry to touch after 3-G run. No fluid reached the white absorbent towels under the UCD.
3	2 of 3	Yes	70	A very tiny amount of fluid was displaced through the top absorbent layer of the UCD and a very small area on the waxy side of the art paper on top of the UCD was damp. The white absorbent towels under the UCD were dry. No beads/gel were displaced through the top porous layer of the UCD.
11	2 of 2	Yes	123	A few beads were displaced through the top porous layer of UCD and attached to wax side of art paper on top of UCD. Large amount of fluid displaced out of UCD; fluid soaked through both sides of art paper. A small amount of fluid leaked on one side of UCD to white absorbent towels under UCD. No beads or gel sitting on top of the porous layer of the UCD.

Appendix 3. (cont)

UCD#	Run	Weight	Vol. (ml)	Brief Observations
8	2 of 2	Yes	70	No gel/bead displacement from the UCD. A small amount of fluid was displaced from both sides of the UCD onto the white absorbent towels under the UCD; one area was approximately 1 x 1/4" and the other area was approximately 2 x 1/4". A patch of approximately 2 1/2" by 3" where the fluid absorbed through both sides of the art paper on top of the UCD.
4	2 of 2	Yes	70	Significant fluid leakage through the plastic gathers on all sides of the UCD; approximately 5 x 6" patch where the fluid was absorbed by the white absorbent towels under the UCD and through both sides of the art paper on top of the UCD.
14	3 of 4	Yes	175	Fluid leakage occurred at maximum fluid capacity. Fluid leakage occurred on the seam of one side of the UCD and a patch of approximately 1 x 4 1/2" on the white absorbent towel under the UCD. A patch of approximately 2 x 4" where the fluid was absorbed by art paper on top of the UCD.
3	3 of 3	Yes	100	No gel/bead displacement in the UCD at the maximum fluid capacity for the UCD. No fluid reached the white absorbent towels under the UCD. A very small amount of fluid was absorbed by the art paper on top of the UCD.
14	4 of 4	Yes	140	At 80% fluid capacity, some bead displacement occurred. Eight to ten beads were attached to wax side of art paper on top. Some fluid leakage occurred; an area of approximately 4 x 6" was noted on the art paper on top of UCD. Fluid also absorbed by white absorbent towels under UCD; an area of approximately 3 1/2 x 3" was noted.

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The results reported herein were obtained under the specific protocol described in the paper. Furthermore, product innovations for "off-the-shelf" constant-wear products result in new or improved constant-wear products in the market. These new products may not be the same as the constant-wear products tested in this protocol.

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