Radiofrequency Treatment of Vaginal Laxity after Vaginal Delivery: Nonsurgical Vaginal Tightening

Leah S. Millheiser, MD,* Rachel N. Pauls, MD,† Seth Jordan Herbst, MD,‡ and Bertha H. Chen, MD*

*Department of Obstetrics and Gynecology, Stanford University School of Medicine, Stanford, CA, USA; †Department of Obstetrics and Gynecology, Division of Urogynecology and Reconstructive Pelvic Surgery, Good Samaritan Hospital, Cincinnati, OH, USA; ‡Institute for Women's Health, West Palm Beach, FL, USA

DOI: 10.1111/j.1743-6109.2010.01910.x

ABSTRACT

Introduction. All women who have given birth vaginally experience stretching of their vaginal tissue. Long-term physical and psychological consequences may occur, including loss of sensation and sexual dissatisfaction. One significant issue is the laxity of the vaginal introitus.

Aim. To evaluate safety and tolerability of nonsurgical radiofrequency (RF) thermal therapy for treatment of laxity of the vaginal introitus after vaginal delivery. We also explored the utility of self-report questionnaires in assessing subjective effectiveness of this device.

Methods. Pilot study to treat 24 women (25–44 years) once using reverse gradient RF energy (75–90 joules/cm^2), delivered through the vaginal mucosa. Post-treatment assessments were at 10 days, 1, 3, and 6 months.

Main Outcome Measures. Pelvic examinations and adverse event reports to assess safety. The author modified Female Sexual Function Index (mv-FSFI) and Female Sexual Distress Scale-Revised (FSDS-R), Vaginal Laxity and Sexual Satisfaction Questionnaires (designed for this study) to evaluate both safety and effectiveness, and the Global Response Assessment to assess treatment responses.

Results. No adverse events were reported; no topical anesthetics were required. Self-reported vaginal tightness improved in 67% of subjects at one month post-treatment; in 87% at 6 months ($P < 0.001$). Mean sexual function scores improved: mv-FSFI total score before treatment was 27.6 ± 3.6, increasing to 32.0 ± 3.0 at 6 months ($P < 0.001$); FSDS-R score before treatment was 13.6 ± 8.7, declining to 4.3 ± 5.0 at month 6 post-treatment ($P < 0.001$). Twelve of 24 women who expressed diminished sexual satisfaction following their delivery; all reported sustained improvements on SSQ at 6 months after treatment ($P = 0.002$).

Conclusion. The RF treatment was well tolerated and showed an excellent 6-month safety profile in this pilot study. Responses to the questionnaires suggest subjective improvement in self-reported vaginal tightness, sexual function and decreased sexual distress. These findings warrant further study. **Millheiser LS, Pauls RN, Herbst SJ, and Chen BH. Radiofrequency treatment of vaginal laxity after vaginal delivery: Nonsurgical vaginal tightening. J Sex Med 2010;7:3088–3095.**

Key Words. Radiofrequency Energy; Vaginal Laxity; Nonsurgical Vaginal Tightening; Sexual Dysfunction after Childbirth

Introduction

Some of the potential medical consequences associated with vaginal childbirth that extend beyond the postpartum period include stress urinary incontinence, bowel incontinence, pelvic organ prolapse, dyspareunia, chronic pelvic pain, and altered sexual function [1–4]. Trauma to the pelvic floor and vagina during pregnancy and vaginal childbirth including stretching of the vaginal introitus may lead to permanent changes resulting in loss of physical and sexual sensation during intercourse, and a reduced sexual quality of life [2,5–7]. Vaginal laxity may occur after the first delivery and worsen with multiparity, delivery of a large fetus, application of forceps, as well as

changes in connective tissue associated with the normal aging process. This condition is rarely discussed between women and their physicians possibly because of the lack of evidence-based treatments, embarrassment, and lack of recognition of the condition. Traditional nonsurgical treatments for relaxation of the vaginal opening have included Kegel exercises or pelvic floor therapy with electrical stimulation of the vaginal musculature to promote perineal muscle strength; these are recommended primarily for stress urinary incontinence. While surgery can be performed to tighten the introitus, pain at incision site can lead to dyspareunia months following the procedure. In this trial we explored the use of nonablative radiofrequency (RF) energy as a nonsurgical approach to modify tissue compliance in the vaginal introitus. Transurethral monopolar RF induced collagen denaturation has been used to treat stress urinary incontinence with minimal risk for adverse events [8,9]. RF energy also has a substantial safe history of use for noninvasive treatment of lax skin of the face and neck [10,11] and for rhytides in the delicate tissue of the periorbital area [12] based on the premise of thermal tissue remodeling rather than ablation.

