INTERVENTIONS

The ThermiVa In Genital Hiatus Treatment (TIGHT) Study

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ABSTRACT

Introduction: Vaginal laxity or the sensation of vaginal looseness affects anywhere from 24% to 50% of postpartum women.

Aim: To evaluate the efficacy and safety of the ThermiVa (ThermiAesthetics, TX, USA) monopolar radiofrequency device in the treatment of vulvovaginal laxity and sexual dysfunction

Methods: The TIGHT study was a prospective single blinded randomized sham-control trial conducted over 3 sites in Australia and India. The study included parous woman over the age of 18 who complained of vaginal laxity/looseness. Participants were randomized into a treatment group and a sham group. Patients in the treatment group were treated with an active probe, whereas, women in the placebo group were treated with sham probes that only reached subtherapeutic temperatures.

Main Outcome Measures: Subjective success was determined by improvement in the Female Sexual Function Index (FSFI), Vaginal Laxity Questionnaire (VLQ), Vaginal Flatus Score (VFS), and the Vaginal laxity Bother Score (VLBS). Objective success was measured via the Modified Oxford Score (MOS) and Genital Hiatus (GH) length.

Results: Sixty-three participants were recruited (sham n = 29, treatment n = 34). In the treatment group, FSFI scores improved at 3 months (mean difference 8-points, *P* value .02), and at 6 months (mean difference 5-points, *P* value .07). At baseline 89.7% and 87.2% of patients in the sham and treatment groups, respectively, classified themselves as "loose" on the VLQ. At 6 months 73.1% of patients in the sham group still identified as "loose" compared to 32.4% of patients in the active group (*P* value .01). Subjective success was also noted in the VLBS (*P* value .02). Results pertaining to VLFS, MOS, and GH did not reveal statistically significant results.

Conclusion: Treatment with ThermiVa was associated with a modest subjective improvement in vaginal laxity and sexual dysfunction and proved to be safe over the 6-month trial period. **Pather K, Dilgir S, Rane A. The ThermiVa In Genital Hiatus Treatment (TIGHT) Study. Sex Med 2021;9:100427.**

Key Words: Vaginal Laxity; Vaginal Looseness; Sexual Dysfunction; Vaginal Rejuvenation; Radiofrequency; Thermiva

INTRODUCTION

Vaginal laxity or the sensation of vaginal looseness affects anywhere from 24% to 50% of post-partum women.[1-4] It occurs secondary to trauma/stretching of vaginal tissues and the pelvic floor as a result of childbirth.[5-7] Laxity can then be worsened by the physiological changes associated with menopause, particularly as a consequence of estrogen deficiency.[6,8,9] Tissue estrogen withdrawal manifests as thinning of the epithelium, smooth muscle dysfunction, connective tissue degradation, and decreased collagen/elastin content of the dermal layer of the vagina.[1] These changes form the pathologic basis for sexual dysfunction, which can significantly impact a woman's quality of life.[3] Symptoms of vaginal laxity and sexual dysfunction are underreported, with only one third of women disclosing symptoms to clinicians and seeking treatment.[3] There are many factors contributing to poor

Received April 9, 2021. Accepted August 2, 2021.

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https://doi.org/10.1016/j.esxm.2021.100427

presentation, but a major barrier remains the cultural taboo surrounding symptoms involving sexuality. Additionally, poor public education, and the lack of evidence-based treatments further reduces the clinician's ability to counsel and manage vaginal laxity appropriately.

Recently, there has been a rise in the use of radiofrequency, and laser devices for the management of vulvovaginal disorders including vaginal laxity.[10-12] ThermiVa is a monopolar radiofrequency device produced by Thermi Aesthetics, Southlakes Texas. It is marketed as a vaginal rejuvenation treatment to improve the symptoms of vulvovaginal laxity as well as improve sexual dysfunction.

The mechanism of action of radiofrequency modalities involves heating the dermal layer of the vaginal mucosa to initiate a cellular regenerative response. Histologically, the vaginal wall is composed of non−keratinized squamous epithelium, but with progression deeper into the dermal layer, the composition changes. This layer has increased deposition of dense connective tissue, smooth muscle, collagen and elastin which imparts strength and elasticity to the tissue.[7, 13] Histologic studies in human and sheep have shown that heating this layer to between 42−45° C activates heat shock proteins and regenerative cellular pathways which ultimately results in increased collagenesis, neurogenesis, elasticity, and increased vascularity.[14,15]

Heat within the dermal layer is achieved via electrical impedance.[6] All molecules within tissue have an electrically charged dipole moment which is randomly orientated. As radiofrequency is applied to tissue an oscillating electrical current is created and molecules re-orientate to align their dipole in the direction of the electrical current, producing heat as a direct by-product.[13] This method avoids applying excess heat to the epithelial layer of the vaginal which can result in thermal injury and pain. Whilst there have been several small studies demonstrating positive results when using ThermiVa, there has to date been no large randomized control trial to demonstrate its safety and efficacy. We hypothesized that ThermiVa is an effective and safe treatment for the management of symptoms of vaginal laxity and symptoms of sexual dysfunction. The research questions answered in this study were: (i) Is ThermiVa an effective treatment in managing symptoms of vaginal laxity & sexual dysfunction, and (ii) Is the treatment safe with no long-term adverse outcomes?

METHODS

The TIGHT study was a multicenter, prospective, randomized single blinded sham-controlled trial conducted between January 2019 and January 2020 at 3 clinical centers located in in Australia and India.

The trials principal investigator and chief supervisor were a consultant Obstetrician & Gynecologist and a Consultant Urogynecologist. All examiners were either Consultant Obstetrician Gynecologists or Advanced trainees/Fellows in Obstetrics and Gynecology. The study gained ethics approval from The Mater Hospital- HREC number 167079.

The same clinical examination and questionnaires were carried out at all clinical sites using a proforma developed by the principal investigator. A video was sent to each of the clinicians involved in the study which outlined the study methods and provided a template for which to base clinic appointments around. This was to ensure uniformity between clinical consultations across all sites as well as to tailor consultations in a respectful and sensitive manner. Overseas sites were encouraged to translate questionnaires for patients of a non−English speaking background.

