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Technical Note

An automatic urine disposal system for urinary incontinence: A pilot study with long-term users for effectiveness and safety

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Abstract.
BACKGROUND: Urinary incontinence is a common problem among the elderly and patients with neurologic disability. The conventional urinary incontinence aids, such as urine-absorbing diapers, pads, and indwelling catheters, frequently cause hygienic problems.
OBJECTIVE: To study the safety and efficacy of a new automatic urine disposal system that can suction and store the urine in a separate container for future disposal.
METHODS: An electromechanical urine disposal system that can collect and transport the urine and cleanse and air-dry the external genitalia was developed. The hygienic effects of using this system were studied in 8 participants after 3 months of use.
RESULTS: The caregivers of all 8 patients reported improved hygiene of their patients. None of the patients suffered from decubitus ulcers, and skin erythema was absent in 4 patients, while markedly decreased in the other 4 patients when compared with the use of urine-absorbing diapers. Four patients experienced minor urine leakage that was manageable with concurrent use of either diapers or bed pads.
CONCLUSIONS: The use of an electromechanical urine disposal system relieves the caregiver from night care, as the urine is automatically collected and stored for disposal the next day. The system improves the hygiene of the patient, as the urine is immediately suctioned and the external genitalia is cleansed and dried after urination.

Keywords: Urinary incontinence, automatic urine disposal, skin erythema, continence aids

1. Introduction

The number of elderly people in need of urinary and/or faecal care is increasing in most countries owing to the aging population [1,2]. The prevalence of UI among nursing home residents is reported to be between 50% and 65% [3–6], and the high prevalence of UI in nursing home residents has been attributed to advancing age and senile dementia that leads to impairment of activities of daily living [6].

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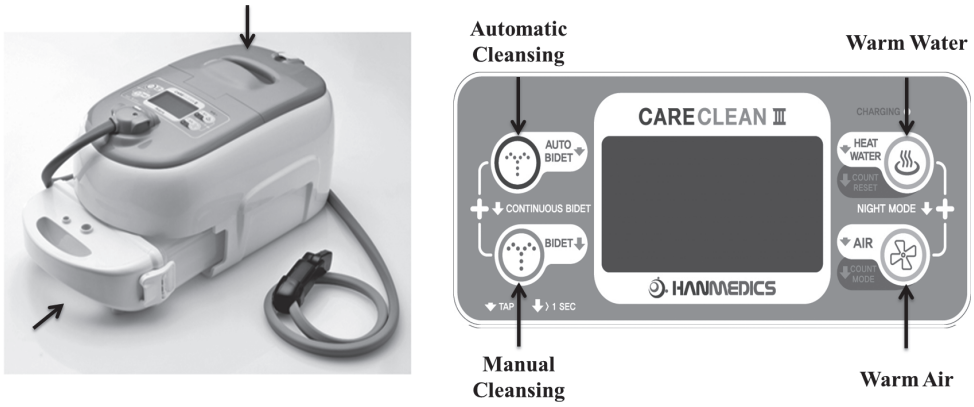

Fig. 1. Main body (A) and LCD display panel (B) of the Care Clean III.

Other than conventional urine absorbing products, the indwelling catheter is the most commonly used urinary incontinence aid, but the catheterization has a high risk of urinary tract infection (UTI), 3–7% a day [7].

There have been trials to develop electromechanical urine disposal systems since 1998 [8]; however, technical developments to document the safety and effectiveness of the system have been slow, and none of these systems has cleared the government regulations for medical device registration. An electric urine/faeces disposal system in the form of inflatable pants was reported in 2008 [9]; the urine is stored inside of the inflatable rubber pants and electromechanically transferred to a separated container for future disposal. After transporting the urine, warm water is supplied to the skin inside of the rubber pants for cleansing, followed by a warm air infusion for drying. However, this system has several hygienic problems; tightly bound rubber pants could cause skin erythema and pressure sores on patient's body, and it is difficult to completely remove remnant urine/faeces, particularly those trapped between the pants and body skin. Another system, the Non-invasive Continence Management System (NCMS), employs electromechanical suctioning of the urine for future disposal and was reported in 2007 [10]. In this system, two types of urinal interfaces were developed for urine collection; one is for female patients who are aware of bladder filling/emptying and who can actively apply the device themselves. Another is for female patients who do not have this sensation, and thus must continuously apply this urine collection device, which is held in place within a pocket built into specially designed underwear. However, the NCMS did not have a modality for cleansing the urine left in the urinal interface device after suctioning. We developed a new electromechanical urine disposal system that is free from the issues of remnant urine and, herein, report the results of a usability study with this new system.

