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A NEW, SIMPLE DEVICE TO MANAGE MALE URINARY INCONTINENCE

Hypothesis / aims of study

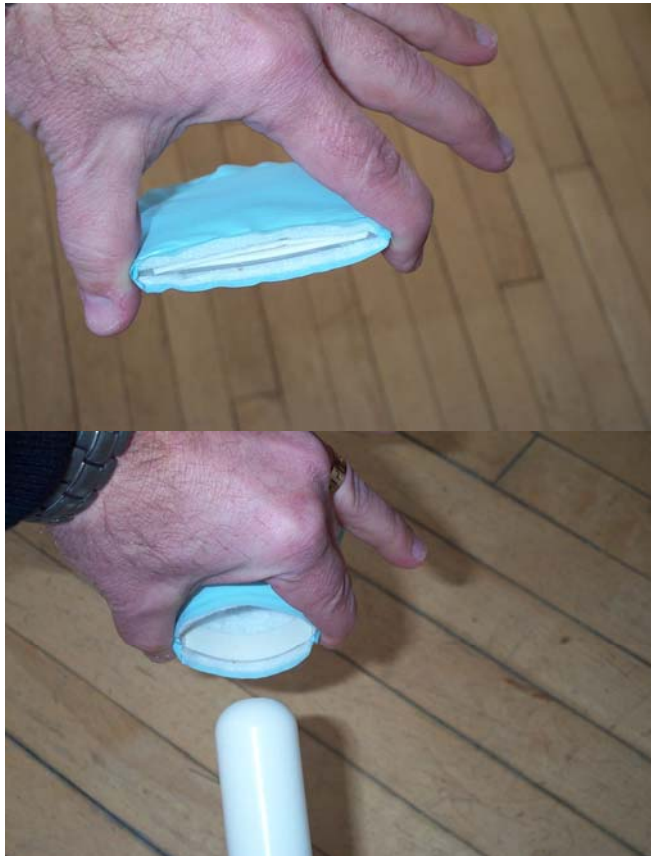
A preliminary trial to determine the comfort and efficacy of a disposable penile compression clamp, affixed with a pad to maximize protection from urine leakage.

Study design, materials and methods

The penile compression clamp with absorbent attachment (Freedom CUF™, NovaTek Medical, LLC, Minneapolis, MN, USA) is an externally applied device placed on the shaft of the penis to occlude the penile urethra and prevent urine leakage. Any urine leakage due to large increases in intraabdominal pressure will be absorbed and retained within an absorbent sleeve attached to the clamp. It can be removed for urination and replaced, and is designed to be invisible under clothing.

The penile clamp is made of medical grade plastic. The clamp is padded on the inside rim for comfort. An absorbent sleeve is affixed to the clamp (see figure).

These devices were given to 8 men with incontinence. Mean subject age was 72 years (range 56-85). The reasons for incontinence included stress urinary incontinence in 4, urge incontinence in 1 and mixed incontinence 3. Baseline incontinence as measured by pad use ranged from 0-4 pads/day. Each subject was given a questionnaire to complete after using 3 pads.





Figures. 1) Clamp is held between thumb and forefinger. 2) A pinching maneuver opens the clamp, and the penis is inserted into the sleeve. 3) The clamp is released onto the shaft of the penis, occluding the penile urethra.

Results

The questionnaire results are listed below:

Did the device reduce your urine leakage?*	greatly 4	somewhat 3	not at all
Did the absorbent attachment absorb leaked urine?*	absorbed well 6	absorbed somewhat 1	did not absorb well
Was the device easy to put on?	very easy to put on 5	somewhat easy 1	difficult to put on 2#
Was the device easy to take off?	very easy to take off 6	somewhat easy 2	difficult to take off
Was the device comfortable to wear?	very comfortable 1	somewhat comfortable 6	not comfortable 1
Would you use the device in the future?	yes 6	no 2	
*One subject did not have daily leakage, so did not experience any change			
# Both subjects were neurologically impaired			

Interpretation of results

The penile clamp with absorbent attachment was well tolerated in this small trial of incontinent men. In men with urinary incontinence requiring pad use, this device provided adequate protection from urine leakage.

Concluding message

The Freedom CUF™ is a comfortable and effective means to manage male incontinence. It may be particularly suitable for those men with mild to moderate incontinence. A larger trial of this device is underway.

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