Patients with symptoms of vaginal laxity after delivery of at least 1 child were the target population for this study. Participants were recruited from the female pelvic health unit or via local medical officers and physiotherapists. In addition, a study poster, and a Patient Information and Consent Form (PICF) were e-mailed to General Practice managers to distribute to General Practitioners. Patients presenting with symptoms of vaginal laxity (vaginal flatus or sexual concerns relating to vaginal laxity) were given the option to participate in the study. Patients who were interested were given the opportunity to review the patient information and consent form and discuss it with family, friends, and their GP prior to commitment to participate.

INCLUSION/EXCLUSION CRITERIA

The TIGHT study included: women who complained of symptoms of vaginal laxity (or looseness), who were over the age of 18, were able to give consent, and had a history of at least 1 vaginal delivery. Women were excluded from the study if they had: any contraindication to radiofrequency (women with cardiac devices, pregnancy, active sexually transmitted disease or urinary tract infections), a Stage II (or greater) prolapse, body dysmorphic disorder, a history of a recto-vaginal fistula, were unable to follow-up for a period of 12 months post-treatment, had a previously abnormal HPV DNA testing (with abnormality in subsequent liquid based cytology), abnormal uterine bleeding or were undergoing physiotherapy or surgical treatment for the management of their vaginal laxity.

RANDOMISATION AND INTERVENTION

The ThermiVa radio frequency generator (K130689-Symphoni RF Generator) and test probes were obtained via a ThermiVa representative from ThermiAesthetics, Southlakes, Texas. Participants were given a participation number and they were randomized into an active treatment group or a sham group based on an online randomizer (www.randomiser.org).. Probes were then provided to the clinical centers with an active or sham probe allocated to each patient. The treating and research team were aware of the status of each probe, however the clinician conducting the follow-up examinations will be blinded to their active/sham status.

Participants in the active group were allocated a probe which achieved therapeutic temperatures of 42−47° C. Sham probes were identical in appearance, however therapeutic temperatures were never achieved during treatment, with probes designed to only reach 25−27° C. The sham probes were designed to give a sensation of warmth and made operational sounds to maintain the blinded status of participants. The vagina was divided into 4 quadrants, with each quadrant receiving treatment for 3 minutes with clinicians being encouraged to spend an equal amount of treatment time for patients in the sham group.

MEASUREMENT TOOLS

At the initial assessment, a thorough medical, obstetric, and gynecologic history was obtained via questionnaire. The majority of this questionnaire was yes/no based, as it was primarily designed to detect additional risk factors in study participants. Vaginal laxity can significantly impact the sexual function of patients and in turn their self-esteem and marital harmony. The symptoms associated with vaginal laxity were assessed by a series of Likert-based questionnaires. The domains included a Vaginal Laxity Score (VLS), Vaginal Laxity Bother Score (VLBS), and Vaginal Flatus Score (VLS). These questionnaires were adapted from previous trials investigating the efficacy of radiofrequency in the management of vaginal laxity.[8,16]

Due to the significant impact the vaginal laxity can impose on a woman's quality of life, it is also important to determine if treatment had any impact on sexual function. This was determined by completing the Female Sexual Function Index (FSFI) questionnaire. The FSFI is a validated questionnaire which measures sexual functioning in women. It has been designed to assess domains of sexual functioning including sexual arousal, orgasms, satisfaction, and pain. A score of <26.55 indicates increased risk of developing sexual dysfunction.

Following the questionnaires, a physical examination was performed. This consisted of an abdominal examination, POP-Q assessment (to detect any evidence of pelvic organ prolapse), Modified Oxford Score (MOS), and Genital Hiatus (GH) measurement. Currently, there is no objective measurement to determine vaginal laxity.[2, 3] After discussion with experts in the field, follow-up examinations focusing on the MOS and GH measurement would serve as an adequate objective measure for the efficacy of ThermiVa. The initial and review physical exams were performed by a consultant Gynecologist or a senior registrar/fellow in Gynecology.

At the 3-month and 6-month follow-up appointments the VLQ, VLBS, VFS, FSFI questionnaires were completed as the subjective measurements of success. This was followed by a re-assessment of the MOS and GH as the objective measure of the study. These data were then analyzed by a statistician utilizing SPSS V25.

RESULTS

Participants

Between October 2018 and January 2019, 63 subjects were recruited. They were randomly allocated into a sham treatment group (n = 29) and a treatment group (n = 34). These participants all met the inclusion criteria and were subjected to a baseline history and physical exam. The patient history encompassed patient characteristics, past medical, surgical, social, medication history as well as a baseline FSFI, VLQ, VFS, and VLBS. The physical exam included an abdominal exam, determination of the GH, and MOS. Table 1 outlines the baseline characteristics of participants.

FSFI

Mean initial baseline FSFI for treatment (53.5) vs sham (57) were similar. The mean change in FSFI is outlined in Table 2. From baseline to 3 months there was a mean difference between

Table 1. Baseline characteristics and medical history

	Sham	Active
Median (upper and lower value)		
Age	36 (31−44)	37 (30−49)
BMI	25.7 (23.4−28)	25 (23−28)
Obstetric History Median (upper and lower value)		
Pregnancies	2 (2−4)	2 (2−3)
Full term deliveries	2 (2−3)	2 (2−2)
Pre-term	0 (0−1)	0
Caesarean Section	0	0
Assisted delivery	0	0
birth weight	3.2	3.2
time since last delivery	12 (4−18) y	11 (5−21) y
Social History Number of patient (% of patients)		
Wanting more children	3 (11.5)	4 (12.9)
Using contraception	10 (34.5)	11 (32)
Domestic Violence	0	0
Sexual Abuse	0	0
Medications Number of patients (% of patients)		
Regular Analgesia	1 (3.7)	0
antidepressants	0	0
anticoagulation	0	0
Medical Comorbidities Number of patients (% of patients)		
Dermatologic	3 (10)	2 (6)
Gynecologic	5 (17)	8 (24)
Sexually transmitted disease	6 (21)	3 (8.8)
Hysterectomy	2 (7)	1 (3)
Vaginal Surgery	3 (10)	1 (3)
Surgery	13 (45)	11 (32)
Psychiatric History	0	0
Cardiac History	0	0

