

Evaluation of a New Energy-Based Modality for Treating Female Sexual Dysfunction: Transvaginal Shockwave Therapy (TVST)

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Abstract

Introduction: Female Sexual Dysfunction (FSD) is a widely common condition lacking proven technology-based solutions.

Aim: To evaluate the therapeutic effects and safety of low-intensity shockwaves, when applied transvaginally for treatment of FSD.

Methods: The study was a single arm pilot study conducted between February-August 2021, whereas 15 female patients aged 45-61 with sexual dysfunction were treated with the MorenovaFem (Hikkonu Ltd., Israel) low-intensity shockwave system and a novel transvaginal treatment probe. Patients were treated by application of shockwaves (energy density = 0.09mJoule/mm²) to the vaginal wall as well as to the labium. Patients received a total of six treatment sessions over the course of three weeks. Ultrasound gel was used as a lubricant.

Measurements and Results: The Female Sexual Function Index (FSFI) questionnaire and ICIQ-UI Short Form were used to assess baseline symptoms, as well as at 1 and 3 month follow-ups to evaluate the clinical benefits. 14 of the 15 patients concluded the treatment and follow-up requirements. None of the patients complained of pain or discomfort during or following treatment, and no side effects or adverse events were recorded. Average baseline FSFI score was 13.6 for the entire cohort, increasing to an average of 22.2 and 20.7 at the 1 month and 3 months post treatment, respectively.

Conclusion: There is a great demand for new interventions for treatment of FSD, related and not related to vaginal atrophy. Treatment with transvaginal low-intensity shockwaves seems to be a safe and efficient new treatment option. The data, although limited in its scope, supports the need for larger scale and controlled studies, ideally targeting different genitourinary conditions.

Methods & Measurements

- n=15 women with Female Sexual Dysfunction (FSD)
- Age 45-61 years (mean age 52.7 years)
- 78.6% post-menopausal
- 40.0% with Stress Urinary Incontinence (SUI)
- Low intensity Large-Area Shockwave Therapy (LAST) with MorenovaFem device
 - 2 weekly sessions for 3 consecutive weeks, totaling 6 sessions
 - Energy density 0.09 mJ/mm²
 - 400 pulses/site, totaling 2400 pulses/session (14,400 pulses for complete protocol)
 - 6 sites (labia minora, labia majora, anterior vaginal wall at 11 & 1 o'clock)
- Treatment performed on an outpatient basis without anesthesia or medication use before or after the intervention (Fig. 1)
- Patients were assessed using:
 - FSFI (Female Sexual Function Index) questionnaire
 - ICIQ-UI SF (International Consultation on Incontinence Questionnaire – Urinary Incontinence, Short Form)
- Efficacy assessment was determined according to MCID (Minimal Clinically Important Differences) on each domain of sexual function.

Conclusions

This prospective study shows evidence of improvements in sexual function and urinary continence in peri- and postmenopausal women across LISWT treatment and follow-up. Additionally, as no tissue heating or ablation is involved, this treatment has a potentially higher safety profile and effectiveness compared to other energy-based technologies. Given the promising results of this study, and the confirmed therapeutic benefits of LISWT to erectile dysfunction over the past decade, MorenovaFem should be considered an effective and well-tolerated alternative treatment, especially in women who do not accept or are at a high risk of complications for hormonal therapy and surgery. Further studies to characterize symptom benefit and long-term outcomes are underway to evaluate this non-surgical vaginal therapy.

Introduction & Aim

Women of all ages experience changes in their genitalia, frequently detrimental to their quality of life. Indications are prevalent, and include vaginal laxity, postmenopausal vulvovaginal symptoms (dryness, burning, itching), stress urinary incontinence, decreased sexual desire, and reduced sensation and tone of the external genitalia.

Energy-based procedures alternative to hormonal therapy and surgery are increasingly offered as vaginal treatments:

- Laser and radio frequency energy devices are used to produce controlled heat and stimulate collagen production.
- Clinical results and risks associated with complications remain controversial.

Low intensity shockwave therapy (LISWT):

- A novel energy-based application of a well-known regenerative treatment modality. Reliable scientific evidence has demonstrated tissue regeneration and angiogenesis following LISWT, through activation of Vascular Growth Factors (VEGF) and collagen gene expressions.
- Although several studies have been performed in recent years demonstrating clinical improvement for women suffering from vulvodynia and urinary incontinence, technological constraints have not previously allowed for low-intensity shockwaves to be applied transvaginally.
- Using Large-Area Shockwave Technology (LAST), MorenovaFem device is specifically designed for both topical and transvaginal application.

