

ACUTE QUALITY OF LIFE IMPROVEMENT FOLLOWING NON-SURGICAL RF MICRO-REMODELING FOR SUI

Hypothesis / aims of study

Non-surgical therapies for female stress urinary incontinence (SUI) due to bladder outlet hypermobility routinely require multiple and, frequently, repeated treatments in order to achieve and maintain effectiveness. For example, Kegel exercises, biofeedback therapy, and pelvic floor muscle electrical stimulation require multiple treatments over several weeks or months in order to result in an improvement in SUI symptoms, and many of these approaches must be continued to maintain symptomatic improvement.

Non-surgical radiofrequency energy (RF) tissue micro-remodeling is a safe, one-time treatment performed in the office setting under local anesthesia. Clinical studies have demonstrated that treated women experience an improvement in quality of life at one and at two years. However, how soon following treatment women experience any improvement in quality of life, and the magnitude of any improvement, is not known.

This clinical trial was aimed at demonstrating the incidence and magnitude of quality of life improvement in women with SUI at one month following non-surgical RF tissue micro-remodeling.

Study design, materials and methods

Thirty-three women suffering from SUI and hypermobility (based upon history and physical examination) were enrolled at three sites into this Institutional Review Board-approved prospective, open-label, single arm clinical trial. Physician investigators included a board-certified urologist and two board-certified gynecologists.

Prior to and at one month following non-surgical RF micro-remodeling, all 33 women completed the validated incontinence quality of life instrument (I-QOL). SUI treatment is aimed at improving scores on the 100-point I-QOL. An increase in I-QOL score of ≥ 10 points is associated with three clinically meaningful outcomes: patient satisfaction with treatment; a $\geq 25\%$ reduction in number of daily incontinence episodes; and a $\geq 25\%$ reduction in incontinence pad weight [1].

All treatments were performed in the physician's office. All women received an oral quinolone, 10mg oral diazepam (Valium), and a simple bilateral periurethral anesthetic block using a total of 10cc of 2% lidocaine with epinephrine. Each woman was placed in the lithotomy position, and treatment was provided using a 21F balloon-palpation-based transurethral RF probe connected to a RF generator. Four 23 gauge needles are deployed into the submucosa, and RF is delivered for 60 seconds, raising the temperature of the submucosa immediately surrounding each needle tip to 65°C. This limited temperature elevation results in focal, microscopic, submucosal collagen denaturation without producing significant tissue necrosis. A series of simple maneuvers allows for micro-remodeling of 36 microscopic sites placed circumferentially within the bladder neck and proximal urethral submucosa.

Non-surgical RF micro-remodeling results in a reduction in the dynamic compliance of the bladder neck and proximal urethral submucosa, inhibiting the inappropriate opening of the proximal urethral lumen during periods of intra-abdominal stress and bladder outlet descent. This mechanism of action is demonstrable as a statistically significant elevation in Valsalva leak point pressure at one year following non-surgical RF micro-remodeling [2]. Clinically, the inhibition of inappropriate proximal urethral luminal opening manifests as the reduction or prevention of urinary leakage.

Results

At one month following non-surgical RF micro-remodeling, 76% of women (25/33) demonstrated an improvement in I-QOL score. Of women whose score improved, 80% demonstrated an I-QOL score improvement of ≥ 10 points.

The mean \pm standard deviation (SD) I-QOL scores at baseline and at one month following non-surgical RF micro-remodeling are presented in the following table:

Baseline Score	1 Month Score	Score Change	p-value
56.4 \pm 17.8	69.4 \pm 26.7	13.0 \pm 25.2	0.006

Interpretation of results

The expectation of women selecting non-surgical treatment for their SUI is an improvement in their quality of life [3]. While any improvement in the 100-point I-QOL score is desirable, an improvement of ≥ 10 points is clinically meaningful and is associated with patient satisfaction with treatment.

At two years following RF micro-remodeling, 77% of 44 women demonstrated I-QOL score improvement in a prospective, open-label, single arm pilot clinical trial (mean improvement \pm SD = 17.8 \pm 23.4). At one year following treatment, 67% of 110 treated women demonstrated I-QOL score improvement in a subsequent prospective, randomized, sham-controlled clinical trial (mean improvement \pm SD = 10.2 \pm 22.6).

This clinical trial demonstrates that within the first month following a single non-surgical RF micro-remodeling treatment, women experienced improvement in their quality of life comparable in incidence and magnitude to that demonstrated at one and two years following treatment. In addition, the mean I-QOL score improvement was clinically meaningful (≥ 10 points) at 1 month, 1 year, and 2 years.

Concluding message

Non-surgical RF micro-remodeling offers women with SUI due to hypermobility the opportunity to avoid the burdensome treatment and compliance requirements associated with other non-surgical therapies. Women experience an improvement in quality of life within the first month following the single treatment. In addition, the magnitude of quality of life improvement immediately achieved is comparable to that demonstrated at 1 and 2 years following treatment.

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

[2] Impact of Menopausal Status on Leak Point Pressure following Non-surgical Radiofrequency Energy Tissue Micro-remodeling in Women Suffering from Stress Urinary Incontinence. *International Continence Society Annual Meeting, 2004* (poster).

[3] What Women Want - Their Interpretation of the Concept of Cure. *International Continence Society Annual Meeting, 2002* (poster).

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