Table 2. Change in median total FSFI

	Sham	Active	*P* value
FSFI (95% Confidence Interval)			
Baseline	51.5 (4.0)	50 (3.5)	.8*
3 mo	52.3 (2.6)	61 (2.4)	.02†
6 mo	59 (3)	64 (3.0)	.07†

*Students *t*-test.
†ANCOVA adjusted with Bonferroni correction.

treatment and sham groups of 8 points (*P* .02, 95% CI 16−1.5). This trend continued from 3 to 6 months, with the treatment group still maintaining higher mean FSFI scores when compared to the sham group. Significant improvements in FSFI continued to be noted in the 6 month data analysis with a mean difference between treatment vs sham groups of 5 points, (*P* .07 CI 95% 115.4−0.8). Table 3 outlines the change in FSI according to the individual domains assessed by the questionnaire. Figure 1 is a graphical representation of the change in FSFI, comparing active (blue) to sham (orange).

Vaginal Laxity Questionnaire

The vaginal laxity questionnaire is an unvalidated subjective measure of success utilized in the TIGHT study. Women were asked to indicate their perceived level of vaginal laxity based on a Likert score from 1(very loose) to 7(very tight). Due to low sample size, the results were analyzed in 3 groups (loose, neither loose or tight, and tight). Analysis revealed a statistically significant transition from the "loose" group to the "tight" in the treatment group compared to the sham group. At baseline 89.7% and 87.2% of patients in the sham and treatment groups, respectively, classified themselves as "loose" on the VLQ. At 6 months 73.1% of patients in the sham group still identified as "loose" compared to 32.4% of patients in the active group (*P* value .01) (Table 4). Figure 2A and B are graphical representations of numbers of patients transitioning from the "loose" group to the "tight" group over the treatment period.

Vaginal Flatus Score

Vaginal Flatus Score (VFS) served as another subjective means of success. This sensation is often felt by women suffering from vaginal laxity, hence was deemed another suitable measure of subjective success of treatment. Patients were asked to score the frequency that they experienced vaginal flatus on a Likert questionnaire at review appointments during treatment. The Likert responses were grouped into patient experiencing vaginal laxity "most of the time," "sometimes" and never/a few times." The original questionnaire asked women to rate the frequency of experienced vaginal flatus into 5 groups: *Almost never* (Score =1),

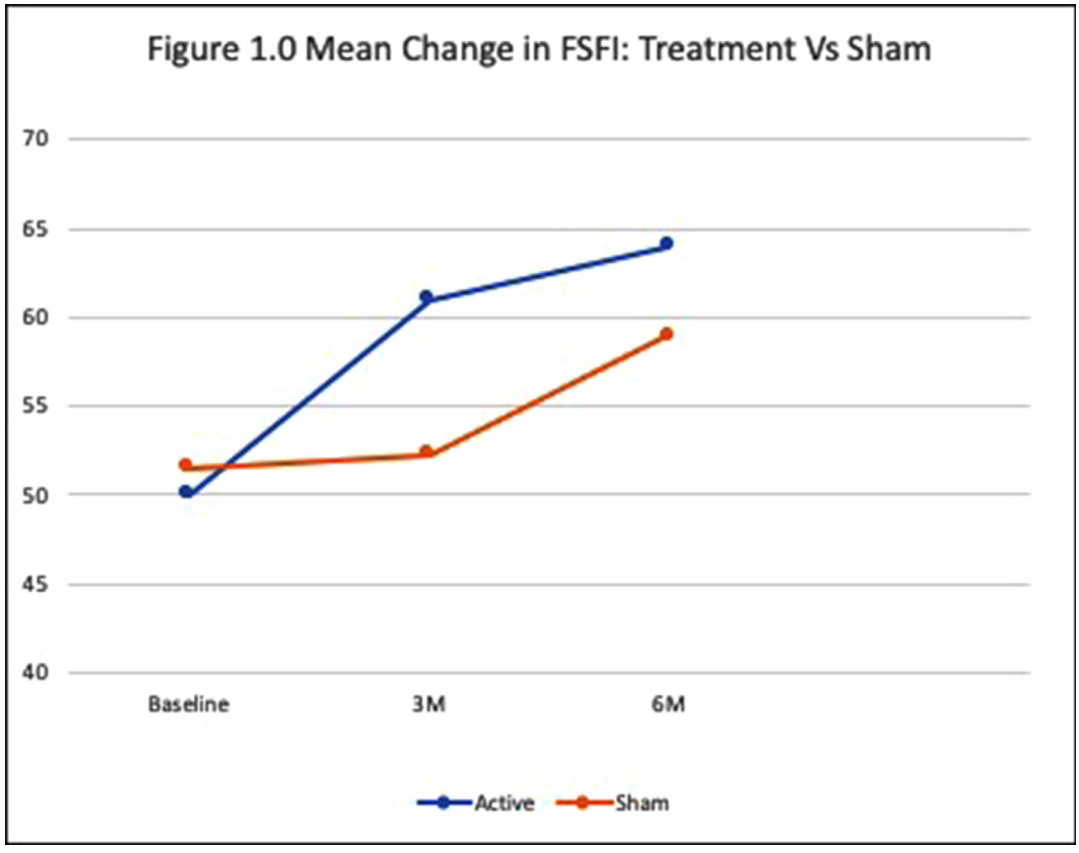


Figure 1. Is a graphic representation of the mean difference in total FSFI score in the Treatment (blue) vs sham (orange) cohorts. Note the positive difference in the treatment group from both baseline and vs the sham group (Color version of the figure is available online.)