2. Materials and methods

2.1. Urine disposal system: Care Clean III

The urine disposal system in this study, Care Clean III, was developed via co-operation of biomedical engineers in Eulji University, Korea University, and Hanmedics, Inc. (Seoul, S. Korea) and commercialized by Hanmedics, Inc. The system comprises of a urine collection cup made of medical-grade silicone, a connecting hose between the urinal cup and the main body. The overall shape of the main body and a

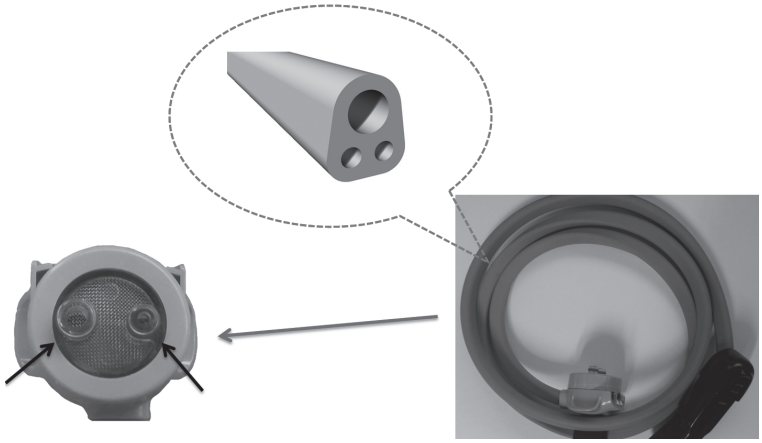

Fig. 2. Connecting hose terminal for the main body receptacle.

detailed view of the LCD operation panel are shown in Fig. 1. The main body has a cleansing water container on the top (arrow) and a cartridge-type fluid waste container at the bottom (broken arrow) as well as a circular-shape receptacle for the connecting hose (top left). The main body also houses pumps for supplying cleansing water after urination, for drying of the genital area, and for fluid waste suctioning. The LCD display panel is shown Fig. 1B; it has buttons for selection of either an automatic cleansing mode or manual cleansing mode. The size of the main body is approximately 33 cm in length, 22 cm in width, and 17 cm in height, small enough to be stored below a wheelchair seat.

2.2. Connecting hose

Figure 2 shows the connecting hose that transports the cleansing water from the main body to the urinal cup, warm air for drying of the genital area, and fluid waste that is a mixture of urine and cleansing waste. The tube has three internal lumens for the fluid waste, the cleansing water and warm air, and an electric wire from the sensor. The electric wire transmits the urine detection signal to the main body PCB for initiation of the cleansing water supply. The connector of the tube to the main body is equipped with a cleansing water inlet (arrow) and a fluid waste outlet (broken arrow), and the electric signal from the urine sensor is transmitted to the main body by the contact of a metallic part of the connector and the receptacle in the main body.

2.3. Urinal cup

The other end of the connector is shown in Fig. 3A. This terminal is equipped with a urine suction inlet (arrow) and urine detection sensors (broken arrows) (Fig. 3B). The cleansing water outlet is located on the opposite side of the urine detection sensors. This terminal end is inserted into the urinal cup in a leakage-free manner (Fig. 3C).

