**Radiofrequency Treatment of Vaginal Laxity - Nonsurgical Functional Vaginal Rejuvenation**

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**Study Objective:** To assess the safety, tolerability, efficacy and performance of a new radiofrequency (RF) system for treatment of women with vaginal laxity using clinical observations, pelvic exams and self-report questionnaires.

**Design:** Open label, pilot study with RF doses of 60, 75 and 90 joules/em". Patients: 24 women (ages 25-44 yrs) with vaginal laxity after at least one full-term vaginal delivery. Setting: Southeastern urban obstetrics and gynecology private practice.

**Intervention:** Single treatment using reverse thermal gradient RF energy technology, delivered through the vaginal mucosa with the TVR System comprised of a RF generator, cooling module, handpiece and treatment tip. Measurements and Main Results: Subject responses were evaluated with the FSFI, FSDS-R, and the Subject Self-Report-Vaginal Laxity/Sexual Satisfaction Questionnaires designed for this study, and administered before treatment and again Month 1 after treatment. Subjects’ sexual satisfaction was rated with 6-level ordered responses (None to Excellent) and vaginal laxity/tightness with 7-level ordered responses (Very loose to Very tight). Pre-treatment Subject Self-Report scores indicated significantly decreased levels of sexual satisfaction (p=0.01, Wilcoxon signed rank test) and increased vaginal laxity (p<0.001) when comparing their status prior to their first vaginal delivery to after their deliveries. At Month 1 after RF treatment, scores improved significantly to “Very Good” for sexual satisfaction (p=0.001); vaginal tightness improved to a level similar to their pre-delivery status (p<0.001). Screening FSFI full scale scores (mean 27.8 ± 3.3) indicated normal sexual function in this cohort, however scores improved significantly at Month 1 (mean 31.0 ± 3.0; p<0.001, paired t test). FSDS-R scores also improved significantly (p=0.001). Procedures at all RF dose levels were well tolerated; no adverse events occurred. No analgesia or topical anesthesia was required. Longer term follow-up continues.

**Conclusions:** TVRS treatment was safe and offers potential as a nonsurgical procedure to improve vaginal laxity and sexual satisfaction.