Table 3. Changes in FSFI domain- treatment vs sham

FSFI Domain		Baseline	3m	*3m P value*	6m	*6m P value*
Desire	*Sham*	5.2 (4.5–6.0)	5.421 (4.9–5.9)		5.5 (5.2–6.0)	
	Treatment	4.7 (4.0–5.3)	5.699 (5.3–6.2)		6.0 (5.6– 6.4)	
				.404		.175
Arousal	*Sham*	10.1 (8.2–12.1)	11.009 (9.8–12.2)		12.0 (10.8–13.2)	
	Treatment	9.6 (7.9–11.3)	11.751 (10.7–12.7)		13.0 (11.8–14.0)	
				.349		.275
Lubrication	*Sham*	12.1 (9.63–14.6)	12.4 (11.3–13.4)		13.6 (12.3–15.0)	
	Treatment	10.8 (8.7–12.8)	13.4 (12.4–14.3)		14.5 (13.3–15.6)	
				.169		.292
Orgasm	*Sham*	5.5 (4.2–6.8)	5.7 (5.1–6.4)		6.8 (6.0–7.5)	
	Treatment	4.9 (3.8–6.0)	6.2 (5.5–6.7)		6.8 (6.2–7.5)	
				.366		.843
Satisfaction	*Sham*	9.4 (7.5–11.4)	13.2 (12.2–14.12)		14.8 (13.7–15.5)	
	Treatment	11.3 (9.6–13.0)	14.6 (13.8–15.5)^		15.6 (14.6–16.7)	
				.029		.269
Pain	*Sham*	4.7 (4.0–5.4)	9.6 (8.3–10.9)		11.24 (10.0–12.5)	
	Treatment	8.5 (6.6–10.3)	11.0 (9.7–12.0)		11.8 (10.7–13.0)	
				.124		.508

Table 4. Change in VLQ- sham vs treatment

Baseline (%)	Group	Loose	Neither loose or tight	Tight	*P* value
	Sham	26 (89.7)	2 (6.9)	1 (3.4)	.9
	Treatment	28 (82.4)	11 (8)	2 (5.9)	
3m (%)					
	Sham	22 (84.6)	4 (15.4)	0 (0)	.001
	Treatment	12 (35.3)	11 (32.4)	11 (32.4)	
6m (%)					
	Sham	19 (73.1)	3 (11.5)	4 (15.4)	.01
	Treatment	11 (32.4)	9 (26.5)	14 (41.2)	

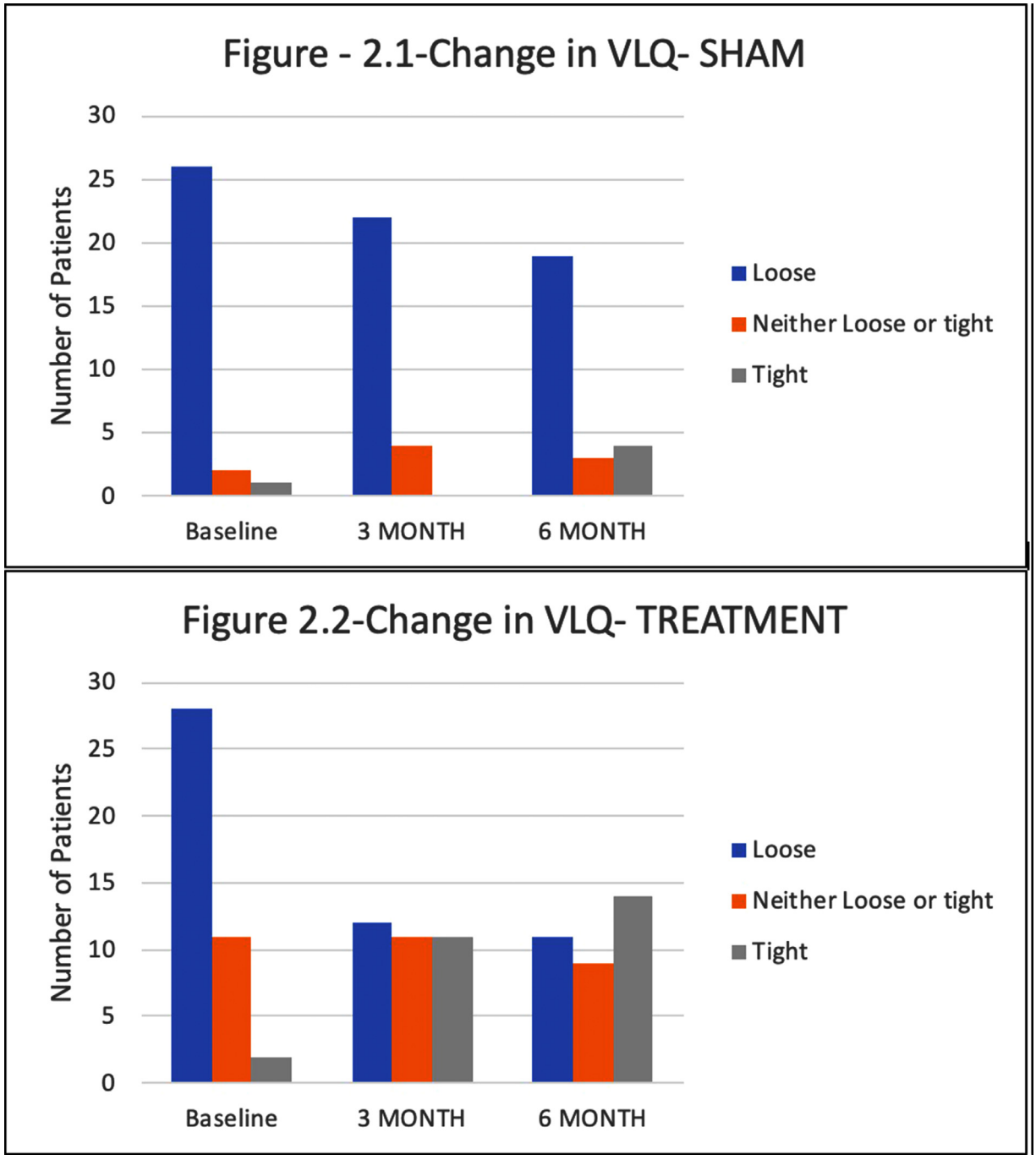
Few times (Score = 2), *Sometimes* (Score = 3), *Most times* (score = 4) and *All of the time* (Score = 5). Analysis of the results showed that whilst women did experience an improvement in the symptom of vaginal flatus, improvement was noted in both the treatment, and sham groups indicating a placebo effect. It can be noted in Figure 3A and B that there is minimal change in VFS noted in the treatment and sham groups. The improvement in VFS did not reach statistical significance between sham and treatment groups at 3 and 6 months (*P* value 1.0 and .8 respectively) (Table 5).