Aim

The primary aim of this study was to assess the short-term safety and tolerability of monopolar RF thermal therapy. Because there are no appropriate questionnaires to assess subjective improvement, we also explored the utility of our newly designed questionnaires to assess participants' perceptions of the effectiveness of the procedure to improve tightness of the vaginal introitus and to improve sexual satisfaction.

Patients and Methods

This was a prospective, open label, single-center, pilot study conducted between November 2008 and September 2009 at the Institute for Women's Health and Body, Wellington, Florida. The protocol was reviewed and approved by the local ethics committee (Independent Investigational Review Board, Inc, Plantation, FL, USA). Women recruited from a private practice obstetrics and gynecology clinic were invited to receive a single treatment of RF energy to the vaginal introitus if they were aged between 25 and 44 years and pre-menopausal, had at least one full term vaginal delivery (>36 completed weeks of gestation) and delivered at least 12 months prior to enrollment. Inclusion criteria consisted of self-reported perceptions of vaginal laxity defined as "very loose," "moderately loose," or "slightly loose" on the Vaginal Laxity Questionnaire (VLQ) designed for this study, no breastfeeding for 3 months prior to enrollment, sexual activity (vaginal intercourse $\geq$ once per month), in a monogamous, heterosexual relationship, and normal Papanicolou smear cytology and negative pregnancy test within 2 months prior to treatment. Excluded were women with evidence of a thin rectovaginal septum, pelvic organ prolapse beyond the hymenal ring, an active sexually transmitted disease (e.g., genital condylomata, herpes), chronic vulvar pain or vulvar dystrophy, those taking medications known to affect sexual function (e.g., antihypertensive, psychotropic, chemotherapeutic agents), unless dosage was to be stable for at least 1 month prior to treatment and no change in regimen was planned during duration of study, they were using use anti-inflammatory drugs on a chronic basis (e.g., ibuprofen, aspirin and steroids) that can affect collagen or healing, or willingly fulfilled a 30 day washout period of such drugs prior to treatment, those with clinically significant anxiety or depression, or a medical problem that might interfere with wound healing. However, those subjects who were on oral contraceptives prior to enrollment continued to take these throughout the study. All patients provided written informed consent before treatment.

The screening assessments included a physical and pelvic examination, patient demographics, and medical and obstetric/gynecological (OB/GYN) history. Prior to treatment and at the 1, 3, and 6 months follow-up visits, participants completed self-report questionnaires to characterize, and follow effects of treatment on sexual function. We utilized the Female Sexual Function Index (FSFI), modified unintentionally as a result of a transcription error (mv-FSFI). This questionnaire comprised the same questions as the original validated instrument [13], but had slight alterations in the wording of certain possible responses to several questions. The ordinal/interval scale of responses from highest to lowest frequency or highest to lowest degree was similar and there was no change in scoring algorithm. The Female Sexual Distress Scale-Revised (FSDS-R) was used to measure sexually related personal distress [14]. These mv-FSFI and FSDS questionnaires had a dual purpose of evaluating both the impact of the pro-

cedure on sexual function as a safety consideration and for evidence of effectiveness.

This study evaluated subjects' perceptions of vaginal laxity/tightness and subsequent sexual satisfaction specifically from vaginal intercourse as unique aspects of sexual function. Because no objective measure or patient self-report instruments are currently available to address these factors, we designed new questionnaires using Likert items to acquire participants' responses [15]. The Vaginal Laxity Questionnaire (VLQ) obtains perceptions on level of vaginal laxity/tightness assessed with 7-level ordered responses (*very loose*, *moderately loose*, *slightly loose*, *neither loose nor tight*, *slightly tight*, *moderately tight*, *or very tight*). The Sexual Satisfaction Questionnaire (SSQ) obtains information on level of sexual satisfaction from vaginal intercourse assessed with 6-level ordered responses (*none*, *poor*, *fair*, *good*, *very good*, *or excellent*). When The VLQ and SSQ were administered at the screening visit, the questions assessed participants' recall of status prior to their first vaginal deliveries. When administered prior to the RF treatment they assessed current status; this was used as the baseline for comparison of therapeutic responses to treatment. For the global index of change, the subjects completed the Global Response Assessment (GRA), a 7-level scale with response to the statement: "How are you now (levels of vaginal laxity/tightness and sexual satisfaction) compared to before treatment" (*markedly improved*, *moderately improved*, *slightly improved*, *no change*, *slightly worse*, *moderately worse*, *markedly worse*?). This Likert item questionnaire was not unique for this study but has been frequently used in clinical trials to determine a patient's subjective response to treatment outcome [16,17].

