

VIDEO URODYNAMIC EVALUATION OF A NONSURGICAL TRANSURETHRAL RADIOFREQUENCY COLLAGEN DENATURATION TREATMENT FOR STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Following nonsurgical, transurethral radiofrequency (RF) collagen denaturation treatment (Novasys Medical, Inc, Newark, Calif) in women with stress urinary incontinence (SUI) due to hypermobility, video urodynamics were evaluated. The study was conducted to assess the ability of RF collagen denaturation to reduce regional dynamic tissue compliance without creating strictures or reducing luminal caliber, thus resulting in a functional rather than a gross anatomic change.

Study design, materials and methods

In a prospective, multicenter, single-arm clinical trial, 137 women with clinically diagnosed SUI were treated with RF collagen denaturation applied to the bladder neck and proximal urethra. All women were treated as outpatients using local anesthesia during the procedure. Video urodynamics were conducted at baseline and at 3 months in patients at 1 study center and included abdominal leak point pressure (ALPP) measurements, cystometrogram, voiding pressure study (VPS), and urinary flow rate. Patients also completed the Incontinence Quality of Life (I-QOL) questionnaire at both time points.

Results

Eight women were available at baseline and 3 months to undergo video urodynamic evaluation. At baseline, the mean ALPP was 123 cm H₂O at 200cc and 111 at 250cc of filling. On video urodynamics during voiding, 6 (75.0%) women had marked decensus and all women had beaking. At the 3-month time point, 3 of the women (37.5%) had no leaks at 200cc, well above the baseline ALPP, and 1 woman (12.5%) showed an improvement of 82 cm H₂O. At 250cc, 2 (25%) women experienced no leaks and 3 (37.5%) women had a mean improvement of 23 cm H₂O, for an overall improvement rate of 62.5% based on urodynamics. On fluoroscopy, 2 of the women had improved from marked decensus (below pubic arch) to decensus (above pubic arch). The bladder neck was flattened during filling but showed beaking in all 8 women during the Valsalva maneuver. Six women (75%) had improved I-QOL scores and 4 women (50%) had ≥10-point improvement by 3 months. Mean overall improvement at 3 months was 25 points.

Interpretation of results

As shown in the pivotal trial at 12 months,¹ RF collagen denaturation resulted in measurable improvement in ALPP by 3 months posttreatment in most women. Video urodynamics may demonstrate a change in bladder outlet appearance during Valsalva movements; however, a change in bladder outlet appearance does not correlate with a change in ALPP. I-QOL scores are associated with specific objective and subjective clinical improvements, with a 10-point increase associated with a 25% or greater reduction in incontinence episode frequency, a 25% or greater reduction in incontinence pad weight, and patient perception of being "much better."² The I-QOL scores at 3 months posttreatment in this study indicated marked improvement in patients who underwent RF collagen denaturation treatment.

Concluding message

The lack of correlation between ALPP improvement and bladder outlet appearance supports the proposed mechanism of action for RF collagen denaturation, which is an increase in bladder outlet and proximal urethral resistance without a direct impact on hypermobility.

References

¹ Neurourol Urodyn 2006;25:331-336.

² Urology. 1999;53:71-76.

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HUMAN SUBJECTS: This study did not need ethical approval because n/a but followed the Declaration of Helsinki Informed consent was obtained from the patients.