Vaginal Laxity Bother Score

The Vaginal Laxity Bother Score (VLBS) is an unvalidated subjective measurement of patient's perceived effect that vaginal laxity has on their quality of life. Women indicated how bothered they were by the sensation of vaginal laxity during the treatment period via a 10-point Likert scale. A score = 1 indicated they were "not bothered at all" and a score = 10 represented "the worst." Analysis of the data show a significant (*P* value .02) improvement in women's perception of vaginal laxity at 3 months which persisted to 6 months when treated with ThermiVa compared to Sham (Table 6). Figure 4 is a graphical representation of improvement of VLBS in active vs placebo treatment.

Modified Oxford Score

Modified Oxford score (MOS) served as an objective measure of success in the TIGHT study. The classical MOS scoring system is graded on a 5-point scale (0 = nothing, 1 = flicker, 2 = weak, 3 = medium contraction, 4 = strong, 5 = strong with lift). In order to facilitate statistical analysis, the grading system was combined into 2 grades: Due to small sample size, the MOS scoring system was adjusted into 2 groups: *"nothing-weak"* and *"moderate-strong."* An improvement in MOS was noted in patients in the treatment group. From analysis of the baseline and 6-month scores, patients who received treatment with ThermiVa had a 2.7 odds ratio (CI 95% 0.92–8.4) of improving



Figures 2. (A and B) are a graphical representation of the change in subjective vaginal laxity at baseline, 3 months and 6 months in the sham group (A) and the treatment group (B). It is apparent in B that there was a significant transition out of the "loose" group into the "neither loose or tight" and the "tight" group in the treatment group. A significant difference is noted in the transition when the patients in the treatment group were compared to the sham group (A).

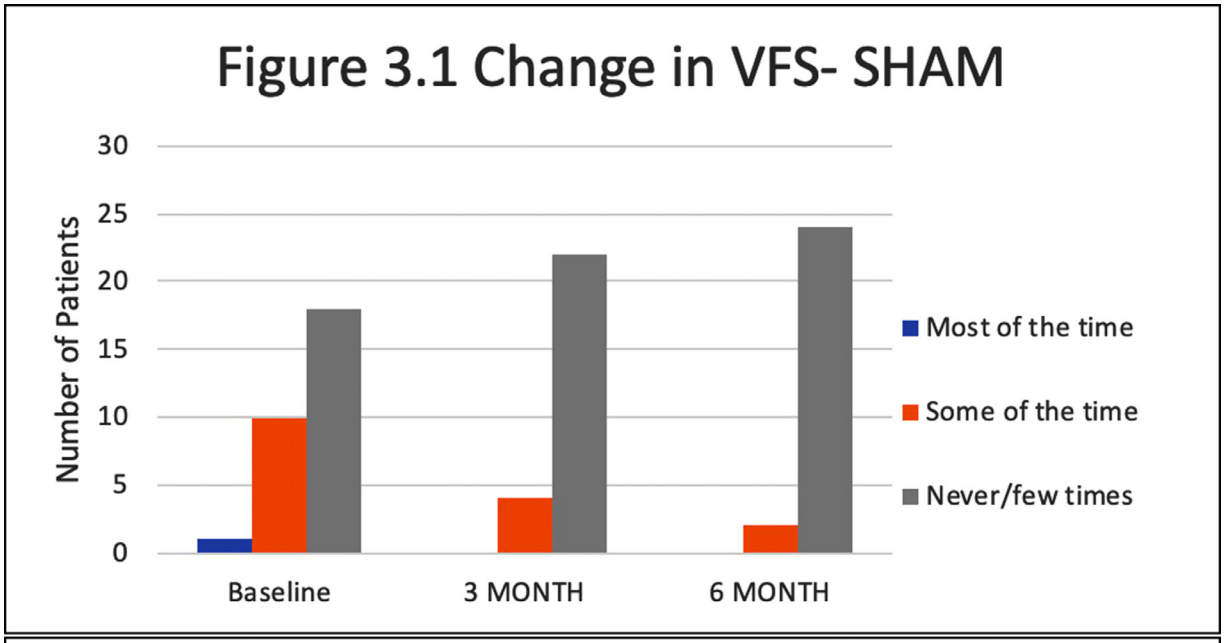
their MOS however this result failed to meet statistical significance ($P = .3$) (Table 7).

