# RADIOFREQUENCY VOLUMETRIC HEATING FOR VAGINAL LAXITY TREATMENT: EFFECT ON SEXUAL SATISFACTION.

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## ABSTRACT

**Introduction:**
Stretching of the vaginal tissue caused by natural factors as aging or childbirth is the primary cause of vaginal laxity and loss of sexual satisfaction in women. Such medical condition can lead to physical and/or psychological health problems that impact relationship happiness. This prospective study investigates the treatment of vaginal looseness and sexual dissatisfaction with a noninvasive radiofrequency device.

**Materials and methods:**
We enrolled 51 patients (average age 44.43±9.85 years) who reported vaginal looseness symptoms and sexual dissatisfaction. They received 3 treatments with the EXILIS ULTRA 360 device (BTL Industries, Boston MA, USA) spaced by one week. Each session consisted of separate consecutive intravaginal and extravaginal application using the disposable tips. Therapy parameters were set according to the manufacturer's recommended protocol. Patient sexual satisfaction was evaluated by the Female Sexual Distress Scale-Revised questionnaire (FSDS-R) and the degree of vaginal looseness was measured by the Vaginal Laxity Questionnaire (VLQ) at the baseline and 90 days post treatments. Patient comfort during each procedure was assessed using a Visual Analogue Scale (VAS). Signed informed consents were obtained from all patients.

**Results:**
The average FSDS-R score improved ($p<0.001$) by 72.79% from 15.60±9.22 to 4.24±5.71 points, with 93.33% of patients showing improvement in sexual satisfaction. Over 55% of patients reported complete absence of any dysfunction 90 days post treatments. VLQ showed vaginal tightness improvement in almost 96% of patients ($p<0.001$) with the average increase of 2.63±1.41 points (1-7 scale). At the follow-up, all patients uniformly reported they don't feel any degree of vaginal laxity at all (VLQ≥4). Some level of discomfort was reported in 2.65% of treatments, with the rounded average VAS discomfort score reaching zero.

**Conclusion:**
The EXILIS ULTRA 360 proved safe and effective for treatment of vaginal looseness which resulted in a significant improvement of sexual life satisfaction.

## INTRODUCTION

With advancing life most women face an increasing looseness of vaginal tissue architecture referred to as vaginal laxity. It's associated with the effects of aging[1], weakening of connective tissue[2], and trauma to the pelvic muscles caused by childbirth[3]. All these factors contribute to an overall sexual dysfunction which may lead to long-term physical and psychological consequences. The exact prevalence of vaginal laxity symptoms is unknown, yet it's generally considered a highly underreported condition as stated by over 80% of the International Urogynecological Association members[4]. If untreated, vaginal laxity can significantly impact patient's self-esteem and quality of life[4]. It's linked with a decreased sexual sensation during intercourse, impeded sexual life satisfaction and dysfunctional relationships[5-7]. Laxity is often observed together with urinary incontinence symptoms or chronic changes in pelvic muscles organization[6,8].

Vaginal looseness can be addressed by exercise-based non-surgical therapies such as the Kegels or through a pelvic floor therapy, but recently various energy-based devices have become widely popular which include minimally invasive fractional $CO_2$ laser ablation and non-ablative radiofrequency (RF) heating[5,6,9,10]. These technologies

allow relatively comfortable and safe treatments focused on the vaginal area, in contrast with a more painful surgery which may often lead to an increased risk of dyspareunia[11]. Surgical interventions are used to perform reconstructive changes of the vaginal area[12] while the energy-based devices rely on natural reparation of laxity through stimulation of collagen/elastin fibers regeneration, contraction of collagen, neovascularization and improved lubrication[13].

This study evaluates the efficacy of RF volumetric heating for treatment of vaginal laxity and sexual dysfunction in women reporting vaginal looseness symptoms.