The shape of the female urinal cup and correct positioning method is illustrated in Fig. 4, where the top (A) and side views (B) of the female urinal cup are shown together with the recommended position of the urinal cup (C). The urinal cups are stabilized in the genital area using specially designed girdles as shown in Fig. 5. The male urinal cup is inserted through the girdle hole and placed to accommodate the penile head. The upper part of the urinal cup for men is fixed to the girdle with use of the three straps

Fig. 3. Connecting hose terminal at the urinal cup end.

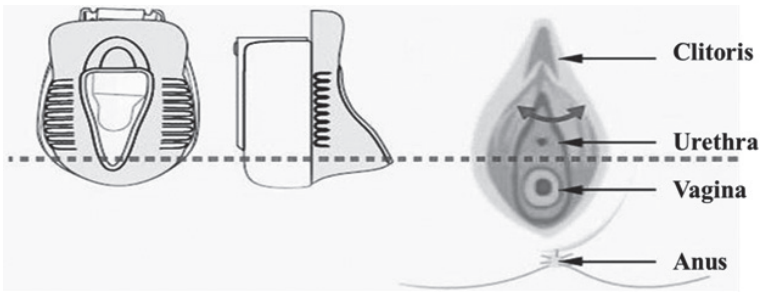

Fig. 4. Correct positioning of female urinal cup.

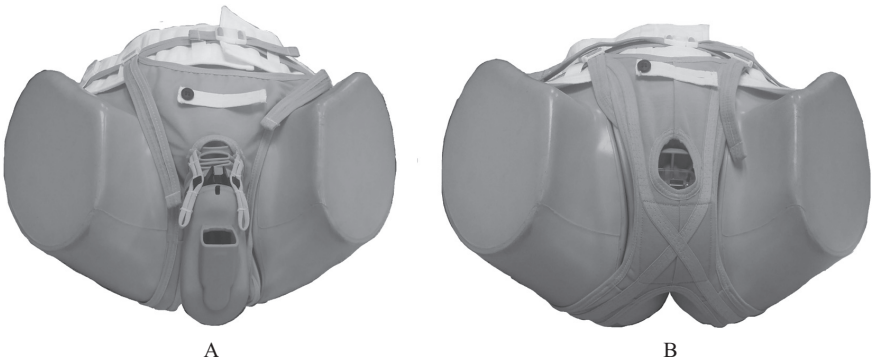

Fig. 5. Stabilization of urinal cups for men (A) and women (B).

as shown in Fig. 5A. The female urinal cup does not need the straps, and the girdle provides adequate stabilization of the urinal cup as shown in Fig. 5B, where the urinal cup is hidden inside the girdle, and only the terminal part of the connecting hose is seen.

This new type of UDS currently does not have an appropriate medical device name in the Korean medical device classification system, and we registered this device as a reusable urine flow meter (code#;

Table 1
Medical conditions of the UDS users

Patient #	Sex/Age	Patient status	UDS experience	Wear time
1	M/75	Prostate surgery mobile/normal daily life complete UI/normal faecal control	24 mo.	night
2	M/89	Senile dementia complete UI/normal faecal control	6 mo.	24 hrs.
3	M/68	Cerebellar dementia complete UI/normal faecal control	3 mo.	night
4	F/32	Morbidity after spinal surgery bed-ridden complete UI/complete FI	84 mo.	24 hrs.
5	F/81	Cerebral stroke bed-ridden complete UI/complete FI	7 mo.	24 hrs.
6	F/24	Traffic accident bed-ridden complete UI/complete FI	33 mo.	24 hrs.
7	F/73	Cerebral stroke bed-ridden complete UI/complete FI	36 mo.	24 hrs.
8	F/62	Cerebral stroke complete UI/normal faecal control	6 mo.	night

A18080.02) with the Korean Ministry of Food and Drug Safety.

2.4. Usability study sample

Among 12 family caregivers of patients with more than 3 months experience with the UDS, eight volunteered to participate in this study. The interview was conducted with family members who were the patients' principal caregivers.