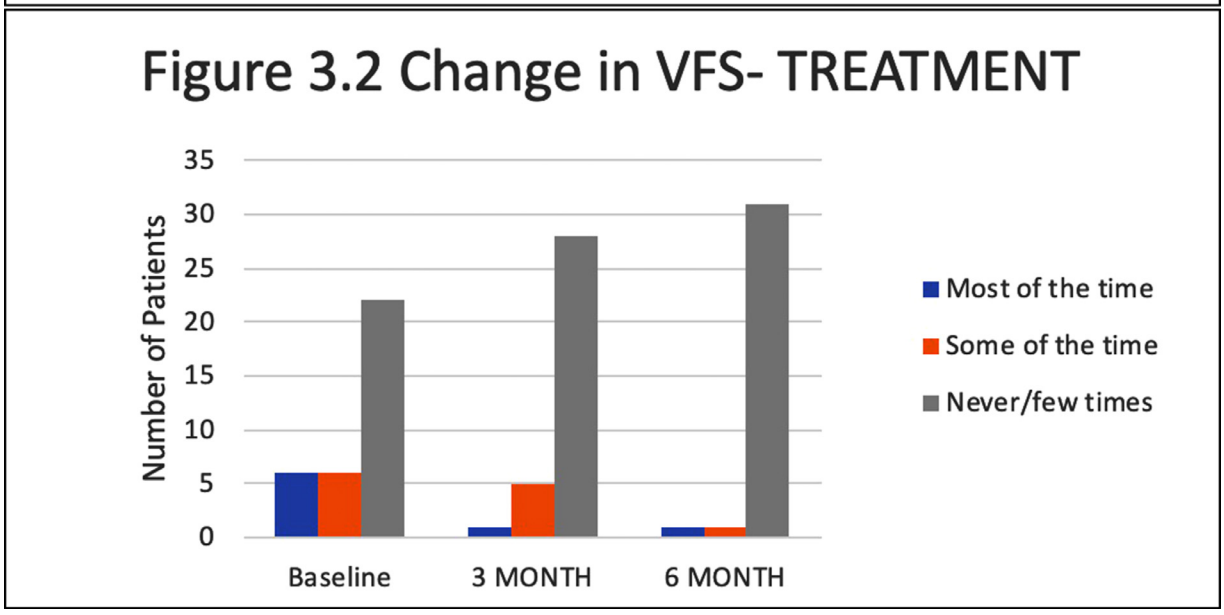
Genital Hiatus

Measurement of the Genital Hiatus served as our second objective measure of success. No significant difference was noted in GH from baseline to 6 months in the treatment or sham groups (Table 8).

DISCUSSION

The TIGHT trial is to date, the largest randomized control trial investigating the efficacy of the ThermiVa radiofrequency





Figures 3. A and B are a graphical representation of the change in subjective vaginal flatus at baseline, 3 months, and 6 months in the sham group (A) and the treatment group (B). As can be seen, there is no significant transition in the number of women experiencing vaginal flatus in the sham vs treatment groups during the treatment phase.

Table 5. Change in VFS- sham vs treatment at baseline, 3 months, and 6 months

Baseline (%)		most time/always	Some times	Never/a few times	*P* value
	Sham	1 (3.4)	10 (34.5)	18 (62.1)	.12
	Treatment	6 (17.6)	6 (17.6)	22 (64.7)	
3m (%)					
	Sham	0 (0)	4 (15.4)	22 (84.6)	1.0
	Treatment	1 (2.9)	5 (14.7)	28 (82.4)	
6m (%)					
	Sham	0 (0)	2 (7.7)	24 (92.3)	.8
	Treatment	1 (3.0)	1 (3)	31 (93.2)	

Table 6. Mean change in VLBS- Sham Vs Treatment at baseline, 3 months, and 6 months

Baseline (95% Confidence interval)		Mean	*P* value
	Sham	5.6 (4.8–6.5)	.4*
	Treatment	6.0 (5.3–7.0)	
3m			
	Sham	5.5 (4.9–6.2)	.04†
	Treatment	4.7 (4.1–5.3)	
6m			
	Sham	5.0 (4.4–5.6)	.02†
	Treatment	4.0 (3.5–4.5)	

*Students *t*-test.
†ANCOVA adjusted with Bonferroni correction.

device in the treatment of vaginal laxity. The trial aimed to establish a positive therapeutic effect by assessing objective and subjective measures of success at baseline, 3 months, and 6 months whilst also monitoring for adverse side-effects associated with radiofrequency therapy.

The FSFI questionnaire is a validated subjective measure of several domains of sexual function. Women who score <26.5 on the FSFI are at increased risk of developing sexual dysfunction. The majority of women included in the TIGHT study, according to the FSFI parameters, were not classified as "at risk" of developing sexual dysfunction, however, the scoring system was included in the TIGHT study to assess for improvements in sexual satisfaction regardless of initial score. The choice of questionnaire is important in assessing sexual dysfunction post medical intervention as studies have demonstrated that subjective success can vary widely depending on the subjective tool used.[17,18] The inclusion of women with normal FSFI scores raises a pertinent issue surrounding patient selection in regard to vaginal rejuvenation therapy. Whilst the device was designed for patients at risk of developing sexual dysfunction and symptoms of vaginal laxity, it has the potential to be used in women who have physiologically normal genitalia. These women seek treatment, not for symptomatic relief, but rather to correct perceived vulvovaginal abnormality. Digital communication, social media, and readily available explicit content are falsely exposing women to what "normal" genitalia should look like. Lack of anatomic knowledge and the taboo surrounding genital appearance leave females as a vulnerable population seeking vaginal rejuvenation therapy without pathologic indication in hopes of achieving more aesthetically "normal" genitalia. Whilst patient autonomy should be respected, clinicians should use the initial consultation to discuss female anatomy and the great diversity in vulvovaginal appearance. This consultation provides clinicians with an opportune setting to break taboos surrounding genital appearance and encourage an open discussion about the patient's motivation and expectations in regard to treatment.

In this study an increase in mean FSFI was observed in both sham and treatment groups indicating an overall improvement in subjective sexual satisfaction. Improved FSFI within the sham group provided evidence for the placebo effect which has not

