

The Contino[®] urethral insert in the treatment of male stress urinary incontinence

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Introduction

Surgical interventions continue to be the mainstay treatment for men with stress urinary incontinence (SUI). For patients with comorbidities that preclude them from surgery or those that are unwilling to undergo invasive therapy, non-surgical options are limited to external compression or collection devices coupled with behavioral modifications. These are often not satisfactory in controlling leakage. The Contino[®] is a self administered device placed into the distal urethra to inhibit urine flow, which is then removed prior to urination. This prospective, non-randomized, single-arm trial was used to assess the efficacy of the Contino[®] device in treating male SUI.

TABLE 1

Up-2.6 ICQ-SF data summaries by day									
Day	n	Mean	SD	MIN	Median	MAX	Q1	Q3	IQR
Baseline	26	16.5	3.7	9	17	21	14	19.8	5.8
Interim	17	13.8	5.4	3	15	21	9	18	9
End	13	12.2	5.5	5	12	21	7	17	10

TABLE 2

Up-2.6 Pad weight data summaries by day									
Day	n	Mean	SD	MIN	Median	MAX	Q1	Q3	IQR
Baseline	26	471.4	310.9	33	403.4	1007	186	778.5	592.5
Interim	11	291.2	261.5	2.7	231.7	721	76.5	472	395.5
End	11	149.1	159.7	1.3	120	433	7.8	261	253.2

Results

A total of 15 participants completed the study (Fig. 1). Repeat subjects or those with missing data were removed from the statistical analysis completed post-hoc by UBC. The use of the device resulted in the reduction of mean scores of ICIQ-SF from baseline (16.5) to day 30 (12.2) (Table 1). Mean pad weight also decreased from baseline (471.4 g) to day 30 (149.1 g) (Table 2). The t-distribution is assumed for calculating confidence intervals. One-sided 95% confidence intervals were used and gave an upper bound of the estimates (Tables 3, 4). The adverse events (AE) were primarily mild and non-serious.

Methods

This multisite study enrolled 36 men with SUI. Each patient subsequently underwent personalized device sizing and teaching. The primary endpoints of the study were a change from baseline to interim/end of study on the following: **1** International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF); **2** pad weight to assess urine loss; and **3** adverse events. The trial was 30 days, with data collected at the start, interim, and end of study.

FIG. 1 STUDY PARTICIPANTS UP-2.6

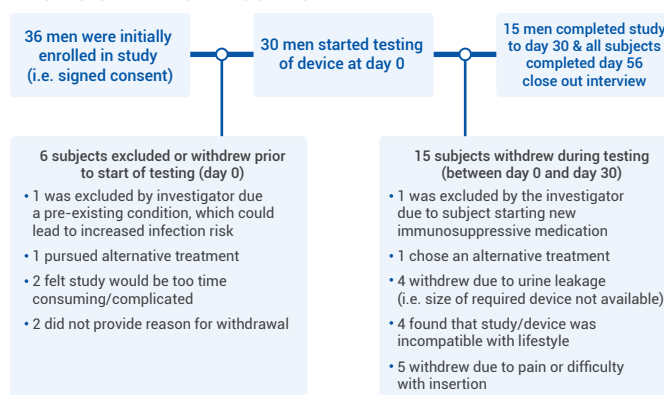


TABLE 3

Up-2.6 Estimated mean difference and 95% upper limit in ICIQ-SF from baseline by day		
Day	Estimate	Upper
Interim	-2.471	-0.796
End	-4	-1.827

TABLE 4

Up-2.6 Estimated mean percent change and 95% upper limit in pad weight from baseline by day		
Day	Estimate	Upper
Interim	-54.21	-38.32
End	-71.76	-54.3

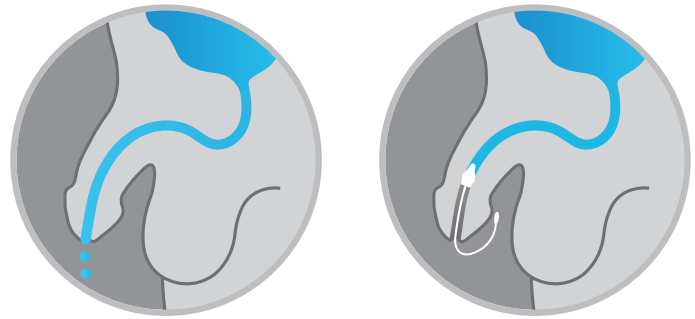
Conclusions

The Contino[®] device resulted in a reduction in urine loss and improved patient perception with urinary incontinence. It is well tolerated with minimal AE. The Contino[®] device may serve as an alternative, non-invasive option for men with SUI.

contino®

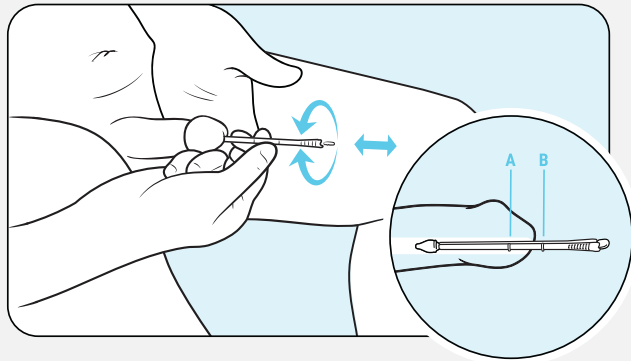
A non-surgical, integrated solution

The Contino® urethral insert, or simply Contino®, is a non-surgical licensed medical device that controls bladder leakage in men. Contino® is self-inserted into the adult male urethra and is removed prior to urination. Much more than just a device, Contino® is an integrated solution that includes personalised fitting and support from experienced incontinence medical professionals, so men can get on with life.

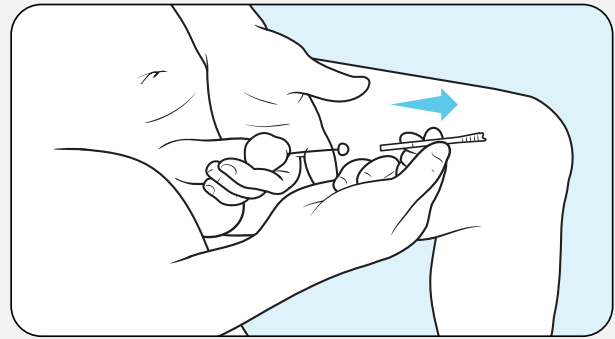


WITHOUT CONTINO®
BLADDER LEAKAGE

WITH CONTINO®
BLADDER LEAKAGE CONTROL



Insert assembled Contino



Remove inserter by pulling gently

Contino® urethral insert in situ

The image to the right is a urethrogram of a subject lying on their back with the Contino® in the “set” position. The dark thick columns above and below the Contino® is radiopaque material used as a contrast material. The image shows the subject’s urethra has collapsed around the Contino® and the radiopaque material (ie. urine) is next to the tip (ie. leading end) of the Contino®. Please note: the radiopaque material below the Contino® is from the syringe used to inject the contrast material during the X-ray.