Self-report questionnaires were anonymous and answered in a private setting in the clinic offices. With exception of the VLQ (pretreatment) used to confirm study eligibility related to vaginal laxity, the study instruments were not scored by the investigators or clinic staff. All were forwarded to an independent center for scoring and data entry.

Treatments were performed as a clinic office procedure using a RF system (Viveve, Inc, Palo Alto, CA, USA) comprised of a RF generator, a cooling module, a horizontal handpiece, and a treatment tip. The system uses reverse thermal gradient RF technology. The monopolar RF pulse is generated to selectively heat a given volume of tissue beneath the surface, while the integrated cryogen is delivered to the inside of the treatment tip to cool and protect the surface tissue—the vaginal mucosa. RF energy pulses delivered at each dose are electronically monitored by the system to operate within the specifications for the RF device within the expected range of total pulses. The RF treatment was administered only once to each subject. According to the study design, the first three subjects were treated at an energy level of 60 joules per cm^2, and in the absence of adverse events, the next three subjects were progressed to 75 joules per cm^2, followed by 90 joules per cm^2 for the remaining 18 subjects. Duration of the treatment was approximately 30 minutes. The treatment protocol was developed following preliminary research utilizing sheep vagina as an animal model [18].

The subject was placed on an examining table in the dorsal lithotomy position. A return pad was attached to the subject and RF generator. The vagina, perineum, and perianal area were cleansed using a nonalcohol based cleanser. A self-retaining retractor designed for use with the RF generator was inserted into the vagina and repositioned or removed as necessary during the procedure. Coupling fluid was used as a lubricant and reapplied throughout the treatment procedure as needed. The treatment area for the procedure was approximately 20 cm^2 based on a vaginal circumference at the hymenal ring of approximately 12 cm. The treatment tip was applied to the mucosal surface of the vaginal introitus starting at the hymenal ring and the entire area from the 1:00 o'clock to 11:00 o'clock position was treated with RF energy pulses at 0.5 cm overlapping intervals, moving the tip in a clockwise direction, then again in a counterclockwise direction. Treatment to the urethral area was avoided. The self-retaining retractor was removed after the treatment.

Safety was assessed by monitoring of vital signs, documentation of adverse events including patient's experience of pain or discomfort during and after the procedure and concomitant medications. Post-treatment assessments were carried out by telephone interviews at 48 hours and 2 months and at clinic visits at 10 days, 1, 3, and 6 months post-treatment. Pelvic examinations were repeated at months 1 and 3 after treatment. The mv-FSFI and FSDS were administered to capture evidence of any adverse effects on sexual function and health.

Descriptive statistics were generated on all demographic, medical history, and physical examination findings including means and standard deviations, for continuous variables, and frequencies and percentages for categorical variables. The

Wilcoxon signed rank test was used as a nonparametric test for repeated measures of ordinal data from the VLQ and SSQ, and the paired *t*-test was used to evaluate changes in the mv-FSFI and FSDS-R scores. Two-sided 95% confidence levels were used, $P < 0.05$ was significant. Statistical analysis was performed using Stata version 9.2 (StataCorp LP, College Station, TX, USA).

Main Outcome Measures

Assessments of safety and tolerability included pelvic examinations and documentation of adverse events. The mv-FSFI and FSDS-R were used both as safety questionnaires to discern any potential deleterious changes in sexual function and as measures of effectiveness to observe any positive changes in sexual health. The VLQ and SSQ, designed for this study, and the Global Response Assessment were criteria to assess the participants' perceptions of the effectiveness of the RF procedure.

Results

Twenty-four subjects received one RF treatment. The mean age was 37 years (range 27–44 years), most (83%) were white, and 92% had education beyond high school (Table 1). All had at least one full term vaginal birth, 63% had two and 21% had three. The interval between subjects' first vaginal delivery and screening visit was a mean 13.9 years (range 1–24 years). One subject moved out of state and was lost to follow up after the month 2 evaluation.

Table 1 Demographic and clinical characteristics of study participants

Personal and OB/GYN History	N	Mean ± SD or %
Age (year)	24	37 ± 5.1
Body mass index	24	25.6 ± 4.9
Ethnicity/Race		
White	20	83
Hispanic or Latino	4	17
Years of education	24	14.1 ± 1.4
Gravidity		
1	3/24	13
2	9/24	38
3	6/24	25
4+	6/24	25
Full term deliveries		
1	4/24	17
2	15/24	63
3	5/24	21
4+	0	0
Delivery type		
Vaginal	45/49	92
Caesarean	4/49	8
Interval from first vaginal delivery to study entry (year)	24/24	13.9 ± 6.6
Breastfeeding history		
No	8/24	33
Yes	16/24	67

