MorenovaFem

A Compendium of Research Articles and Conference Posters
on the Integration of Morenova into Women's Health

MORENOVA Fem

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Learn from Leading Practitioners

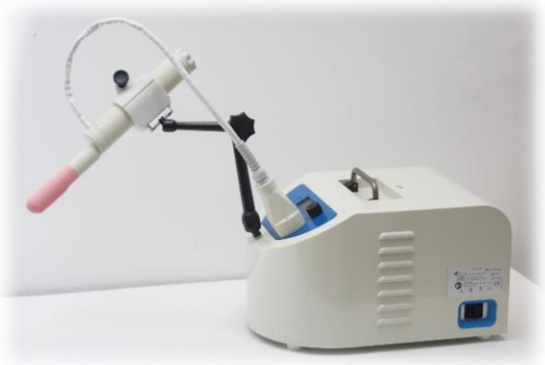
This compendium lists selected publication references, synthesizing the knowledge and experiences from leading practitioners, and documenting a range of applications and models for implementing MorenovaFem in routine practice.

- We hold ourselves to a high standard when it comes to accumulating clinical evidence
- We are committed to extending research opportunities to medical professionals worldwide
- We strive to engage the professional community to explore existing guidelines in order to reach knowledge-based consensus recommendation for change, while recognizing the valued relationship between uro-gynecologists and industry

To learn more about how MorenovaFem can benefit you and your patients, please contact us at:

https://direxgroup.com

info@direxgroup.com

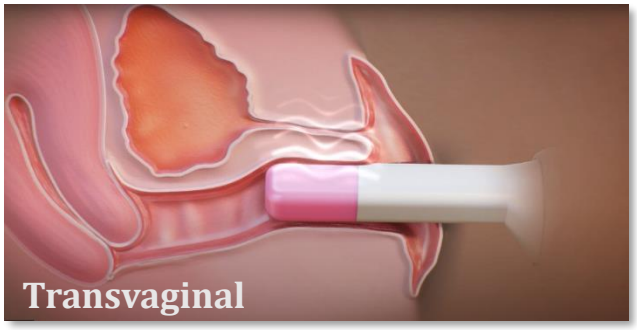


MorenovaFem at a Glance

MorenovaFem is a new-generation shockwave-based non-surgical vaginal treatment aimed at restoring vaginal form and function for women of any age

Application made easy

Uniquely designed hand-held or arm-mounted applicators are shaped for smooth penetration and ease of comfort for both women and caregivers. The shape and size harmonize with the body's contours and have been downsized to enable intimate applications to the clitoral/labia area, as well as the vaginal and pelvic zones.



Clinical Indications for Utilizing MorenovaFem

Indications in Urogynecology:

- Stress Urinary Incontinence (SUI)
- Female Sexual Dysfunction (FSD)
- Symptoms related to Genitourinary Syndrome of Menopause (GSM)

Clinical benefits

- Low- to zero-risk, no heating, no ablation, no side effects
- High safety and efficacy across various indications/ages
- Clinically validated regenerative effect
- Multiple feminine health indications
- Non-surgical, non-pharmacological
- Improved patient compliance
- Low interoperator variability
- Durable results

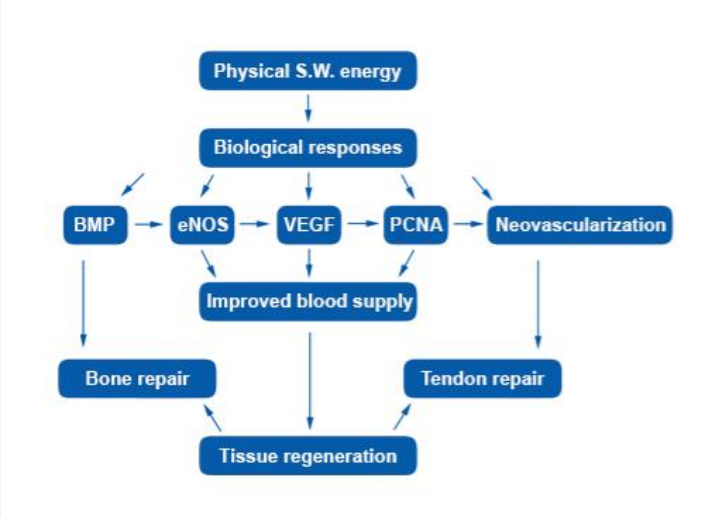
Features and highlights

- Proprietary Large-Area Shockwave Technology (LAST) electromagnetic technology
- Optimal comfort: outpatient setting, anesthetic-free, quick and painless
- Time efficient: no preparations, no downtime, no recovery time
- Fits in standard workflow, requires no additional equipment
- Noticeable results directly after the first few sessions
- Exclusive hands-free application
- Straight-forward procedure

Molecular Mechanism of Action

Shockwaves are characterized by jump change in pressure, high energy peak, high amplitude and non-periodicity. The energy is transferred to the transmitter at the end of the applicator and further into the tissue.

