

DURABLE QUALITY OF LIFE IMPROVEMENT FOR WOMEN WITH MODERATE TO SEVERE STRESS URINARY INCONTINENCE FOLLOWING NON-SURGICAL RF TISSUE MICRO-REMODELING

Hypothesis / aims of study

One major factor limiting the usefulness of several non-surgical approaches to the treatment of female stress urinary incontinence (SUI) is the limited durability of treatment efficacy. Thus in order to maintain quality of life improvement, many women must continue pelvic floor exercises or biofeedback therapy, or undergo additional injection therapy, often within months of the initial treatment. This limited durability of treatment efficacy may be even more problematic for women suffering from more severe SUI. This study demonstrates the durability of quality of life improvement resulting from a novel, non-surgical treatment for women with moderate to severe SUI.

Study design, materials and methods

Non-surgical radiofrequency energy (RF) tissue micro-remodeling utilizes a 21F transurethral, palpation-based RF delivery probe containing four 23-gauge needle electrodes to denature collagen within microscopic, submucosal, lower urinary tract targets. Micro-remodeling does not cause tissue necrosis or shrinkage and does not narrow leaving luminal caliber. The mature submucosal micro-remodeling targets measure approximately 150-200Å in diameter. Circumferential micro-remodeled tissue confers reduces tissue compliance on the treated region, measurable as an elevation in leak point pressure. This functional change is clinically manifested as reduced SUI which does not impact normal micturition.

In a prospective, single arm Phase I/II Clinical Trial, 40 women suffering from moderate to severe SUI, defined as a baseline Incontinence Quality of Life (I-QOL) score of 0-60 points, underwent outpatient treatment under conscious sedation in which submucosal targets within the proximal urethral, with or without bladder neck and/or distal bladder outlet, were micro-remodeled. These women completed the I-QOL at 12 and 24 months following treatment. In a prospective, randomized, controlled Phase III Clinical Trial, 27 women with moderate to severe SUI underwent micro-remodeling of 36 circumferential sites within the proximal urethral and bladder neck submucosa, while 14 control arm women underwent a virtually identical "sham treatment." Phase III women completed the I-QOL at 12 months following treatment.

The efficacy outcome for both trials was the incidence of ≥ 10 point I-QOL score improvement, a magnitude of change associated with $\geq 25\%$ incontinence episode frequency reduction, and $\geq 25\%$ stress pad weight reduction, and patient perception that she is "much better" following treatment [1,2].

[1] Quality of Life of Persons with Urinary Incontinence: Development of a New Measure. *Urology* 47:67-72, 1996

[2] Quality of Life of Women with Urinary Incontinence: Further Development of the Incontinence Quality of Life Instrument (I-QOL). *Urology* 53:71-76, 1999.

Results

In the Phase I/II Trial, ≥ 10 point I-QOL score improvement was demonstrated in 66% of women at 12 months (n=35) and in 68% at 24 months (n=19). In the Phase III Trial, ≥ 10 point I-QOL score improvement was demonstrated in 81% of treated (n=21) and 40% of sham treated (n=10) women at 12 months (p=0.04).

Interpretation of results

Women with moderate to severe SUI who undergo RF tissue micro-remodeling demonstrated improvement in their quality of life that was not only statistically significant at 12 months relative to sham treatment (Phase III results), but was also maintained from 12 to 24 months following treatment (Phase I/II results). The durability of quality of life improvement applied not only to incidence of improvement (the number of treated women who remain improved) but also to magnitude of improvement (≥ 10 points on the I-QOL score, associated with

significant reduction in incontinence episode frequency and pad weight as well as with patient satisfaction with treatment).

Concluding message

Women suffering from SUI continue to favor non-surgical treatment options which can improve their quality of life. Unfortunately, most non-surgical therapies require more than one treatment, especially when used to treat women with more severe SUI. In fact, many modalities require chronic treatment to maintain efficacy, while others frequently require additional treatments within months of initial therapy. Thus patient compliance burdens and the feasibility and cost of repeat treatments limit the acceptance and utility of many currently available non-surgical SUI therapies. Non-surgical RF tissue micro-remodeling is a safe and effective therapy which has demonstrated durable improvement in patient quality of life at 12 and 24 months following a single outpatient treatment in patients suffering from moderate to severe SUI. This durability of efficacy suggests that RF micro-remodeling may be a more appealing first-line therapy for many women suffering from SUI.

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