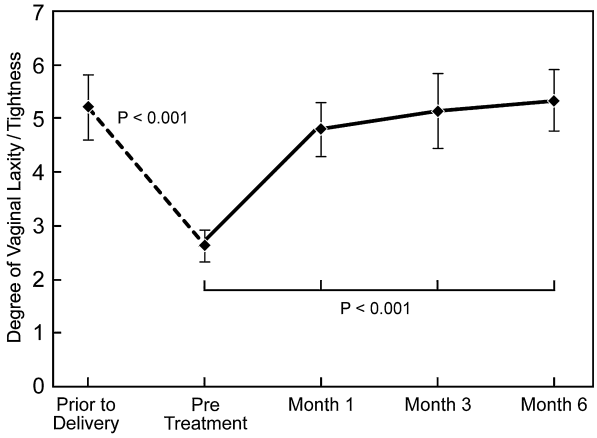

Figure 1 Vaginal Laxity Questionnaire (VLQ) scores throughout the 6 months of follow-up after a single RF treatment. Descriptions of ordered response categories on VLQ and corresponding numbers: very tight (7), moderately tight (6), slightly tight (5), not tight or loose (4), slightly loose (3), moderately loose (2), very loose (1). Data are mean with 95% confidence intervals (error bars). *P* values, Wilcoxon signed rank test.

The RF treatment procedures were well tolerated. Subjects experienced a sensation of warmth during delivery of the RF energy pulses, but no reports of pain necessitated the use of topical anesthetics or analgesics. The delivery of incremental doses of RF energy beginning at 60 joules/cm^2 in the first three subjects, then up to 90 joules/cm^2 was completed successfully. Eighteen of 18 procedures were conducted at the highest energy level per protocol design. No treatment-related adverse events occurred. All subjects had normal pelvic examinations with no clinical evidence of gross tissue changes resulting from the treatment. No subjects reported pain during vaginal intercourse in the 6-month evaluation period.

As early as 1 month after treatment, all subjects showed increased VLQ scores of at least one category compared to pretreatment ($P < 0.001$), indicative of perceived improved vaginal tightness; 67% had VLQ scores that were 2–4 levels higher (Figure 1). The VLQ scores remained significantly improved throughout the 6 months of post-treatment follow-up, mean score (95% confidence interval, CI) of 5.0 (4.8–5.9) compared with 2.6 (2.3–2.9) pretreatment ($P < 0.001$). Eighty-seven percent of subjects reported 2–4 levels of improved

Table 2 Changes in sexual function (mv-FSFI) and sexually related personal distress (FSDS-R) scores before and after RF treatment

Questionnaire	Possible score (range)	Pre-treatment N = 24	Month 1 N = 24	*P* value	Month 3 N = 23	*P* value	Month 6 N = 23	*P* value
mv-FSFI								
Desire	(1.2–6)	4.1 ± 0.9	4.7 ± 0.9	0.008	4.8 ± 0.8	0.002	4.8 ± 0.8	0.002
Arousal	(0–6)	4.5 ± 0.9	5.2 ± 0.8	<0.001	5.5 ± 0.5	<0.001	5.5 ± 0.5	<0.001
Lubrication	(0–6)	4.6 ± 1.1	5.3 ± 0.8	<0.001	5.3 ± 0.9	0.010	5.5 ± 0.8	0.001
Orgasm	(0–6)	4.1 ± 1.2	5.0 ± 1.2	0.001	5.4 ± 0.9	<0.001	5.3 ± 1.1	<0.001
Satisfaction	(0.8–6)	4.4 ± 1.0	5.1 ± 1.0	0.002	5.3 ± 0.7	<0.001	5.3 ± 0.7	<0.001
Pain	(0–6)	5.9 ± 0.5	5.8 ± 0.5	0.354	5.8 ± 0.4	0.732	5.6 ± 0.9	0.255
Total score	(2–36)	27.4 ± 3.6	31.1 ± 3.0	<0.001	32.2 ± 2.7	<0.001	32.0 ± 3.1	<0.001
FSDS-R								
Total score	(0–52)	13.6 ± 8.7	7.0 ± 6.5	0.001	4.4 ± 5.9	<0.001	4.3 ± 5.0	<0.001

Data are mean ± SD.
P value determined by paired *t*-test at months 1, 3, and 6 compared with pretreatment.
N = number of subjects; mv-FSFI = modified Female Sexual Function Index; FSDS-R = Female Sexual Distress Scale-Revised; RF = radiofrequency.

tightness scores at month 6. The subjects' impressions of their improvements after treatment as recorded on the GRA correlated with the increases in VLQ score increases at months 3 ($r = 0.79$, $P = 0.0027$) and month 6 ($r = 0.77$, $P < 0.001$). Vaginal tightness after treatment was characterized as "moderately to markedly improved" by 52% of subjects at both months 3 and 6. For the remaining subjects at month 6, a slight improvement was reported on the GRA by 26% and no change from pretreatment in 22%. No subject indicated a worsening or deterioration of tightness at any assessment. The "moderately improved" status on the GRA was associated with a median of 3 levels of score increase and a "markedly improved" with a median of 4 levels of score increase on the VLQ. There was no correlation between the dose level and number of pulses of RF treatment and VLQ score improvements.