Our bodies have a remarkable capacity to heal themselves. Low Intensity Shockwave Therapy (LISWT) augments the body's natural cellular repair mechanisms, using acoustic pressure waves which carry low-intensity energy to tissues. The cascade of biological actions that follows LISWT leads to accelerated tissue regeneration and cell growth, and is able to restore, improve, and even normalize tissue form and function.



Wang CJ, Wang FS, Yang KD,
Biological mechanism of musculoskeletal shockwaves
ISMST Newsletter 2006, 1 (I), 5-11

During and after treatment, LISWT delivers pulse waves to the vagina and pelvic region, stimulating the following regenerative and reparative processes simultaneously:

- ANGIOGENESIS AND NEOVASCULARIZATION

  Nutrient blood supply and tissue oxygenation are vital to initiate and maintain the healing processes of damaged tissue structures. By causing capillary microruptures in the tissue, LISWT stimulates the recruitment of platelets and the subsequent increased expression of growth factors, which in turn activate the propagation and formation of new blood vessels.

- DECALCIFICATION OF PLAQUES AND ARTERIAL REMODELLING

  Vascular and fibrocellular tissue calcification commonly result from repetitive stress, microtrauma and aging. Calcium build-up can lead to histologic and structural changes, reduce tissue elasticity and impact vessel hemodynamics. LISWT-induced shear stress breaks up fibrosis and existing calcifications, leading to fragmentation of calcium deposits into granular particles, which are then removed by the lymphatic system.

- STIMULATION OF COLLAGEN PRODUCTION AND RESTRUCTURING

  Collagen plays an important role in maintaining the integrity of myoskeletal and ligamentous structures. LISWT accelerates collagen synthesis and deposition, forming denser and stiffer fibers, and creating a firmer structure.

- REVERSAL OF CHRONIC INFLAMMATION

  Mast cells are the foundation of inflammatory response, wound healing and defence against pathogens. LISWT increases Mast cell activation, followed by the production of chemokines and cytokines. initially enhancing the inflammatory process, these pro-inflammatory compounds ultimately allow for halting of chronic inflammation conditions and associated pain.

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Low Intensity Extracorporeal Shock Wave Therapy for Female Stress Urinary Incontinence: A Single-Blind, Randomized-Controlled Trial

Anna Padoa, Eyal Levy, Roni Tomashev, Anna Tsviban, Tal Fligelman

The 25rd ESSM Annual Congress | European Society of Sexual Medicine (ESSM) | FEB 2024

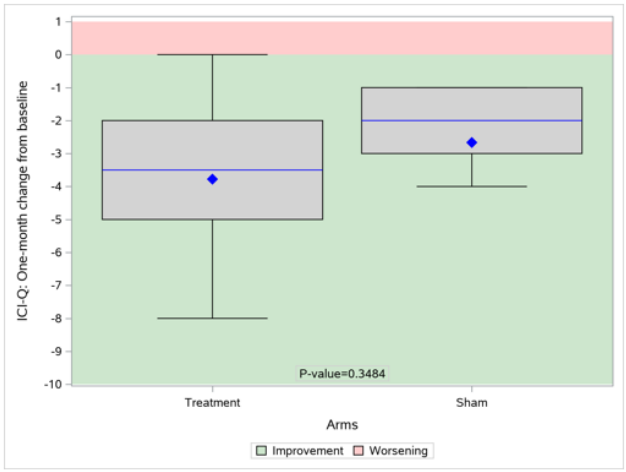
Objectives: Studies indicate a potential role for low-intensity extracorporeal shock-wave therapy (LiESWT) for stress urinary incontinence (SUI). Our objective was to assess safety and efficacy of LiESWT using a novel trans-vaginal probe for SUI and sexual function (SF).

