FINAL REPORT

Evaluation of Urinary Collection Device

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PREPARED

by

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FORWARD

This is the final report on the Project # NAS 9-9940 concerned with evaluation of an improved method of inflight urinary collection. The research was collected by Russell Scott, Jr., M. D., Professor and Head, Division of Urology, Baylor College of Medicine for the National Aeronautics Space Administration, Houston, Texas, under Contract No. NAS 9-9940. This report covers the period August 18, 1969 through April 18, 1970.

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Respectfully submitted,

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Introduction

The purpose of this research project was to field-test for the acceptability of the form-fitted urinary collection device with the following requirements:

A. Lack of skin irritation

B. Ability of the condom to stay on the penis

C. Comfort

D. Ease of urination

Field testing involved utilization of six hospital patients and six normal volunteers. The hospital patients and volunteers wore the form-fitted urinary collection device for five consecutive days without removal. The volunteers and patients were examined daily. If any adverse skin irritations were noted in a test subject at any time, the test was terminated for that individual at that time.

Results

Group I - Normal Volunteers

A. Skin irritation - none of the subjects tested showed signs or symptoms of skin irritation for the period of five days during which the condom device was worn.

B. Ability of the condom to stay on the penis - it was felt by the entire

group that the condom was too short for the length of the penis in every size tested. When the condom became distended with urine, it had a tendency to flip off of the penis. Also, the condom was very difficult to apply as it could not be rolled on and had to be stretched and forcibly pulled over the penis in order to apply. It was subsequently found that the only way the condom could remain on the penis for five days without coming off would be to apply Benzoin ointment to the penis which provided a sticky surface to which the condom could adhere. In addition, the proximal portion of the condom was then taped to the penis. It was only then that the condom could stay on for any longer than a period of 48 hours at one time without coming off in a normal subject whose activity was not limited in any manner.

C. Comfort - once the form-fitting urinary collection device had been applied, it required only an hour or two before the subject had become adapted to this and there were no complaints of discomfort by any of the subjects. The condoms were also distensible in that should penile erection occur, they were not so painful as to require require removal of the condom.

D. Ease of urination - in the normal group of subjects going about their daily activities, they were able to void without difficulty provided there was a straight connection between the end of the condom and the tube collecting the urine. However, if the end of the condom became bent or in any manner occluded, there was some initial hesitancy before the force of the urine could distend the collapsed or twisted terminal portion of the condom or

the urine collection tube. If micturition were initiated while standing with the legs straight, there was no difficulty at all. However, all subjects noted some difficulty in voiding with their legs crossed or legs in a rather severely angulated position.

Group II - Hospital Patients

A. Skin irritation - none of the subjects tested showed any signs or symptoms of skin irritation for the period of five days.

B. Ability of the condom to stay on the penis - the same problems were experienced in this group in their attempt to keep the condom applied. It was further noted in this group that spontaneous erections caused the condoms to peel off the penis. This, again, was felt to be caused by the inadequate length of the condom and not because of its lack of distension.

C. Comfort - none of the patients experienced any discomfort while wearing this form-fitting urinary collection device.

D. Ease of urination - here again, the results were very similar to those found in the normal volunteers. Providing there was no outlet obstruction to urinary flow from the distal tip of the condom catheter or from the urinary tube collecting device, urination was accomplished without difficulty. However, should the end of the condom become twisted or otherwise occluded, urine had a tendency to dissect back toward the proximal end of the penis and cause the condom to flip off or to leak urine. However, if the condom were properly applied and there was no distal obstruction, then there was no problem.

Recommendations

The basic idea of a form-fitting closed system urinary collection device is a good one. The material used for the condom was excellent. It produced no skin irritation, was very distensible, and was not uncomfortable to the subjects who tested it. However, before this can be worn in the field, several minor improvements should be made:

1) An easier method of applying the condom should be found. It would be my suggestion that the condom should be made like a normal proprietary condom; that is, it should be made to roll on. This would prevent the extreme difficulty in applying the condom with its present square ring and the often-experienced tears in the condom while applying it.

2) The condom should be made longer in all sizes tested; that is, it should be made to roll on the penis and what additional length is not required could remain rolled on the rubber ring at the proximal end of the condom.

3) Possibly the outlet at the distal portion of the condom could be slightly enlarged so there would be a greater surface area through which the urine could exit at one time which might prevent the ballooning out of the distal tip of the condom and dissection of the urine in a retrograde manner as was experienced by subjects who tested this device when an outlet obstruction was present.

4) Although the condom could be made to be applied easily, I would still suggest that Benzoin and tape be applied to the penis to give added safety and prevent urinary leakage, as well as providing more freedom of movement.