# METHODS

In total 51 sexually active women (all of whom reported vaginal laxity and/or sexual life dissatisfaction) were enrolled into a single-arm prospective study. See Table 1 for detailed data. The following exclusion criteria were applied: age<25, sexual inactivity, active gynecologic problems (bleeding, injury, infection or pain), metal IUD, current pregnancy, or any contraindication to RF energy treatments. Written informed consents were obtained from all participants.

| | |
|---|---|
| Patients (N) | 51 |
| Age (avg±SD) | 44.43±9.85 |
| BMI (avg±SD) | 28.80±5.66 |
| Natural deliveries | |
| (N) | 74 |
| (Avg±SD) | 1.45±1.12 |
| Number of natural deliveries (N/%) | |
| 0 | 14 (27.45%) |
| 1 | 11 (21.57%) |
| 2 | 16 (31.37%) |
| 3 | 9 (17.65%) |
| 4+ | 1 (1.96%) |
| C-Section | |
| (N) | 27 |
| (Avg±SD) | 0.53±0.92 |
| Number of C-Sections (N/%) | |
| 0 | 35 (68.63%) |
| 1 | 8 (15.69%) |
| 2 | 6 (11.76%) |
| 3 | 1 (1.96%) |
| 4+ | 1 (1.96%) |

Table 1. Demographic and clinical data.

Subjects were treated in 3 sessions across 3 weeks. Each session comprised both an intra-vaginal and an extra-vaginal application using the EXILIS ULTRA 360 device (BTL Industries, Boston MA). The one-off disposable applicator tips were used.

The Female Sexual Distress Scale-Revised questionnaire (FSDS-R) was used to assess changes in patents' confidence about their sexuality. A 7-point scale Vaginal Laxity Questionnaire (VLQ) was used to evaluate changes in patients' subjective perception of vaginal laxity/looseness. All evaluations were made at the baseline and 90 days post-treatments. Immediately after each session a 0-10 Visual Analogue Scale (VAS) was used to determine the level of patient's treatment discomfort. Paired t-test (α=5%) was used to determine the statistical significance of results.

### Results

No anesthetics were required. The procedures were well tolerated when 94.12% of patients (N=48) didn't report any pain at all with regards to the RF delivery throughout the 3 sessions, while in 2.65% of procedures the patient reported certain level of discomfort (avg. score 0.085 out of 10). No adverse events were reported.

The results presented herein include FSDS-R data from 45 subjects (four subjects had a score of 0 already at the baseline; two subjects were lost to follow-up) and VLQ data from 49 subjects (two subjects were lost to follow-up). The average FSDS-R score improved by 72.79 % from 15.60±9.22 (baseline) to 4.24±5.71 (follow-up) ($p<0.001$) with statistically significant improvement in 12 out of 13 questions. In total 42 subjects (93.33%) reported improvement, with 25 subjects (55.55%) reaching a zero FSDS-R score at the follow-up, indicating a total absence of any sexual dysfunction. Three patients didn't respond to the treatments and either reported no improvement (2.22%) or worsening of the initial condition (4.44%). See Table 2 for detailed data of patient's score improvement in each question.

The average VLQ score improved by 76.33% (2.63±1.41) from 3.45±1.26 at the baseline (corresponding to slight looseness/neither tightness nor looseness) to 6.08±0.72 at the follow-up (corresponding to moderate tightness) ($p<0.001$). In total 47 (95.92%) patients reported some level of improvement while 2 (4.08%) patients didn't feel any change. The percentage of subjects who reported perception of vaginal laxity improved from 57.14% (baseline) to 0% (follow-up). At the follow up, 97.96% of patients reached some degree of tightness. See Table 3 for detailed data.