Methods: In this single-blind, randomized-controlled trial, women with SUI were randomly assigned to either LiESWT with 0.1 mJ/mm^2 intensity, 1600 pulses, twice weekly for 4 weeks, or sham treatment, without energy transmission. Both were administered by a vaginal probe (MoreNovaFEM, Hikkonu Medical Systems Ltd, Ramat Hasharon, Israel), designed to deliver the pulses towards the peri-urethral tissue. Efficacy at 1 month was evaluated using the Patient Global Impression of Improvement (PGI-I); changes from baseline in scores of the International Consultation on Incontinence, Short Form (ICI-Q-SF), Urinary Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7); cough-stress test; 1-hour pad test. SF was evaluated by the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR).

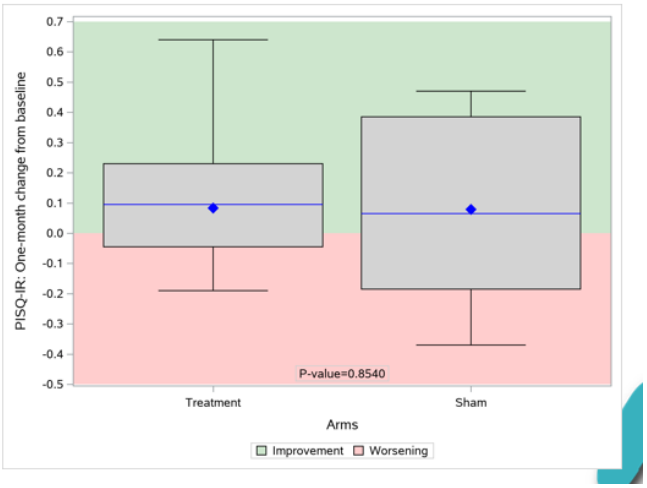
Results: Twenty-seven women were recruited: 18 in the study group and 9 in the control group. Age was 50.1±8.6 vs 46.4±9.8 (p=0.3404), BMI was 25.1±3.7 vs 27.3±4.4 (p=0.1729), respectively. Median parity was 3.0 (2.0–3.0) in both groups (p= 0.8066). Seven (38.9%) women in the study group and 4 (44.4%) in the sham group were post-menopausal. Pain visual analogue scale (VAS) at treatment n. 8 was 0.6±1.0 and 0.1±0.3, p= 0.2146. Improvement in IIQ-7 scores was significantly greater in the study group (-15.9±25.8 vs -1.0±7.3, p= 0.0239). Changes in urinary and sexual function were otherwise similar (Table 1). Possible procedure-related adverse events were mild and patients fully recovered: spotting (2 women, study group), UTI (1- study group, 1- sham), bacterial vaginosis (1- study group).

Conclusion: LiESWT for SUI by a vaginal probe is well-tolerated and safe. We observed significantly greater improvement in the impact of urinary incontinence in the study group, indicating LiESWT is a promising, energy-based alternative for SUI.

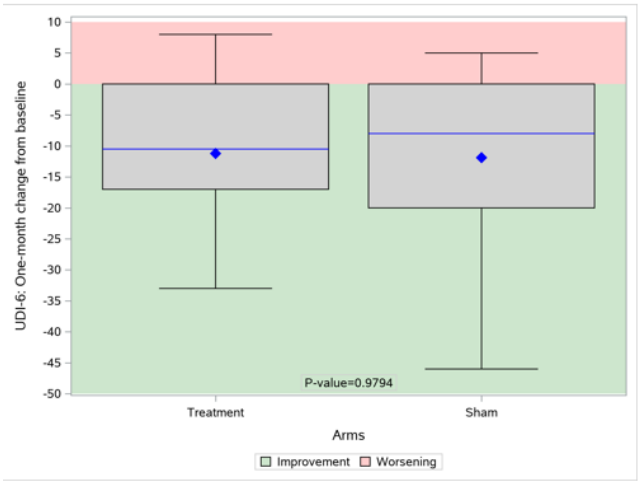
ICI-Q at 1 month



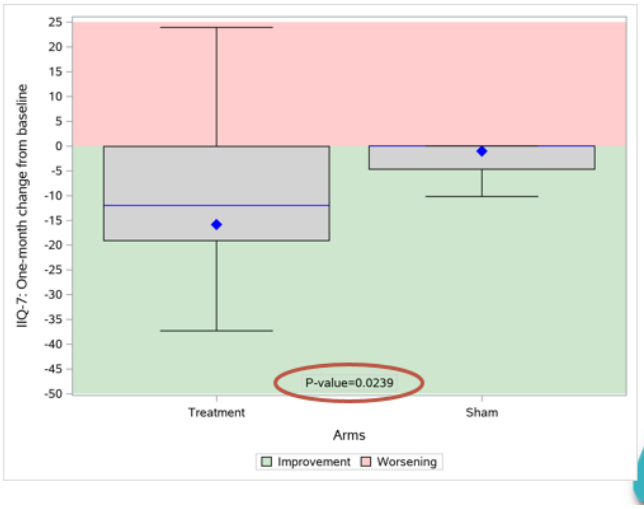
PISQ-IR at 1 month



UDI-6 at 1 month



IIQ-7 at 1 month



A Novel Treatment Modality for Premenopause Female Sexual Dysfunction

Kornya L

The 23rd ESSM Annual Congress | European Society of Sexual Medicine (ESSM) | FEB 2022