While the degree of sexual satisfaction from vaginal intercourse was not a discriminate criterion for inclusion in the clinical study, two distinct cohorts were identified with the SSQ at screening; 12 of 24 subjects expressed a diminished level of sexual satisfaction after their vaginal deliveries (cohort A) and the remaining 12 reported either no change or an increase in sexual satisfaction after vaginal births (cohort B) (Figure 2). The SSQ scores improved significantly throughout the 6 months after treatment in all of the subjects in cohort A. The mean SSQ score (95% CI) prior to treatment was 2.5 (2.1–2.9) compared with 4.1 (3.8–4.6) at month 6 ($P = 0.002$). The changes in scores in the other cohort were not statistically significantly. For all subjects treated, the levels of sexual satisfaction on the GRA were characterized as "moderately to markedly improved" by 48% at month 3 and by 61% at month 6.

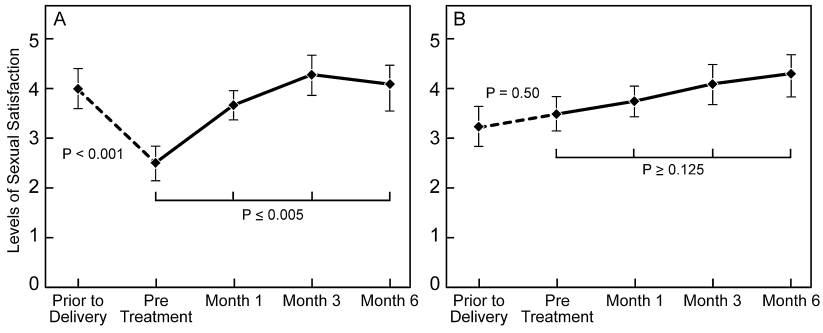

Figure 2 Sexual Satisfaction Questionnaire (SSQ) scores throughout the 6 months of follow-up after a single RF treatment. (A) Subjects (12/24) who at screening expressed diminished sexual satisfaction from vaginal intercourse since deliveries. (B) Subjects (12/24) who at screening expressed either no change or improved sexual satisfaction since deliveries. Descriptions of ordered response categories on SSQ and corresponding numbers: excellent (5), very good (4), good (3), fair (2), poor (1), none (0). Data are mean with 95% confidence intervals (error bars). *P* values, Wilcoxon signed rank test.

Table 3 Subjects with sexual function scores above and below the optimal cutoff mv-FSFI total score for sexual dysfunction [19]

Questionnaire (N)	Possible score (range)	Pretreatment	Month 1	*P* value	Month 3	*P* value	Month 6	*P* value
mv-FSFI total score ≤ 26.55 indicative of risk for sexual dysfunction								
mv-FSFI total (10)	(2–36)	24.1 ± 2.4*	29.9 ± 2.9	0.001	31.7 ± 3.2	<0.001	31.7 ± 3.2	0.001
FSDS-R (10)	(0–52)	19.7 ± 5.8†	8.5 ± 5.5	0.002	4.8 ± 5.1	<0.001	6.6 ± 5.4	0.001
mv-FSFI total score > 26.55 indicative of normal sexual function								
mvFSFI total (14)	(2–36)	29.7 ± 2.0	32.0 ± 2.9	0.001	32.5 ± 2.3	0.005	32.3 ± 3.0	0.028
FSDS-R (14)	(0–52)	8.9 ± 7.1	5.9 ± 7.0	0.086	4.0 ± 6.6	0.013	2.3 ± 4.1	0.003

Data are mean ± SD
P values determined with paired *t*-test at months 1, 3 and 6 compared with pretreatment.
*Mean pretreatment mv-FSFI total scores for these subjects with SD were significantly less than for "normal" subjects, $P < 0.001$ (Student's *t*-test).
†Mean pretreatment FSDS-R scores for these subjects with SD were significantly greater than for "normal" subjects, $P < 0.001$ (Student's *t*-test).
FSDS-R = Female Sexual Distress Scale-Revised.

