Radiofrequency Treatment of Vaginal Laxity – Nonsurgical Vaginal Tightening

Seth Jordan Herbst MD, Leah Millheiser MD, Rachel Pauls MD, Sandra Carson MD, Jonathan Parmer MD, Cynthia Willson RN, Roger Stern PhD and Bertha Chen MD
Disclosures

• SJ Herbst - Consulting fee (Viveve)

• RN Pauls, LS Millheiser, S Carson, B Chen-
  – Members of Scientific Advisory Board, stock options (Viveve)

• J Parmer - Former employee, shareholder (Viveve)

• C Willson - Employee, stock options (Viveve)

• R Stern – Shareholder, stock options (Viveve)

Study sponsored by Viveve Inc, Palo Alto California
(Formerly TivaMed, Inc.)
Study Objectives

• Evaluate safety and tolerability of radiofrequency (RF) thermal therapy

• Evaluate effectiveness as nonsurgical treatment to tighten the vaginal introitus in women with vaginal laxity
Study Participants

• Major Eligibility Criteria
  – At least one or more full-term vaginal deliveries
  – Self-reported vaginal laxity* after deliveries described as “slightly loose, moderately loose or very loose”

* Using Vaginal Laxity Questionnaire (VLQ)
Study Participants

- 24 healthy, sexually active, pre-menopausal women, mean age 37 yr (range 27-44 yr)

- Median 2 (1-3) full-term vaginal deliveries

- Median 13.9 yr (1-24 yr) between first delivery and study screening

- No chronic pelvic pain conditions (vaginismus, dyspareunia)

- No evidence of fistula or thin recto-vaginal septum, or pelvic organ prolapse beyond hymenal ring
RF Device and Treatment Procedure

- Heat delivered to submucosal tissue of introitus while simultaneous cryogen surface cooling protects the epithelial layer

- Multiple RF pulses at overlapping intervals avoiding the urethral area
Treatment Procedures

• Office-based procedure, takes ~ 30 minutes

• Only one RF treatment per subject

• Safety evaluation-3 RF doses; 60, 75, 90 J/cm²
Outcome Assessments

• **Safety**: Clinic observations and pelvic exams at 10 days, 1 and 3 months after treatment

• **Effectiveness**:
  - Vaginal Laxity Questionnaire (VLQ)
    • 7-point rating scale laxity/tightness (very loose to very tight)
  
  - Sexual Satisfaction Questionnaire (SSQ)
    • 6-point rating scale (none to excellent)
  
  - Female Sexual Distress Scale-Revised (FSDS-R)
  
  - Global Response Assessment
Results: Safety

• All RF doses well tolerated
  – 18 of 24 subjects treated at highest level (90 J/cm²)

• No topical anesthetics required

• No adverse events
Results: Effectiveness for Vaginal Tightness

• All 24 subjects reported one or more levels of improved vaginal tightness (VLQ) at Month 1

• Responses sustained or further improved at Month 3 compared to pre-treatment (p<0.001)
Changes in Vaginal Tightness after RF Treatment

Very tight [7], moderately tight [6], slightly tight [5], not tight or loose [4], slightly loose [3], moderately loose [2], very loose [1]. Data are mean with 95% confidence intervals (error bars). P values, Wilcoxon signed rank test.
Results: Effectiveness for Sexual Satisfaction

• At screening, 12 of 24 subjects reported decreased sexual satisfaction from vaginal intercourse (SSQ) after vaginal deliveries

• At Months 1 and 3 after RF treatment, all reported improved satisfaction compared to pre-treatment ($p\leq0.002$)
Subjects with Decreased Sexual Satisfaction after Vaginal Deliveries

Excellent [5], very good [4], good [3], fair [2], poor [1], none [0]. Values are mean ± 95% CI.

P values, Wilcoxon signed rank test.
Personal Distress from Sexually Related Activities

• At Month 1 and 3 after RF treatment

  – Significantly decreased personal distress from sexually related activities (FSDS-R) ($p<0.001$)
Personal Distress from Sexual Activity

Changes in FSDS-R Scores after RF Treatment

Data presented as mean ± 95% CI. (error bars)
P values, paired t tests comparisons Months 1 and 3 versus Pre-treatment
Conclusions

• RF procedures were safe and well tolerated

• Procedure offers potential as a nonsurgical modality to improve tightness of the vaginal introitus

• Subject self-reports indicated significantly.....
  - decreased sexual distress from sexual activity
  - improved vaginal tightness
  - improved sexual satisfaction

• Further studies are warranted for adequate evaluation of this modality