OBJECTIVE

To assess the safety profile and clinical benefit of a new transvaginal application of low intensity shockwaves for treatment of FSD.

METHODS

This was a single arm pilot study including 15 premenopause female patients aged 30-46 with sexual dysfunction symptoms. Patients were treated with the Morenova (Hikkonu Ltd., Israel) low intensity shockwave system and a newly introduced transvaginal treatment probe. Application of shockwaves (energy density= 0.09 mJoule/mm2) was to the vaginal wall and to the labium minora and majora. Patients were provided with six treatment sessions in a clinic setting and at a rate of two sessions/week, each session lasting approx. 20 minutes.

RESULTS

We interviewed the patients before the treatment and at 4 weeks and 12 weeks post treatments and used the Female Sexual Function Index (FSFI) questionnaire for assessing the clinical impact. All 15 patients concluded the treatment and 14 patients are cooperating fully with the follow up visits.

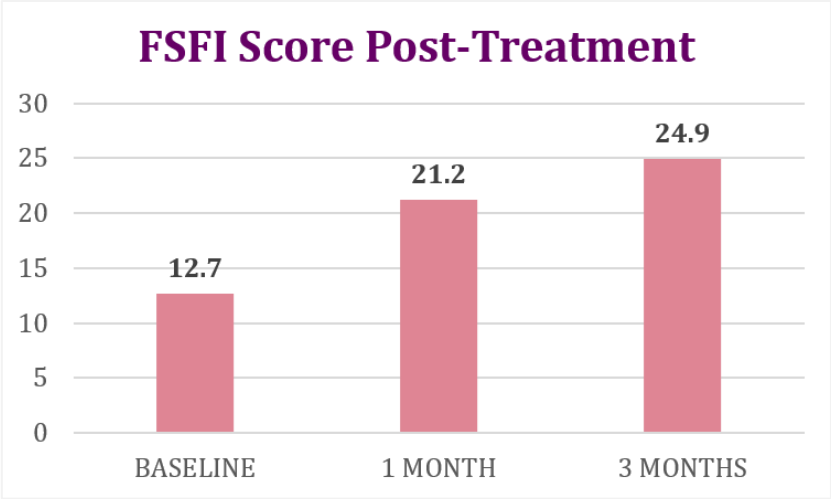
The average baseline FSFI score of all patients was 12.7. At the one month follow up assessment the average FSFI score was 21.2. At the time of this submission, 10 patients had concluded their 3-month evaluation with an average FSFI score of 24.9.

There were no side effects experienced by patients related to these treatments. The transvaginal application was easily performed whereas no patients complained of pain or discomfort.

CONCLUSIONS

FSD is highly common among women of menopause age, but also of younger ages, and there is a need for new technology based treatment solutions with a high safety profile. Transvaginal low intensity shockwave therapy seems to be a safe and efficient new treatment option. This limited pilot study supports the need for larger and controlled studies to better understand the clinical benefit for women suffering from FSD related, and not related, to Genitourinary Syndrome of Menopause.


23rd CONGRESS
OF THE EUROPEAN SOCIETY
FOR SEXUAL MEDICINE


FSFI Score Post-Treatment
30
25
20
15
10
5
0
12.7
21.2
24.9
BASELINE
1 MONTH
3 MONTHS

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

INTRODUCTION & AIM

This is a pilot study designed to evaluate the therapeutic effects and safety of low intensity shockwaves, when applied for treatment of sexual dysfunction symptoms and utilizing a novel transvaginal shockwave transducer designed to deliver therapeutic transvaginal shockwaves – TVST, in addition to transdermal application.

