Original Article

Long-Term Results of the FemSoft® Urethral Insert for the Management of Female Stress Urinary Incontinence


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Abstract: A 5-year ongoing, controlled multicenter study enrolled 150 women. Outcome measures included pad weight tests (PWT), voiding diary (VD), quality of life (QOL) and satisfaction questionnaires. Outcome measures during the baseline period were compared to evaluations during follow-up. Concurrent evaluations with and without device use were also performed. Safety evaluations included urinalysis and culture, leak-point pressure (LPP) and cystoscopy. Adverse events (AE) were recorded throughout the study. One to 2 years of follow-up were collected on all study participants (mean 15 months). Statistically significant reductions in overall daily incontinence episodes (P<0.001) and PWT urine loss (P<0.001) were observed with the device at all follow-up intervals, and 93% of women had a negative PWT at 12 months. Women were satisfied with ease of use of the device, comfort and dryness, and significant improvements in QOL were observed (P<0.001). Subgroup analysis revealed that the insert was effective, despite the presence of urgency, low LPP, failed surgery and advanced age. AE included symptomatic urinary tract infection in 31.3%, mild trauma with insertion in 6.7%, hematuria in 3.3%, and migration in 1.3% of women. The results of PWT and VD demonstrated device efficacy. Women were satisfied and significant improvements in QOL were observed. AE were transient and required minimal or no treatment. The urethral insert should be considered as an option for the management of SUI.

Keywords: Female incontinence; Non-invasive therapy; Stress incontinence; Urethral insert

Introduction

Although surgery has been the most effective treatment for stress urinary incontinence (SUI) it is associated with potential complications and is not always successful in the short or long term. Managing women with coexisting urgency symptoms, low leak-point pressure or who are postoperative failures can be particularly difficult. Over the past decade there has been increasing interest in the non-surgical management of SUI by both clinicians and patients.

The Agency for Health Care Policy and Research guidelines recommend that the ‘least invasive and least dangerous’ treatment that is appropriate for the patient should be tried first [1]. Major non-surgical modalities include pelvic muscle re-education, electrical stimulation therapy, bladder retraining, medications, and vaginal and urethral devices. Varying degrees of success have been reported with these options, and reports in the current literature are hampered by short (usually 6–12 weeks) follow-up, analysis of study completers only, unclear definitions of treatment success, lack of consideration of whether treatment affected quality of life, and lack of validated outcome tools [1–8]. New non-surgical options that provide repeatable results in a broad segment of the female SUI population are needed.

The objectives of this study were to assess the long-term safety, efficacy and patient acceptance of a new
non-surgical option, the *FemSoft*™ Urethral Insert (Rochester Medical Corp.), in the management of female SUI. The study design addressed the shortcomings of studies of other incontinence treatments noted above. It was postulated that the device would provide a significant, measurable reduction in urine loss and improve quality of life in both mild and severe SUI, or mixed urge/SUI due to intrinsic sphincter deficiency (ISD) or urethral hypermobility. Further, it was anticipated that the device would be easy to use, comfortable, and well tolerated by women.

**Materials and Methods**

**Device**

The *FemSoft*™ Insert is a single-use intraurethral device intended to prevent involuntary urine loss in females with SUI. It is intended for use during waking hours and activity-specific pursuits.

The device consists of a short silicone tube encapsulated by a fluid-filled (mineral oil) silicone sheath (Fig. 1). The sheath is asymmetric, with a bulbous tip, and is designed to conform and coapt to the bladder neck and urethra. The device is placed into the urethra by the patient with the aid of an applicator (Fig. 2). During insertion, the bulbous tip is compressed and the fluid is pushed distally along the sheath of the device shaft. When the device tip enters the bladder the fluid preferentially flows back to the bulbous tip, creating a soft oil-filled balloon. A soft silicone flange prevents device migration into the bladder and is used to remove the device. A new sterile device is used when desired. The device is available in three diameter sizes (16, 18 and 20 Fr) and two lengths (3.5 and 4.5 cm).

**Study Design**

A multicenter non-randomized study was conducted using the patient as her own control. Institutional review board approval was obtained at all institutions.

Included were women 18 years or older with documented stable SUI, or mixed SUI and urge incontinence with a dominant stress component. At least three incontinent episodes per week, measurable urine loss of $\geq 2\) g by pad weight test (PWT), and sufficient motivation and manual dexterity to use the device were required. Excluded were women with primary urge incontinence, cystometric bladder capacity of $<200\) ml, postvoid residual $>100\) ml, neurogenic bladder, recurrent urinary tract infections (UTI) ($>2\) in the previous year), a history of lower urinary tract malignancy, pelvic radiation therapy, ongoing pharma-