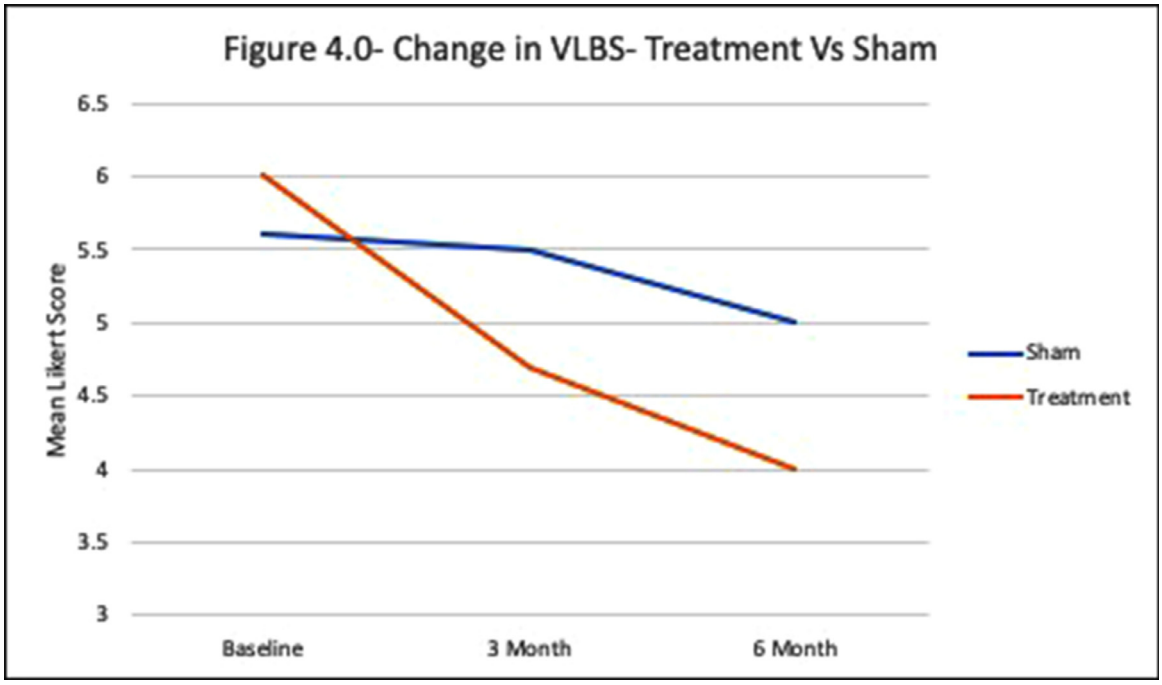


Figure 4. A graphical representation of the decrease in Vaginal Laxity Bother Score between the treatment (orange) and sham (blue) treatment groups. A significant decrease in bother score can be noted in the treatment group over the study period when compared to the sham cohort (Color version of the figure is available online.)

Table 7. Change in modified oxford score- sham vs treatment

Baseline n (%)	Sham	Active	*P* value
nothing-weak	13 (44.8)	12 (36.4)	.5
moderate- strong	16 (55.2)	21 (64)	
3 mo n (%)			
nothing-weak	11 (38)	8 (23.5)	.12
moderate- strong	15 (52)	26 (77)	
6 mo n (%)			
nothing-weak	12 (41.4)	8 (23.5)	.3
moderate- strong	14 (48.3)	26 (77)	

Table 8. Change in genital hiatus- sham vs treatment

		Mean length (cm)	*P* value
Baseline (95% CI)			
	Sham	3.3 (3.0–3.6)	.5*
	Treatment	3.4 (3.2–3.6)	
3m			
	Sham	3.525 (3.351–3.698)	.097^^
	Treatment	3.329 (3.175–3.483)	
6m			
	Sham	3.508 (3.324–3.693)	.392^^
	Treatment	3.403 (3.242–3.563)	

*Students *t*-test.
^^ANCOVA adjusted with Bonferroni correction.

been demonstrated in previous studies investigating ThermiVa. Despite this, the FSFI mean improvement in the treatment group was noted to be significantly greater at 3 months (*P* value .02) and approached statistical significance at 6 months (*P* value .07). No statistically significant differences were noted in individual domains of the FSFI (Desire, Arousal, Lubrication, Orgasm, Satisfaction, and Pain). Improvement in the FSFI after radiofrequency treatment has previously been established by the Viveve Trial.[3] This was a large randomized control study which determined the efficacy of their radiofrequency device solely by monitoring improvements in FSFI domains. This trial showed significant improvement in Arousal, Lubrication, and Orgasm. Several other smaller studies also reported improvements in FSFI associated with treatment with radiofrequency.[8]

This current study differed from the Viveve trial by inclusion of a series of Likert questionnaires which served as an additional means of measuring subjective success. These questionnaires assessed perceived vaginal laxity (vaginal laxity questionnaire), vaginal flatus (vaginal flatus score), and effect of laxity on a woman's quality of life (vaginal laxity bother score).

The Vaginal Laxity Questionnaire is a 5-point Likert questionnaire, however, due to small sample size, the questionnaire was analyzed according to 3 groups: "loose," "neither loose nor tight," and "tight." Analysis of the results show that women in the treatment group were more likely to transition out of the "loose" category indicating a subjective feeling of vaginal tightening with treatment. Analysis of the data revealed a significant difference at 3 months (*P* value .02) which has the potential to persist up to 6 months, although not statistically significant. (*P* value .07). These results indicate subjective success in the treatment of vaginal laxity, which has the potential to persist up to 6 months. These results have been replicated in similar smaller studies. Millheiser et al. (2010) and Alinsod (2016) both conducted small trials (n 25 and n 24 respectively) which included VLQ questionnaires as a primary measure of success of radiofrequency in the treatment of vaginal laxity. Both studies noted improvement in subjective assessment of vaginal laxity. Millhesier et al. (2010) reported that women experienced significant feeling of continued tightness 6 months post treatment compared to pre-treatment scores ($P < .001$). In support of subjective improvement in sexual dysfunction, Alinsod (2016) also noted that the mean time to orgasm was reduced by 50% post treatment in 19 of 25 patients.

Vaginal flatus is a normal physiological response to increased vaginal laxity. The results also had to be reduced to 2 outcomes due to sample size: "never" and "sometimes." Results indicated that both the sham and treatment cohorts had women who experienced decreased frequency of vaginal flatus during the treatment period. No statistically significant difference in perception of vaginal flatus was noted between the treatment and sham groups. This indicates that the VFS potentially is not a reliable subjective test of the efficacy of vaginal rejuvenation therapy or perhaps indicates that the study is required to be better powered to reveal its significance.

The CLOSER and REVIVE trials, both demonstrated that sexual dysfunction significantly affects a woman's quality of life and puts significant strain on intimate relationships.[19] The results of this study highlighted the importance of sexual intimacy in the preservation of long-term relationships and should be a subject that women can discuss openly with their family physician or gynecologist. The presence of laxity is known to significantly contribute to sexual dysfunction. The vaginal laxity bother score is an unvalidated questionnaire designed to determine the extent that vaginal laxity impacts a woman's quality of life. Analysis of the results indicated a significant decrease in the VLBS in women treated with ThermiVa. The positive impact was noted at the 3-month review (*P* value .04) and persisted through to the 6-month review (*P* value .02).

