Symposium: Non-Surgical Treatment of Urinary Incontinence

Introl™ Bladder Neck Support Prosthesis: International Clinical Experience

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Abstract: The Introl™ bladder neck support prosthesis is a ring-shaped silastic device with two prongs located at one side such that when placed within the vaginal canal the bladder neck is suspended in a fashion similar to a surgical urethropexy. Since its initial description in 1988 the device has undergone clinical trials in the US and Japan, documenting its effectiveness in the treatment of stress and mixed incontinence in women. Introl™ is available for clinical use in the United States and has been well accepted by practicing clinicians. In Japan, exposure has occurred through clinical trials, which resulted in a high efficacy rate, i.e. 81% of the patients had either maximum benefit or benefit in the global usefulness rating, and 26% experienced minor adverse effects. This paper will summarize Introl™ clinical study findings and describe various clinical observations made during increased clinical usage.

Keywords: Bladder neck support prosthesis; Non-surgical therapy; Stress incontinence

Introduction

The Introl™ bladder neck support prosthesis (BNSP) is a vaginal device designed to support the bladder neck, much as during a Marshall test or after the performance of a surgical bladder neck suspension. It is ring-shaped and has two prongs at one side (Fig. 1) [1]. Once placed within the vaginal canal, the heel of the device sits in the posterior fornix and the two prongs are located retropubically alongside the urethrovesical junction (Fig. 2), supporting it in a high retropubic position. Unlike vaginal pessaries, the device is loosely fitting and is intended to function dynamically, improving bladder neck support by augmenting the reflexive pelvic floor contractions that occur during stressful activities.

Various clinical studies have been performed in order to identify optimal Introl™ candidates and evaluate its impact on incontinence reduction. In the United States, a short-term pilot study was performed in Colorado, followed by a multicenter study at eight continence centers. Concurrent clinical studies have been performed in Japan using similar clinical protocols. Subjects who chose to continue device usage after completion of the initial short-term study have been followed for a period of up to 46 months.
United States Clinical Studies

The BNSP received FDA approval for marketing in May 1995. The approval was based on clinical data obtained during a pilot study performed between July and December 1992 [2]. For this study, women with symptomatic stress incontinence underwent urodynamic testing and a diagnosis of genuine urinary stress incontinence was made. Subjects were then fitted with a BNSP and seen on a weekly basis in order to optimize fit and achieve continence. After four visits, with the best-fitting BNSP in place, subjects underwent repeat urodynamic testing to evaluate the actual urodynamic effects of the device on lower urinary tract function. Objective measurements of continence degree included a 7-day bladder diary and standardized stress testing at baseline and with the best-fitting BNSP in place. Subjects were also asked to complete a satisfaction questionnaire.

This pilot study demonstrated a statistically significant reduction in bladder diary-documented stress incontinence episodes, as well as a marked reduction in urine loss during stress testing. In fact 80% of subjects were dry with the best-fitting BNSP in place. Urodynamic data demonstrated a lack of urethral obstruction by maintenance of a normal postvoid residual, as well as maximal urethral closure pressure and uroflowmetry parameters. There were no changes in cystometric parameters. Dynamic urethral function, as measured by a full bladder pressure/transmission ratio, demonstrated normalization of urethral dynamic function to a statistically significant degree. Subjectively, patients rated the BNSP satisfactory to very satisfactory in various parameters, including comfort, continence, convenience and ease of insertion. Ease of removal received a satisfactory rating but was given a somewhat lower rating by the subjects. This had led to further analysis of the optimal removal technique. Of the 32 subjects initially enrolled, 30 completed the 4-week initial phase of the pilot study and 13 went on to continued device use. Of those who dropped out after the initial phase, the most frequently cited reason was difficulty of compliance with the study protocol, and difficulty with device removal. The subjects were required to remove the device nightly for continued enrollment. In the extended phase, subjects were seen twice a year. At the time of writing this, 4 subjects are still enrolled, 46 months later.

A multicenter study was designed as a follow-up to the initial pilot study in order to evaluate usage of the BNSP in the hands of other clinicians [3]. The enrollment scope was also expanded to include women with mixed incontinence whose symptoms were primarily stress related. For this study, subjects were required to demonstrate urethral hypermobility with a positive Q-tip test (>30°) and performed a standardized pad test in addition to the bladder diary as an objective measure of incontinence severity. The Incontinence Impact Questionnaire (IIQ) was used as an additional measure. The study was likewise performed with a 4-week initial phase followed by long-term elective enrollment. Impact on continence demonstrated during the multicenter study was similar to that found during the initial pilot study. There were statistically significant reductions in urine loss on pad testing as well as on bladder diaries in both the stress and mixed groups. Urodynamic testing revealed no evidence of urethral obstruction as determined by postvoid residual or uroflowmetry parameters. There was a normalization of pressure/transmission ratio with no increase in maximal urethral closure pressure. Quality of life analysis revealed improvement in the social activities/relationships component of the IIQ. However, there was no statistically significant improvement in the composite score of the IIQ. Of 70 women initially enrolled, 53 completed the initial 4-week phase of the study; 42 subjects (79%) continued usage beyond this initial phase.

Since publication of the data from the two US clinical studies, we have looked at various additional outcome aspects. In subjects with mixed incontinence in the multicenter study, we identified a reduction in urinary urgency from 73 to 55 events on a 7-day bladder diary. Although this did not reach statistical significance ($P=0.086$), the trend revealed a reduction in reported urgency. This may be due to decreased bladder neck funneling with the BNSP in place. We also analyzed the improvement in continence in those women for whom an optimal fit was found. This was determined by complete