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IMPACT OF MENOPAUSAL STATUS ON LEAK POINT PRESSURE FOLLOWING NON-SURGICAL RADIOFREQUENCY ENERGY TISSUE MICRO-REMODELING IN WOMEN SUFFERING FROM STRESS URINARY INCONTINENCE

Hypothesis / aims of study

The relationship between menopause and stress urinary incontinence (SUI) and, more specifically, the effects of menopausal hormonal changes on lower urinary tract collagen are not yet completely understood [1,2]. Non-surgical radiofrequency energy (RF) tissue micro-remodeling is a new treatment approach to female SUI. This novel therapeutic modality targets microscopic regions of collagen within the submucosal layer of the bladder neck and proximal urethra for thermal denaturation. Micro-remodeling results in reduced regional dynamic tissue compliance and clinical improvement. This study analyzed the impact of menopausal status on elevation in leak point pressure 12 months following RF tissue micro-remodeling in women with SUI.

[1] Periurethral connective tissue status of postmenopausal women with genital prolapse with and without stress incontinence. *Acta Obstet Gynecol Scand* 82:659-664, 2003.
[2] Paraurethral connective tissue in stress-incontinent women after menopause. *Acta Obstet Gynecol Scand* 77:95-100, 1998.

Study design, materials and methods

Outpatient RF micro-remodeling was performed under conscious sedation, using the 21F RF micro-remodeling probe attached to a RF generator. The probe was passed transurethrally, and 36 circumferential sites within the bladder neck and proximal urethral submucosa underwent microscopic collagen denaturation via nine one-minute periods of RF delivery. These micro-remodeled sites, each approximately 150-200Å in diameter, reduce the regional dynamic tissue compliance without narrowing luminal caliber. The safety and the durable quality of life improvement associated with RF micro-remodeling therapy have been demonstrated [3].
173 women with SUI were enrolled into a prospective, patient-blinded, randomized, controlled, 12 month clinical trial. 110 women underwent RF micro-remodeling and 63 underwent a sham procedure, which differed from actual treatment only in that RF was not delivered to the transurethral probe. Women with leak point pressure (LPP) <60cmH_2O were excluded from enrollment. At 12 months, 136 women were available for LPP analysis.
[3] Transurethral delivery of radiofrequency energy for tissue micro-remodeling in the treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 14:373-379, 2003.

Results

Table 1 presents baseline and 12 month improvement in mean LPP for treatment and sham treatment arm subjects:

Table 1.

	Treatment Arm (n=87)	Sham Treatmen Arm (n=49)	p-value
Baseline Mean LPP	91.3 +/-26.6 cm H_2O	94.0 +/-30.0 cm H_2O	0.6
12 Month Change in Mean LPP	13.2 +/-39.2 cm H_2O	-2.0 +/-33.8 cm H_2O	0.02

Table 2 presents baseline and 12 month improvement in mean LPP for pre-menopausal treatment and sham treatment arm subjects:

Table 2.	Pre-Menopausal Treatment Arm (n=36)	Pre-Menopausal Sham Treatmen Arm (n=23)	p-value
Baseline Mean LPP	97.6 +/-25.5 cm H_2O	104.4 +/-27.3 cm H_2O	0.3
12 Month Change in Mean LPP	15.6 +/-39.9 cm H_2O	-1.4 +/-33.3 cm H_2O	0.09

Table 3 presents baseline and 12 month improvement in mean LPP for post-menopausal treatment and sham treatment arm subjects:

Table 3.	Post-Menopausal Treatment Arm (n=51)	Post-Menopausal Sham Treatmen Arm (n=26)	p-value
Baseline Mean LPP	86.8 +/-26.8 cm H_2O	84.8 +/-29.8 cm H_2O	0.8
12 Month Change in Mean LPP	11.0 +/-38.6 cm H_2O	-2.5 +/-34.9 cm H_2O	0.1

Table 4 presents baseline mean LPP for all subjects (treatment and sham treatment arm) segregated by menopausal status:

Table 4.	All Pre-Menopausal Subjects (n=59)	All Post-Menopausal Subjects (n=77)	p-value
Baseline Mean LPP	100.2 +/-26.2 cm H_2O	86.1 +/-27.6 cm H_2O	0.003

Interpretation of results

RF micro-remodeling resulted in an elevation in mean LPP at 12 months following treatment, while mean LPP fell below baseline level following sham treatment (p=0.02). Both pre and post-menopausal subjects who underwent RF micro-remodeling demonstrated mean LPP elevation at 12 months, while similarly segregated sham treatment subjects demonstrated mean LPP reduction (the differences did not achieve statistical significance with these smaller sample sizes). Mean LPP increased to a similar extent in both pre and post-menopausal women with SUI 12 months following RF micro-remodeling treatment.

Of note, there was a statistically significant difference in baseline LPP between pre and post-menopausal women with SUI (Table 4), with mean baseline LPP 14.1cmH_2O higher in the pre-menopausal subjects. This finding appears to further support a measurable physiologic effect of menopause on the lower urinary tract which may have the potential to affect continence. Additional comparative studies, controlled for post-menopausal hormonal therapy use, may further delineate the relationship between menopausal hormonal changes, lower urinary tract collagen, and SUI.

Concluding message

RF tissue micro-remodeling in women suffering from SUI results in a statistically significant elevation in mean LPP at 12 months following treatment. This tissue effect is evident regardless of menopausal status, with mean LPP increased similarly in both pre and post-menopausal women who receive treatment.

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