3. Results

3.1. Patient data

The personal data and medical conditions of the UDS users are presented in Table 1. Three patients were male, and five were female. All of the patients have had complete UI and had used diapers before adopting the UDS. The main causes of the complete UI were prostate surgery, senile dementia, cerebellar dementia, cerebral stroke, spinal surgery, and traffic accident. One male patient always stayed home and used the UDS 24 hours a day. The two other male patients used a diaper when going out for several hours. Among the five female patients, the four bed-ridden patients used the UDS virtually 24 hours a day, while the remaining one mobile female patient used the disposal system during the night and wore a urine-absorbing diaper during the day.

3.2. Leakage and skin problem

The replies and comments of the caregivers to the questionnaires related to the use of the UDS are collected in Table 2. No male patients reported leakage problems, but four of the five female patients experienced minor leakage from the urinal cup. The leakage was controllable with concurrent use of a diaper in two female patients and a bed pad in the other two female patients.

All eight main patient caregivers reported that the occurrence of skin erythema significantly decreased when compared to diaper use. The caregivers of four female patients who reported minor leakage of urine from the urinal cup said that the leakage is not significant enough to cause skin erythema. None of the caregivers of the male patients reported problems with skin erythema. There was no case of decubitus ulcer reported from the caregivers while using the UDS.

All eight main patient caregivers reported that use of the UDS relieved them from the chores of night care for the patient, and that they slept better during the night when their patient used the UDS compared with the diaper.

Table 2
Replies from the caregivers

Patient #	Sex/ age	Leakage/ absorbent	Skin erythema/ decubitus ulcer	Cleaning	
				Fluid waste container	Connecting hose
1	M/75	No	No/No	Daily (detergent solution)	Weekly (detergent solution, immersion)
2	M/89	No	No/No		Weekly (detergent solution, immersion)
3	M/68	No	No/No		3–4 times a week (detergent solution, circulation)
4	F/32	Yes/Pad	Decreased/No		Weekly (detergent solution, immersion)
5	F/81	Yes/Diaper	Decreased/No		2–3 times a week (detergent solution, circulation)
6	F/24	No	No/No		2–3 times a week (detergent solution, circulation)
7	F/73	Yes/Diaper	Markedly decreased/No		Weekly (detergent solution, immersion)
8	F/62	Yes/pad	Decreased/No		Monthly (Peroxide solution)

3.3. Odour and cleaning

Compared with the diaper use, the caregivers reported that issues of bad odour were much improved when using the UDS. The users reported that they could keep the fluid waste container odourless by cleaning it on a daily basis with ordinary detergent solution. However, the cleaning method of the connecting hose was not the same among the users, as shown in Table 2.

4. Discussion

Urine detecting technology using humidity sensors has been reported in the literature, and these sensors have been applied for electromechanical urine disposal systems [9–14]. This UDS, Care Clean III, is better than the inflatable rubber pants system reported by Nagoya et al. [9], since the urine contacting area of the patient's body is much smaller, decreasing the possibility of skin problems caused by remnant urine. The Care Clean III has both similarities and differences from the NICMS reported by Macaulay et al. [10]. Both systems run on electricity; however, the NICMS has only a vacuum pump for transportation of urine from the urinal cup to the urine-storing container, whereas the Care Clean III system has pumps for cleansing water supply for warm air drying, as well as for fluid waste suctioning. The cleansing and drying function is particularly important for patients who do not have bladder filling and emptying sensations, since these patients need to apply the UDS continuously and have high risks of skin problems. The cleansing process also provides an opportunity to wash the pathway from the urinal cup to the fluid storage container, reducing the possibility of bacterial growth inside of the system.

The prolonged contact time of the Care Clean III urinal cup with the genital area, the entire night for three patients and the entire day for five patients, could have caused significant skin problems. The absence of significant skin problem in this study could be attributable to careful selection of the urinal cup material, a medical grade silicone that passed ISO 10993-1 standard tests such as cytotoxicity, sensitization, and irritation.

