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Title (type in CAPITAL LETTERS): FEMSOFT™ URETHRAL INSERT FOR THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE

Aims of Study: The Femsoft™ urethral insert is designed to prevent female genuine stress urinary incontinence. A short silicone tube encapsulated by a soft, compressible fluid-filled sleeve, the device is easy to place, retrieve and conforms to the bladder neck. The objectives of this study are to evaluate device safety and efficacy, patient satisfaction and influence on quality of life.

Methods: A multi-center observational non-randomized study enrolled 148 patients between February 1997 and September 1998. All patients underwent history, physical examination, validated quality of life survey, urine culture, pad weight test, urodynamic evaluation including valsalva leak point pressure (VLPP), and cystoscopy. Only patients with urodynamically documented SUI and positive pad test (>2 g) were included. Follow up data was collected at 3 months, 6 months, and 12 months.

Results: The mean patient age was 54 years (range 27-78). The mean duration of stress incontinence was 11 years and prior therapy was reported by 64/148 (43%). Urgency symptoms were reported in 72/148 (49%), detrusor instability was documented in 6 (4.1%). VLPP was $\leq$ 70 in 76 (52%) and > 70 in 50 (34%) with no leakage observed in 20 (14%). At the 12 month visit pad weight testing revealed 0.6g with device vs. 16.8g without device ($p< 0.001$). The were 0.35 incontinence episodes per day with device vs. 1.38 without device ($p< 0.0001$). When asked if any urinary leakage occurred with device, 83% of responses were never or rarely, 12% occasionally, 3% frequent, and 8% did not answer. The overall subject satisfaction (desire to continue device use) was 94%. Quality of life improvement at 3, 6 and 12 months was highly significant ($p< 0.0001$). Complications included symptomatic urinary tract infection in 22%, urethral discomfort in 5% and gross hematuria in 1%.

Conclusion: The Femsoft™ urethral insert is safe and effective in the treatment of female stress urinary incontinence. Patient satisfaction is excellent (94%), significant improvement in quality of life is reported ($p< 0.0001$) and complications are minimal.

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