

Treatment of Exercise Incontinence With a Urethral Insert

A Pilot Study in Women

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ABSTRACT

OBJECTIVE: This study sought to evaluate the short- and medium-term effectiveness of an intraurethral device (*FemSoft*[®] Insert, Rochester Medical Corporation, Stewartville, Minnesota) in the treatment of exercise-induced incontinence in women.

DESIGN: An unblinded, controlled trial of device efficacy during supervised exercise sessions (phase 1) was followed by a 3-month uncontrolled trial of device effectiveness (phase 2). The setting was a tertiary care center, and female participants were 6 community adults with symptoms of significant stress incontinence during exercise. Phase 1 consisted of four standardized exercise sessions, two with and two without the insert in place. In phase 2, patients performed unsupervised exercise using the insert during a 3-month period. The main outcome measure was change in urine loss during exercise sessions performed with and without the device, as measured by change in pad weight. Secondary outcome measures were results of satisfaction surveys and occurrence of adverse events.

RESULTS: Median urine loss during standardized exercise sessions decreased from 20 g (range, 4.9 to 80.2 g) without the device to 2.6 g (range, 1.3 to 6.8 g) with the device ($P=0.03$). Five women used the device at home during unsupervised exercise; one subject had a urinary tract infection. At the end of 3 months, satisfaction and comfort were rated high on a 5-point scale.

CONCLUSION: The *FemSoft* urethral device is an effective, safe, and comfortable treatment for exercise incontinence in women.

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