There is no internationally recognized measurement method to objectively assess or score the severity of vaginal laxity. After discussion with experts in the field of Urogynecology, this trial attempted to postulate an objective measure of success by measuring the Genital Hiatus length and Modified Oxford Score in response to treatment with ThermiVa. Results from this study indicated that there was no statistically significant change in Genital Hiatus in the treatment group vs sham. The modified oxford score was developed as an objective measure to evaluate the strength of the pelvic floor.[20] It was hypothesized that increased collagenesis, blood flow, and elasticity of vaginal tissues

would correlate to an improvement in pelvic floor muscle function and hence produce an improvement in the MOS. Women who received active treatment appeared to have improvements in their MOS over a 6 month period, being 2.7 times more likely to experience improvement when compared to sham (CI 95% 0.92−8.4). This change failed to reach statistical significance over the 6-month period. Alternatively, clinicians should consider that no actual objective change in vaginal laxity could be measured because radiofrequency devices target the dermal and epithelial layers of the vagina and do not treat the underlying fascial and muscular structures, nor do they re-approximate these structures to their original anatomic locations.

The data gained from the objective measures of success revealed that the positive subjective measures of success were failed to be replicated in the objective measures used in the TIGHT trial. It is evident that the physiological change associated with ThermiVa treatment is not associated with a reduction in the vaginal introitus which would have been evident with decreasing GH measurements. The results also indicate that treatment with ThermiVA has no association with an improvement in pelvic floor function which would have been evident in an improvement in MOS score. Overall analysis of these results shows that our original hypothesis that GH and MOS would serve as an objective measure of success for vaginal rejuvenation therapies was incorrect. The positive subjective success demonstrated from this trial indicates that there must be another objective measure that is more suitable to measure the physiological change associated with radiofrequency treatment. Vaginal Tactile Imaging has proved to be useful in characterization of pelvic organ prolapse and may have a role in future studies trying to establish an objective measure of success for vaginal rejuvenation therapy.[21]

The physiological changes that may be responsible for the positive subjective findings associated with ThermiVa have been demonstrated in several other studies.[13,22] The majority of these studies were conducted on ovine/swine models given structurally similarity to the human vagina. Wilson et al. (2018) conducted a small study (n 10) on women with moderate vulvovaginal laxity.[23] Five subjects underwent pre- and post-treatment biopsies of the labia majora and vaginal canal for histology. Symptoms of vaginal laxity were noted to significantly improve on Day 10 and persisted through to Day 120 (P = .001 and .001, respectively). Histologically, the vaginal canal exhibited an improvement in epidermal maturity, basal layer organization, collagenesis, elastinogenesis, and increased numbers of fibroblasts. Increased vascularity, and neurogenesis were also witnessed in some tissue specimens. Although, small, these studies provide a physiological explanation why women experience subjective improvements in vaginal laxity as evident in our study.

The results of the TIGHT study show statistically significant improvements in subjective vaginal laxity. The postulated measures of objective success failed to demonstrate significant improvement over the 6-month treatment period. The improvement in symptoms is comparable to other more invasive surgical rejuvenation treatments. Several other studies have also documented an increase in FSFI scores at 6 months post-surgical treatment, however these treatments have been associated with increased rates of dyspareunia.[24-27] Goodman et al. (2016) conducted a prospective trial to determine the impact of genital plastic/cosmetic surgery (FGPS) on sexual dysfunction using the validated Index of Sexual Satisfaction (ISS). In this study subjective success of surgical intervention, as demonstrated by the ISS, persisted to 24 months (P *value* <.0001).[28] It would be interesting to compare the subjective success rate of ThermiVa to surgical management at longer follow-up intervals in future studies. Despite demonstrating subjective success, these trials also failed to establish a standardized objective measure of success to compliment validated subjective improvements. A significant finding to note during the TIGHT study was the lack of any adverse reactions to treatment over the 6-month period. This is particularly relevant given the latest RANZCOG position statements warning against vaginal rejuvenation treatments due to lack of appropriate safety data.

There are several limitations to the TIGHT study. The most significant being failure to recruit enough participants to achieve a significantly powered study. Issues surrounding vaginal laxity still remain largely taboo which hampered efforts to recruit at general practitioner clinics. The majority of recruitment had to be obtained via word of mouth given resistance to advertisement in general practitioner clinics which highlights the tendency to maintain the taboo status of sexual dysfunction even amongst medical practitioners. A large number of potential patients were disinterested in the trial as success of the treatment could not be guaranteed. As knowledge improves surrounding vaginal laxity improves and the symptoms become more socially acceptable to allow discussion, we hope that future recruitment will not be as problematic for researchers. Data collection and follow-up of patients proved difficult in some instances due to the COVID-19 pandemic. Co-ordination of our multi-centered study was impeded by different restrictions according to global location.

CONCLUSION

Vaginal laxity and symptoms of sexual dysfunction are considered taboo topics despite a significant number of women suffering from these symptoms. ThermiVa offers a minimally invasive radiofrequency treatment modality to treat the symptoms of vulvovaginal laxity. Analysis of the TIGHT study revealed statistically significant improvements in subjective sensation of vaginal laxity and sexual dysfunction as evidenced by the VLQ, VLBS, and FSFI when treatment was compared to sham. An improvement was noted in MOS, but this failed to reach statistical significance. This indicates that GH and MOS may not be an appropriate objective measure of success in the treatment of vaginal laxity. A major finding established by the TIGHT study was that treatment with ThermiVa proved safe over a 6-month

period and was an easy to use outpatient treatment modality for vaginal laxity. Despite promising result, further randomized control trials are warranted given the inadequate power of this study and presence of placebo effect.

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Conflict of Interest: The authors report no conflicts of interest.

Funding: None. ThermiVa treatment and sham probes were provided by ThermiVa, Thermi Aesthetics, Southlake, Texas.

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