The mv-FSFI and FSDS-R scores revealed no deleterious effects on sexual function related to RF treatment or a specific RF energy dose. Throughout 6 months of post-treatment evaluations, mv-FSFI total and domains scores with exception of pain (chronic vulvar pain was an exclusion criterion) improved significantly ($P < 0.001$), and personal distress from sexual activity decreased significantly ($P < 0.001$) for all 24 treated subjects (Table 2). Based on the suggested criterion designated by Wiegel et al. for the clinical cutoff FSFI score for subjects at risk for sexual dysfunction [17], the study participants were divided into two groups (Table 3). The first group included 10 of the 24 (42%) subjects with mv-FSFI total scores ≤ 26.55, a level at which they might be considered at risk for sexual dysfunction. The mean mv-FSFI total score (±SD) of 24.1 ± 2.4 in this group was significantly lower ($P < 0.001$, *t*-test) than for the mean of 29.7 ± 2.0 for the 14 subjects in the second group with mv-FSFI total scores >26.55. After treatment, the mv-FSFI total and FSDS-R scores improved significantly ($P \leq 0.001$ at month 3, $P = 0.001$ at month 6) (Table 3).

Discussion

Sexual health is an integral part of general health. The context in which women experience their sexuality may be equally or more important than the physiologic outcomes that she experiences. Women have concerns about the potential negative effects of vaginal childbirth on their sexual health and sex lives [2,3]. Among the very few reported studies of postnatal sexual health only one addresses vaginal looseness/lack of muscle tone reported by approximately 20% at 3 months after births and 12% (49 of 403) at 6 months [1]. Others have reported improved sexual satisfaction following colpoperineoplasty procedures for a wide vagina [20,21]. The incidence of vaginal laxity is unknown; contributing to this lack of information is the limited dialog about postnatal sexual problems with healthcare providers and few seeking help for a sexual concern [1,22,23].

Use of the VLQ and SSQ questionnaires developed for the study and the sexual function instruments allowed us to make several interesting observations. The participants in this clinical trial reported a significant change in their perceptions of vaginal laxity as compared with recollection of their vaginal tone prior to having vaginal births. For half of these women this was accompanied by decreased sexual satisfaction during vaginal coitus. In addition, the mv-FSFI scores for 10 (42%) of the women in our study were below the optimum cutoff level at which they might be considered at risk for sexual dysfunction [19]. However, over the period of 6 months following RF treatment, sexual function scores improved in our study sample of women, and levels of personal distress decreased significantly in those women with scores greater than 15.

This study represents the first application of monopolar RF thermal therapy for vaginal laxity after childbirth. The procedure is minimally invasive and limited to treatment of the vaginal introitus. It relies on the concept that carefully controlled RF energy can be used to heat deeper submucosal tissue in conjunction with concomitant cryogen cooling to prevent superficial heat injury. The therapeutic goal is to stimulate connective tissue restoration with subsequent tissue tightening. RF energy has been extensively used for tissue tightening of human skin [10,11]. Increased collagen formation appears to contribute to the mechanism of skin tightening over time

[24–27]. We hypothesize that a similar process of neocollagenesis and neoelastogenesis with dermal collagen remodeling as a restorative process after exposure to RF thermal energy also might also occur in vaginal tissue.

Using the sheep vagina as a animal model system with histological similarity to the human vagina, tissue changes associated with an RF treatment procedure identical to that used in this human report were evaluated in serial tissue biopsies taken immediately, 1 week, and 1, 3, and 6 months after a single treatment [18]. Focal underlying soft tissue stromal remodeling with fibroblast activation was primarily identified between 1 week and 1 month after treatment and variably increased submucosal and/or muscularis collagen was focally present over the 6-month post-treatment period. The findings support a putative mechanism of action for this RF-based therapy that involves connective tissue remodeling with fibroblast activation and new collagen production. The absence of ulceration, regional necrosis, and effacing dense collagen scarring over the 6-month follow-up period support an acceptable safety profile for this treatment regimen. The temporal changes of collagen tissue remodeling in the sheep vagina reflect a possible mechanism to explain the subjects' perceptions of increased vaginal tightness in the 1–6-month period after RF treatment as reported in the our clinical study.