Results

The total FSFI scores rose from a median of 13.6 at baseline to 22.2 at 1 month (Fig. 2), with significant improvements in all six FSFI domains: desire, arousal, lubrication, orgasm, satisfaction and pain (Fig. 3).

- At 3 months, the median FSFI total and domain scores remained significantly improved than baseline, with a median of 20.7 (Fig. 2).
- A significant proportion of our cohort achieved the MCID for all six FSFI domains both at 1 and 3 months follow-up (Fig. 4), thereby showing impactful clinical improvement.
- Of the 6 patients suffering from SUI symptoms, 4 showed a decrease in their average ICIQ-UI SF score from 10.3 (baseline) to 6.3 to 2.9, at 1 and 3 months follow-up respectively.

Fig. 1 Clinical Setting of MorenovaFem Device

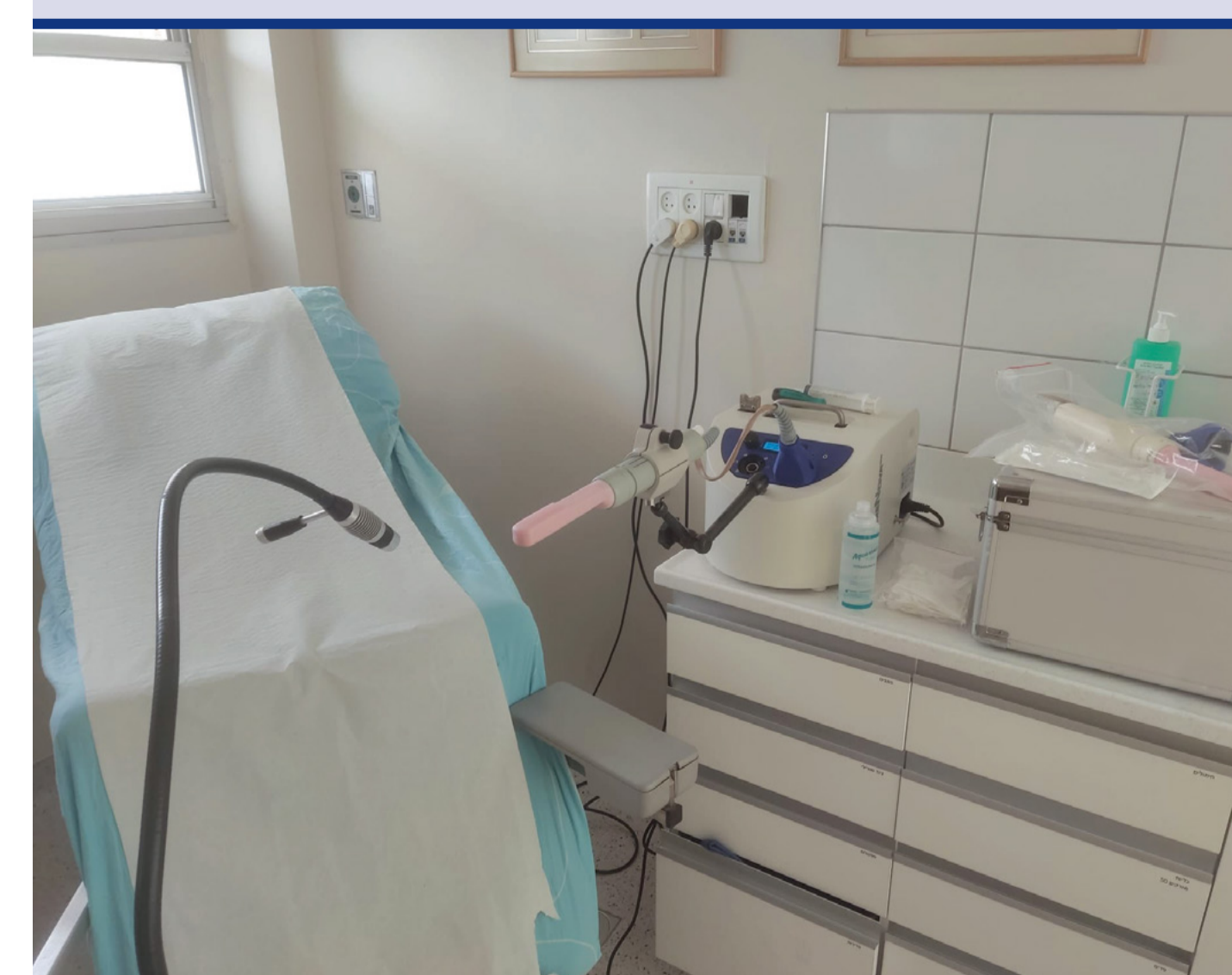


Fig. 2 Mean FSFI Total Score

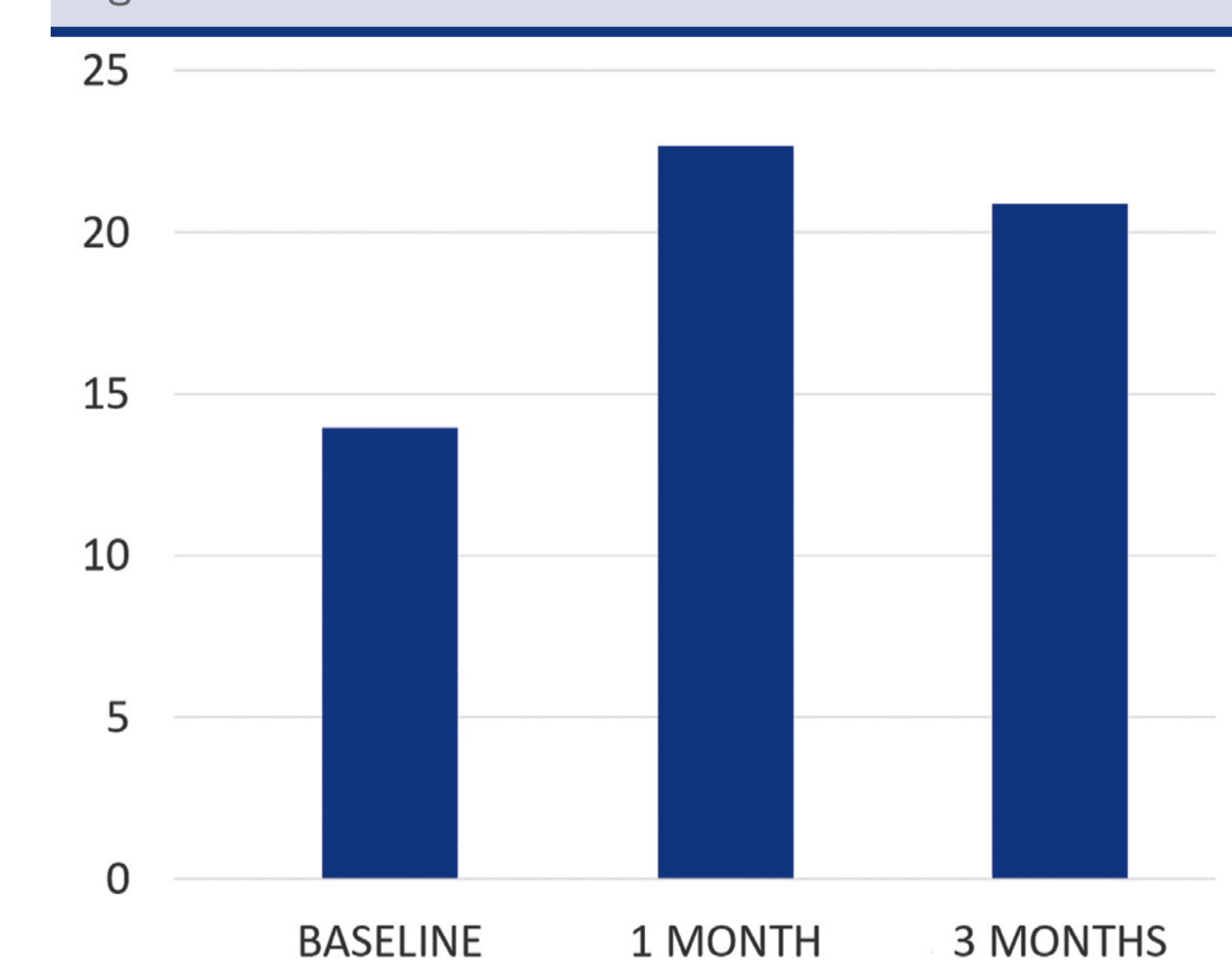


Fig. 3 Improvement in FSFI Domains

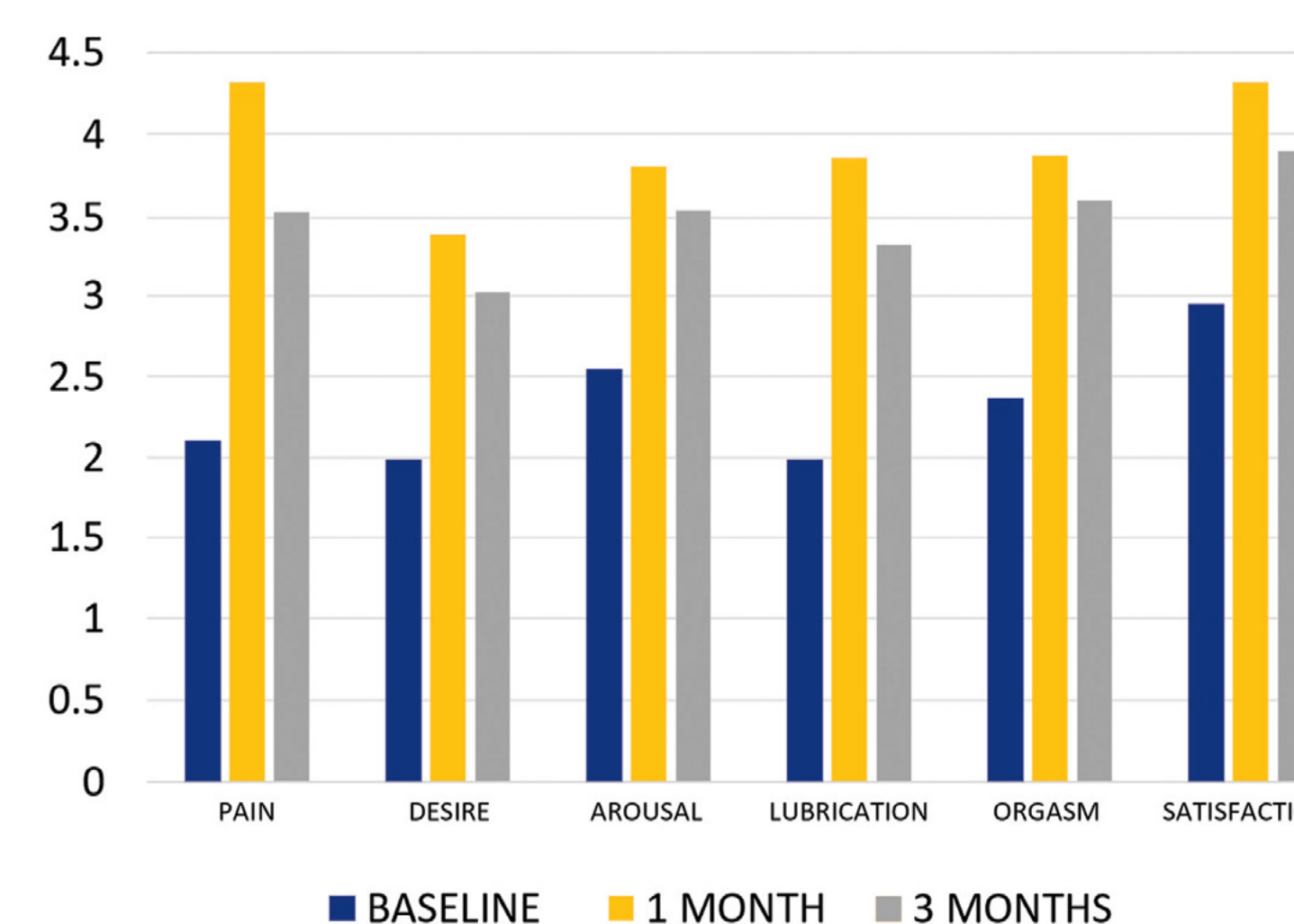


Fig. 4 Patients Achieving MCID (%)

