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Introduction: What is multimodal vaginal toning? **

Intravaginal application of low-level light therapy, heat, and therapeutic vibration

- **Low-level light therapy** (red and near-infrared wavelength spectrum (662–855 nm)) can produce photochemical reactions that act on mitochondria to increase adenosine triphosphate production. Light therapy “increases protein synthesis and the modulation of growth factors, inflammatory mediators, and increased tissue oxygenation and repair”!
- **Heat** (40–42 °C is elicited by this device) increases circulation and metabolism. Denaturing and reconfiguring of collagen bonds is thought to occur, which increases the elasticity and strength of collagen fibers
- **Therapeutic vibration** (80–110 Hz) effects connective tissue by “taking advantage of the body’s reaction to mechanical stress; a state in which higher levels of tenascin and collagen XII are produced by fibroblasts attached to strained collagen, compared with relaxed collagen”

**Multimodal silicone intravaginal device** (vSculpt, Joylux, Seattle, WA, USA)

- Treatment: Dilator shaped device is inserted in vagina for up to 10 min
- Water-based lubricant (water, glycol, and hydroxyethyl cellulose) is used for insertion and to augment the transfer of light energy
- Device settings are determined by comfort level
  - Three light therapy modes (6, 8, or 10 min)
  - Six sonic vibration modes (constant, wave, or pulse; each at high or low intensity).

**Aim of this study:** To test hypothesis that multimodal vaginal toning therapy would improve bladder symptoms and quality of life (QoL) in women with postpartum SUI and sexual function complaints.

**Study Design:** Prospective case series held at an OB/Gyn clinic in Seattle, WA.

**Subjects:** Consecutive patients were screened for study eligibility between May 2016 and July 2016.

**Inclusion criteria:** women 30 - 59 years old; self-reported symptoms of SUI; postpartum with one or more vaginal births; painful intercourse with male partner; and dissatisfaction with intercourse.

**Exclusion criteria:** UTI, active sexually transmitted disease; diabetes; neurological disorder; morbid obesity; current or attempted pregnancy; breastfeeding or lactating; history of cancer, chemotherapy, or radiation therapy; previous vaginal surgery or toning therapy; vesicoureteral reflux; bladder calculi/tumor; conservative pelvic floor treatment (e.g., pelvic floor exercises, estrogen cream) in the last 6 months.

**Initial Evaluation:**

- **55 patients** were enrolled in the study-48 patients completed. 5 patients withdrew from the study
  - 4 for reasons unrelated to the study and 1 who reported discomfort related to device warmth. 2 patients were excluded from analyses secondary to poor (<30%) compliance
  - Mean patient age was 46± 7 years,
- **Visual inspection:** the lead author or a nurse practitioner examined vaginal tissue
- **Pelvic floor muscle strength:** Oxford Grading System (also by lead author or nurse practitioner)
- **1-h pad weight test (PWT)** was performed during 1 h of standardized activities and exercises.
- **Questionnaires**
  - Urogenital Distress Inventory Short Form (UDI-6)
  - Incontinence Impact Questionnaire-Short Form (IIQ-7)
  - Female Sexual Function Index (FSFI)
Results:

- Female Sexual Distress Scale-Revised 2005 (FSDS-R)

**Baseline patient findings:**
- UDI-6: 88% reported SUI symptom bother was moderate or great
- Pad Weight Test: 79% had a positive (>1 g) 1-h PWT
- Pelvic floor muscle strength was low overall—42% of patients were unable to elicit voluntary contraction (grade 0) and 42% elicited a flicker only (grade 1)

**Methods**

*Initial safety testing* with the device was conducted in 20 women. After using the device for 10 min, the mean temperature at the surface of the device measured via thermocoupling was 41.2 °C (range: 38.6° to 44.1 °C). All values were below the 48.0 °C maximum allowed under the International Standard for medical electrical equipment. Additionally, no adverse events or visual changes in vaginal tissue were noted.

**Use of device:** Patients were instructed to use device every other day for 45 days, while maintaining their current lifestyle and refraining from PFMT or any increase in physical activity that might influence the study results.

**Follow-up after 45 days of treatment**

- All examinations and questionnaires were repeated
- PFM strength at was assessed by the other rater, who was blinded to the pre-treatment values.
- Safety of device was evaluated by determining the incidence of adverse events that took place at any time during study, including any severity of discomfort with device insertion or use, local tissue warmth, nerve tingling, cramping, vaginal discharge, vaginal irritation, vaginal infection, or vaginal sensitivity.
- Patient satisfaction was assessed using a 5-point scale (extremely satisfied, somewhat satisfied, neutral (neither satisfied or dissatisfied), somewhat dissatisfied, and extremely dissatisfied).
- Treatment success was defined as PWT Increase of <1 g
  - Values of 1–10g Mild, 11–50g Moderate, and >50 g Severe
  - A clinically meaningful level of improvement in pad weight was defined as >50% reduction relative to baseline

**Results:**

- Patients underwent 24± 5 treatment sessions and returned for follow-up at 50± 11 days
- 1-hour pad weight test; 38 (79%) had positive PWT at baseline
  - Treatment success, defined as >50% improvement relative to baseline, was achieved in 84% of patients.
- Incontinence-related quality of life
  - UDI-6 total score improved in 92% of patients.
  - IIEQ-7 total score improved in 85% of patients.
- Sexual function quality of life
  - Total FSDS-R score improved in 81% of patients.
  - Total FSFI score increased in 77% of patients.
- Pelvic floor muscle strength
  - Significant improvement was noted (p < 0.001). Strength improved by one grade in 43% of patients and by two grades in 11% of patients.
  - None of the patients experienced a decrease in PFMS. Patients with the lowest baseline PFMS were most responsive to therapy.
- Patient satisfaction
  - Patient satisfaction was 83%.
  - The sole predictor was the magnitude of relative improvement in the UDI-6 total score
- Adverse events: 2 (3.6%) reported an adverse event.
  - One patient withdrew with c/o excessive device warmth
  - One UTI was reported in a patient who did not properly sterilize the device after each use. She
discontinued use for 2 weeks until the infection resolved, then resumed therapy and completed the study with no further issues.
  o No additional reports of discomfort were stated or observed

Weakness of study
  • Both authors are consultants with JoyLux, Inc (Women’s health technology company creating innovative products for pelvic floor wellness). Dr Sarah de la Torre received research funds from JoyLux, Inc
  • No control group and no long term follow-up
  • It is difficult to know which modality is providing the results or is it the combination of modalities (LED, heat, vibration)?
  • Need further blinded placebo studies

Strengths
  • Innovative device
  • Can be used in privacy of home and less expensive than in-office procedures
  • Thorough baseline and follow-up measures
  • Significant improvements noted in results

Discussion
vSculpt is not available in the USA. A similar device, vFit (but with no infrared) is sold in the USA. Are any of your patients asking about this device?

**July 30, 2018: FDA alerted and warned “patients and health care providers that the use of energy-based devices to perform vaginal rejuvenation, cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function may be associated with serious adverse events. The safety and effectiveness of energy-based devices for treatment of these conditions has not been established.”
https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm615013.htm

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