| FSDS-R QUESTION | AVERAGE SCORE | | | PATIENTS IMPROVED (%) |
|---|---|---|---|---|
| | PRE-TX | 3-M FU | P-VALUE | |
| 1) How often do you feel distressed about your sex life? | 1.56 | 0.44 | <0.001 | 75.56% |
| 2) How often did you feel unhappy about your sexual relationship? | 1.47 | 0.44 | <0.001 | 71.11% |
| 3) How often did you feel guilty about your sexual difficulties? | 1.33 | 0.36 | <0.001 | 62.22% |
| 4) How often did you feel frustrated by your sexual problems? | 1.31 | 0.29 | <0.001 | 68.89% |
| 5) How often did you feel stressed about sex? | 1.33 | 0.36 | <0.001 | 64.44% |
| 6) How often did you feel inferior because of sexual problems? | 1.02 | 0.29 | <0.001 | 55.56% |
| 7) How often did you feel worried about sex? | 0.98 | 0.22 | <0.001 | 51.11% |
| 8) How often did you feel sexually inadequate? | 1.24 | 0.29 | <0.001 | 62.22% |
| 9) How often did you feel regrets about your sexuality? | 0.78 | 0.27 | <0.01 | 42.22% |
| 10) How often did you feel embarrassed about sexual problems? | 1.04 | 0.29 | <0.001 | 55.56% |
| 11) How often did you feel dissatisfied with your sex life? | 1.47 | 0.36 | <0.001 | 68.89% |
| 12) How often did you feel angry about your sex? | 0.44 | 0.27 | >0.05 | 22.22% |
| 13) How often did you feel bothered by low desire? | 1.62 | 0.38 | <0.001 | 71.11% |
| **TOTAL STUDY AVERAGE AND OVERAL IPROVEMENT** | **15.60** | **4.24** | **<0.001** | |

Table 2. FSDS-R questionnaire evaluation.

| SCORE | INTERPRETATION | PRE-TX | | 3M FOLLOW-UP | |
|---|---|---|---|---|---|
| | | Patients (N) | Patients (%) | Patients (N) | Patients (%) |
| 1 | Very loose | 2 | 4,08% | 0 | 0,00% |
| 2 | Moderately loose | 9 | 18,37% | 0 | 0,00% |
| 3 | Slightly loose | 17 | 34,69% | 0 | 0,00% |
| 4 | Neither tight/loose | 11 | 22,45% | 1 | 2,04% |
| 5 | Slightly tight | 6 | 12,24% | 8 | 16,33% |
| 6 | Moderately tight | 4 | 8,16% | 26 | 53,06% |
| 7 | Very tight | 0 | 0,00% | 14 | 28,57% |

Table 3. Evaluation of vaginal laxity.

## Discussion

This study evaluated non-invasive RF treatments of sexually active women after childbirth affected by sexual dysfunction. The physiological response to the heating is described as a re-activation of fibroblast cells leading to neocollagenesis and neoelastogenesis. This concept was proven in both animal and human studies when treating the skin[14,15], as well as after treating the vaginal tissue[16].

RF heating for treating vaginal laxity and sexual functions was already documented by previous authors[6,7,10,17]. The data presented herein show significant improvement in all FSDS-R dimensions ($p<0.01$) except for question 12 ($p>0.05$) which can be attributed to the low baseline score limiting any improvement potential. Overall the results suggest a substantial improvement in patients' sexual intercourse satisfaction. The average FSDS-R improvement exceeds what Sekiguchi et al have reported and is comparable to results published by Torre and Miller, while the latter study included 22 treatments over 45 days and reported a lower percentage of patients responding to the therapy.

The subjects treated in this study reported on average much less severe vaginal laxity before treatments than what is shown in previous publications[6,7,10,17], yet the average VLQ improvement post-treatments reaches similar values. This suggests that the treatments are highly effective for a wide spectrum of women, including those with only a mild or a less sever condition. The relatively higher average pre-treatment VLQ score may also help justify why close to 98% of the treated patients reported some degree of vaginal tightness at the follow-up. The arbitrarily small average discomfort score is consistent with previous studies on RF vaginal application except Sekiguchi et al.

Although previous authors have confirmed that patients preserve the improvement 6 and 12 months after similar RF-based treatments, future research might be necessary to validate such hypothesis for the investigated device, as well as to confirm its efficacy in a sham-controlled study.

## Conclusion

The investigated device is safe and effective for treating sexual dysfunction and vaginal laxity in post-pubertal women non-invasively.

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