We are aware of limitations of our study. It is not currently possible to predict how long the participants' perceptions of improved vaginal tightening will last, as the tissue changes from RF energy may be vulnerable to natural tissue changes with aging or further childbearing. We did not objectively quantify girth of the vaginal introitus pre- and post-treatment; however, there are no currently available devices to easily standardize this assessment. To our knowledge this is the first study to address the concern of vaginal laxity after childbirth and to determine the feasibility of conducting a trial to evaluate a nonsurgical procedure with thermal energy as a therapeutic option. As such it was necessary to create new questionnaires to document subjects' perception of vaginal laxity and sexual satisfaction from vaginal intercourse. These are unique to this study and are not validated instruments for assessment. The mv-FSFI questionnaire was unintentionally modified during the transcription process and therefore is not the exact instrument validated by Rosen et al. [13] although it was found to be useful to evaluate subject self-reports of sexual function before and after treatment. The number of subjects was small and longer term follow-up for assessment of safety will be required for adequate evaluation of this modality. The potential for a placebo response does exist; a randomized, sham-treatment control is necessary to examine this effect. Subject selection for the study was based on women's perceptions and experiences of her sexuality and quality of vaginal intercourse after vaginal deliveries; however the study could not examine the psychosocial or personal-partner relationship issues that may impact the response outcomes over time.

Conclusion

Our pilot data suggest that this nonsurgical RF treatment is well tolerated, 6-month safety is excellent, and there is subjective improvement of vaginal tightness. These objective and subjective data will guide us in our design of a full-scale randomized, controlled clinical trial to examine the effectiveness, and assess long-term safety of RF treatment for vaginal laxity after vaginal deliveries.

Acknowledgments

We thank Elaine K. Orenberg, PhD for assistance with data and statistical analysis and preparation of the manuscript and Buddy Hutchins PhD for data compilation. This study was presented in part at the Annual Meeting of the American Urogynecology Society, September 2009, Hollywood, Florida and at the Annual Meeting of the American Association of Gynecologic Laparoscopists, November 2009, Orlando, Florida. Clinical study supported by Viveve, Inc, Palo Alto, California.

Corresponding Author: Leah S. Millheiser, MD, Female Sexual Medicine Program, Division of Gynecologic Specialties, Department of Obstetrics and Gynecology, Stanford University School of Medicine, 300 Pasteur Drive, Room HH333, Stanford, CA 94305, USA. Tel: +650-725-9447; Fax: +650-723-7737; E-mail: sempre@stanford.edu

Conflict of Interest: Drs. Leah Millheiser, Rachel Pauls and Bertha Chen: Members of Scientific Advisory Board and stock options, Viveve, Inc. Dr. Seth Herbst: No conflicts of interest.

Statement of Authorship

Category 1

(a) Conception and Design
Leah S. Millheiser; Rachel N. Pauls; Seth Jordan Herbst; Bertha H. Chen

(b) Acquisition of Data
Seth Jordan Herbst

(c) Analysis and Interpretation of Data
Leah S. Millheiser; Rachel N. Pauls; Seth Jordan Herbst; Bertha H. Chen

Category 2

(a) Drafting the Article
Leah S. Millheiser; Rachel N. Pauls; Seth Jordan Herbst; Bertha H. Chen

(b) Revising It for Intellectual Content
Leah S. Millheiser; Rachel N. Pauls; Seth Jordan Herbst; Bertha H. Chen

Category 3

(a) Final Approval of the Completed Article
Leah S. Millheiser; Rachel N. Pauls; Seth Jordan Herbst; Bertha H. Chen

