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TWELVE-MONTH DURABILITY OF EFFECTIVENESS OF TRANSURETHRAL RADIOFREQUENCY COLLAGEN DENATURATION (RENESSA®) FOR TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

Hypothesis / aims of study

Nonsurgical, transurethral radiofrequency collagen denaturation, a safe one-time treatment for women with stress urinary incontinence (SUI) due to bladder outlet hypermobility, is performed in an office setting in about 30 minutes using local anesthesia. This clinical trial aimed to demonstrate its long-term effectiveness.

Study design, materials and methods

A 3-year prospective, single-arm, open-label study has thus far conducted patient evaluations at baseline and at 3, 6, and 12 months following treatment at 13 physician offices or ambulatory surgery centers in the United States. The study includes women with SUI due to bladder outlet hypermobility for at least 12 months who had failed prior conservative treatment. Women with urge or mixed urinary incontinence or who had prior definitive treatment (eg, incontinence surgery or bulking agents) were excluded. All patients received a preoperative oral antibiotic, an oral sedative if requested by the patient, and local periurethral lidocaine injection. The procedure was then performed as has been previously described.[1,2] Patients completed the Incontinence Quality of Life (I-QOL) questionnaire, the Patient Global Impression of Improvement (PGI-I) scale, and the Urogenital Distress Inventory (UDI-6). Each patient also recorded the number of daily SUI episodes they experienced and underwent a 1-hour in-office stress pad weight test. Adverse events, changes in concomitant medications, and responses to satisfaction questions were also noted. Twelve-month results are reported.

Results

In all, 139 women were enrolled (mean age, 48.1 years; age range, 26-87 years) and 136 women received treatment. Approximately one third returned to normal daily activities within 1 day, while most were able to return within 48 hours.

At baseline, the mean number of stress leaks reported was 3.8/day (26.6/week); mean I-QOL score was 51.3, and mean UDI-6 score was 52.7. At 6 months, 119 patients were evaluated. Stress leaks were reduced by at least 50% in 63.1% of patients. Mean I-QOL and UDI-6 score improvements were 16.4 and 17.3 points, respectively (both $P<.0001$). On the PGI-I scale, 32.7% of patients reported that their incontinence symptoms were very much or much better compared with baseline.

At 12 months, 73 patients were evaluated, and the mean number of stress leaks reported was 1.9/day. Additionally, 69% reported a 50% or greater reduction in leaked volume (median reduction, 15.2g) on the stress pad weight test ($P<.0001$). The pad weight test revealed that 45% of the women evaluated were dry (29% had no leakage; 16% had <1g leakage). The mean change in I-QOL scores from baseline was 19.6 points ($P=.0001$), and 74% of the women had improved UDI-6 scores (Table). Mean UDI-6 improvement was 17.6 points ($P=.0001$). On the PGI-I scale, 42.3% of patients reported that their incontinence was very much or much better compared with baseline. Among the women assessed at 12 months, 29.1% of patients reported being somewhat or very satisfied with the results of the procedure, versus 20.1% who were somewhat or very dissatisfied; 35.1% reported that they would definitely or probably recommend transurethral collagen denaturation to a friend with SUI versus 14.2% who were probably or definitely not likely to recommend the procedure.

Figure 1. Changes from baseline in adjusted Incontinence Quality of Life and Urogenital Distress Inventory scores at 6 and 12 months.

	Baseline (N = 137)	**6 Months† (n = 118)**	**12 Months† (n = 73)**
I-QOL			
Mean score (± SD)*	51.2 ± 19.67	81.9 ± 22.4	82.00 ± 22.76
Mean change from baseline (± SD)	—	16.9 ± 26.4‡	19.64 ± 24.15‡
Patients with ≥10-point improvement, n (%)	—	50 (57.5)	44 (60.3)
UDI-6			
Mean score (± SD)*	52.3 ± 15.9	35.0 ± 22.0	6.30 ± 4.24
Mean change from baseline (± SD)	—	–17.3 ± 24.0‡	–4.00 ± 4.4‡
Patients with improvement, n (%)	—	70 (73.9%)	52 (71.2)

*For I-QOL scores, increase indicates improvement; for UDI-6 scores, decrease indicates improvement.
†Not all patients completed each measure at each time point; change from baseline is based only on baseline scores for those patients evaluated at each time point.
‡$P<.0001$.

Interpretation of results

Transurethral collagen denaturation showed measurable durable improvement at 12 months, with no serious adverse events reported at any time point following treatment. This procedure is well tolerated, as evidenced by the finding that most patients returned to normal daily activities within 1 or 2 days, and has demonstrated long-term effectiveness, as indicated by significant improvements in the number of stress leaks and in I-QOL and UDI-6 scores at 12 months. Patient satisfaction with the procedure continued to improve since the 6-month evaluation, with scores on the PGI-I scale for much or very much better increasing from 32.7 to 42.3.

Concluding message

Nonsurgical transurethral collagen denaturation is effective and well tolerated, and may allow women with SUI to avoid surgery or the burdensome compliance requirements of other nonsurgical therapies. Ongoing evaluation of this study population will further assess the long-term durability of this treatment.

References
1. Neurourol Urodyn 2006;25:331-335.
2. Curr Med Res Opin 2007;23:1279-84.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**IRB Project # is 20052168. The study was IRB approved by the Western IRB on 11/1/05 and Dr. Elser received her study approval from Western IRB on 12/13/05.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**