There were some comments from the caregivers for device improvement:

1) Four out of five female patients reported a minor leakage problem from the urinal cup. This result is believed to originate from the diversity in the shape and size of the female external genitalia and suggests that the manufacturer should provide a more diversified urinal cup with various sizes and shapes.
2) One mobile female patient wanted to wear the device during the day sitting on a sofa or chair, but she could not because the urinal cup was displaced when she sit down. Thus, there is a need for position-adaptable urinal cup. No wheelchair-bound patient was included in this study, and a subsequent study should be directed toward testing of this device for wheelchair-bound patients.
3) Although minor, the cleaning procedure for the connecting hose is not standardized, and the manufacturer provided too many methods for cleaning the connecting hose. An optimum cleaning method of the connecting hose needs to be developed and provided in the user manual.

5. Conclusions

The use of an electromechanical UDS provides definite advantages for caregivers, especially during the night when he/she does not need to care for the patient as the urine is automatically collected and stored for disposal the next day. The use of this device for UI patients greatly improves the hygiene of the patients, as there is less risk of urine contact with the patient's body, thus decreasing the incidence of both skin erythema and decubitus ulcers. Further work is warranted, however, to broaden the applicability of this system to more mobile UI patients.

Conflict of interest

The authors have no conflict of interest to report.

References

[1] Brown JS, Seeley DG, Fong J. Urinary Incontinence in Older Women: Who Is at Risk? Obstet Gynecol. 1996; 87(5): 715-721.
[2] Hellström L, Ekelund P, Milsom I, Mellström D. The prevalence of urinary incontinence and use of incontinence aids in 85-year-old men and women. Age Ageing. 1990; 19(6): 383-389.
[3] Leung Felix W, John FS. Urinary and fecal incontinence in nursing home residents. Gastroenterol Clin North Am. 2008; 37(3): 697-707.
[4] Chiang L, Ouslander J, Schnelle JF. Dually incontinent nursing home residents (clinical characteristics and treatment differences). J Am Geriatr Soc. 2000; 48(6): 673-676.
[5] Lee SH, Kang JS, Kim J-W, Lee SJ. Incontinence pad usage in medical welfare facilities in Korea. Int Neurourol J. 2013; 17(4): 186-190.
[6] Saga S, Vinsnes AG, Mørkved S, Norton C, Seim A. What characteristics predispose to continence in nursing home residents? A population-based cross-sectional study. Neurourol and Urodynam. 2015; 34(4): 362-367.
[7] Wang L, Lansing B, Symons K. Infection rate and colonization with antibiotic-resistant organisms in skilled nursing facility residents with indwelling devices. Eur J Clin Microbiol Infect Dis. 2012; 31(8): 1797-1804.
[8] Fujimoto T, Hashimoto T, Sakaki H. Automated handling system for excretion. In Engineering in Medicine and Biology Society. Proceedings of the 20th Annual International Conference of the IEEE. 1998; 4: 1973-1976.
[9] Nagoya K, Kojima T, Hosoya S, Eda K, Ando Y, De-Liang G. Self washing underwear type toilet and its control method using humidity sensor and rotary valve with electric current control. INT J Appl Elctrom. 2008; 27: 75-91.
[10] Macaulay M, van den Heuvel E, Jowitt FA, et al. Noninvasive continence management system: Development and evaluation of a novel toileting device for women. J Wound Ostomy Continence Nurs. 2007; 34(6): 641-648.

[11] Jung YG, Koh E, Park S. Advances in urine and feces disposal systems for the treatment of incontinence. Information. 2015; 18(4): 1463-1468.
[12] Wai AAP, Foo SF, Jayachandran M. Towards developing effective Continence Management through wetness alert diaper: Experiences, lessons learned, challenges and future directions. In Pervasive Computing Technologies for Healthcare (PervasiveHealth). 2010 4th International Conference on-NO PERMISSIONS. IEEE. 2010: 1-8.
[13] Ishitsuka Y, Kobayashi J, Machida SUS. Patent No. 7,220,250. Washington, DC: U.S. Patent and Trademark Office. 2007.
[14] Ishitsuka Y, Kobayashi J, Machida SUS. Patent No. 7,939,706. Washington, DC: U.S. Patent and Trademark Office. 2011.