References

1 Barrett G, Pendry E, Peacock J, Victor C, Thakar R, Manyonda I. Women's sexual health after childbirth. Br J Obstet Gynaecol 2000;107:186–95.
2 Griffiths A, Watermeyer S, Sidhu K, Amso N, Nix B. Female genital tract morbidity and sexual function following vaginal delivery or lower segment caesarian section. J Obstet Gynaecol 2006;26:645–9.
3 Aslan E, Fynes M. Female sexual dysfunction. Int Urogynecol J 2008;19:293–305.
4 Yang SH, Yang JM, Wang KH, Huang WC. Biologic correlates of sexual function in women with stress urinary incontinence. J Sex Med 2008;5:2871–9.
5 Klein MC, Kaczorowski J, Firoz T, Hubinette M, Jorgensen S, Gauthier R. A comparison of urinary and sexual outcomes in women experiencing vaginal and Caesarean births. J Obstet Gynaecol Can 2005;27:332–9.
6 Pauls RN, Occhino JA, Dryfhout VL. Effects of pregnancy on female sexual function and body image: A prospective study. J Sex Med 2008;5:1915–22.
7 Safarinejad MR, Kolahi AA, Hosseini L. The effect of the mode of delivery on the quality of life, sexual function, and sexual satisfaction in primiparous women and their husbands. J Sex Med 2009;6:1645–67.
8 Dillon B, Dmochowski R. Radiofrequency for the treatment of stress urinary incontinence in women. Curr Urol Rep 2009; 10:369–74.
9 Elser DM, Mitchell GK, Miklos JR, Nickell KG, Cline K, Winkler H, Wells G. Nonsurgical transurethral collagen denaturation for stress urinary incontinence in women: 12-month results from a prospective long-term study. J Min Invasive Gyncecol 2009;16:56–62.
10 Weiss RA, Weiss MA, Munavalli G, Beasley KL. Monopolar radiofrequency facial tightening: A retrospective analysis of efficacy and safety in over 600 treatments. J Drugs Dermatol 2006;5:707–12.
11 Dover J, Zelickson B, the 14-Physician Multispecialty Consensus Panel. Results of a survey of 5,700 patient monopolar radiofrequency facial skin tightening treatments: Assessment of a low-energy multiple-pass technique leading to a clinical end point algorithm. Dermatol Surg 2007;33: 900–7.
12 Fitzpatrick R, Geronemus R, Goldberg D, Kaminer M, Kilmer S, Ruiz-Esparza J. Multicenter study of noninvasive radiofrequency for periorbital tissue tightening. Lasers Surg Med 2003;33:232–42.
13 Rosen R, Brown C, Heiman J, Leiblum S, Meston C, Shabsigh R, Ferguson D, D'Agostino R Jr. The Female Sexual Function Index (FSFI): A multidimensional self-report instrument for the assessment of female sexual function. J Sex Marital Ther 2000;26:191–208.
14 Derogatis L, Clayton A, Lewis-D'Agostino D, Wunderlich G, Fu Y. Validation of the female sexual distress scale-revised for assessing distress in women with hypoactive sexual desire disorder. J Sex Med 2008;5:357–64.
15 Herbst SJ, Pauls R, Millheiser L, Carson S, Parmer J, Willson C, Stern R, Chen B. Radiofrequency treatment of vaginal laxity-nonsurgical vaginal tightening. J Min Invasive Gynecol 2009;16:S90.
16 Propert KJ, Mayer RD, Wang Y, Sant GR, Hanno PM, Peters KM, Kusek JW, Interstitial Cystitis Clinical Trials Group. Responsiveness of symptom scales for interstitial cystitis. Urology 2006;67:55–9.
17 FitzGerald MP, Anderson RU, Potts J, Payne CK, Peters KM, Clemens JQ, Kotarinos R, Fraser L, Cosby A, Fortman C, Neville C, Badillo S, Odabachian L, Sanfield A, O'Dougherty B, Halle-Podell R, Cen L, Chuai S, Landis JR, Mickelberg K, Barrell T, Kusek JW, Nyberg LM, Urological Pelvic Pain Collaborative Research Network. Randomized multicenter feasibility trial of myofascial physical therapy for the treatment of urological chronic pelvic pain syndromes. J Urol 2009;182: 570–80.
18 Coad JE, Vos JA. Non-invasive radiofrequency tightening of the vagina in a sheep model. J Sex Med 2010;7(suppl 3):131.
19 Wiegel M, Meston C, Rosen R. The Female Sexual Function Index (FSFI): Cross-validation and development of clinical cutoff scores. J Sex Mar Ther 2005;31:1–20.
20 Pardo JS, Sola VD, Ricci PA, Guiloff EF, Freundlich OK. Colpoperineoplasty in women with a sensation of a wide vagina. Acta Obstet Gynecol Scand 2006;85:1125–7.
21 Adamo C, Corvi M. Cosmetic mucosal vaginal tightening (lateral colporrhaphy): Improving sexual sensitivity in women with a sensation of wide vagina. Plast Reconstr Surg 2009;123:212–3.
22 Glazener CM. Sexual function after childbirth: Women's experiences, persistent morbidity and lack of professional recognition. Br J Obstet Gynaecol 1997;104:330–5.
23 Lukes A, Kingsberg S. OB/GYNs attitudes and perceptions regarding sexual health of patients after delivery. J Sex Med 2010;7(suppl 3):129.
24 Zelickson BD, Kist D, Bernstein E, Brown DB, Ksenzenko S, Burns J, Kilmer S, Mehregan D, Pope K. Histological and ultrastructural evaluation of the effects of a radiofrequency-based nonablative dermal remodeling device: A pilot study. Arch Dermatol 2004;140:204–9.
25 Alster TS, Lupton JR. Nonablatve cutaneous remodeling using radiofrequency devices. Clin Dermatol 2007;25:487–91.
26 Hantash BM, Ubeid AA, Chang H, Kafi R, Renton B. Bipolar fractional radiofrequency treatment induces neoelastogenesis and neocollagenesis. Lasers Surg Med 2009;41:1–9.
27 Hodgkinson DJ. Clinical applications of radiofrequency: Nonsurgical skin tightening (Thermage). Clin Plast Surg 2009;36: 261–8.