MATERIALS & METHODS

This pilot study included 15 female patients diagnosed with sexual dysfunction with ages ranging between 45-61 were recruited. Patients received TVST treatments twice a week for 3 consecutive weeks totalling 6 treatment sessions per patient. Each treatment session included administration of low intensity shockwaves to 6 different regions: 2 applications were transvaginal (11 and 1 o'clock positions) and 4 were transdermal: bilateral application to the labia minora and to the labia majora. 400 shocks were administered to each treatment region, totalling 2400 shocks per treatment session. Ultrasound gel was used as a lubricant and for ensuring a smooth transmission of shockwave energy to the targeted tissue. Energy density of the applied shockwaves was 0.09 mJoule per squared mm and the treatment efficiency was recorded by patient interviews utilizing the FSFI and ICIQ-UI SF questionnaires at baseline as well as 1 month and 3 months following the final treatment session.

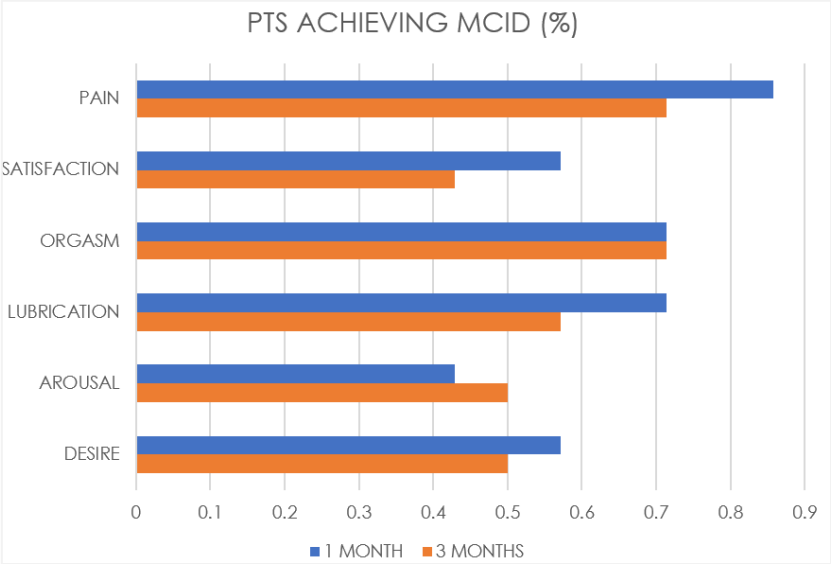
RESULTS

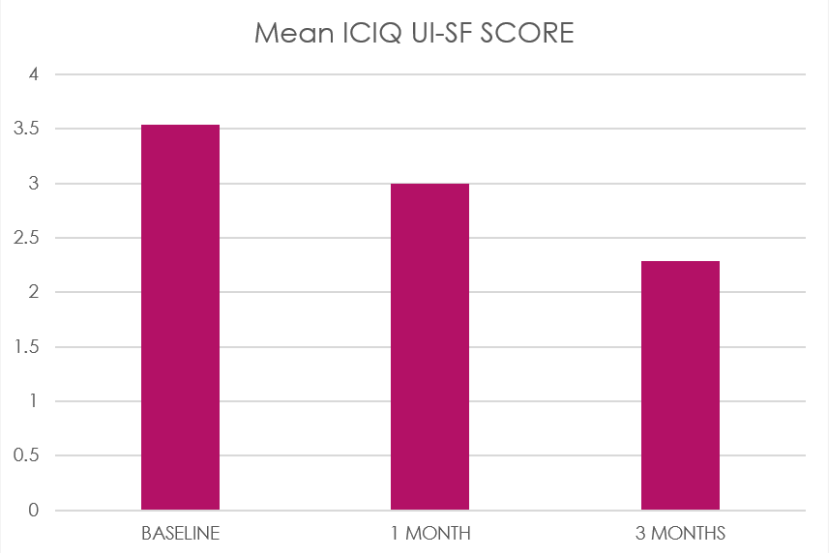
Average baseline FSFI score was 13.3 for the entire cohort and the average FSFI score of the first 8 patients to record their 1-month follow-up data was 23.4. Of the 5 patients suffering from SUI symptoms, 3 have presently concluded their 1-month follow-up review and showing a decrease in their average ICIQ-UI SF score from 11.3 to 9.0. None of the patients complained of pain or serious discomfort during the treatment sessions or afterwards. No side effects were experienced and no adverse effect recorded.

The initial results of this pilot study demonstrate substantial increases in all chapters of the sexual dysfunction questionnaire, including: desire, arousal, lubrication, orgasm, satisfaction and pain reduction. The average increase in FSFI scores is over 10 points. We intend to present at EUGA the 3-month follow-up data of the entire cohort of patients treated which will be available by then.

CONCLUSIONS

There is a growing demand and need for new and safe minimally invasive solutions for women suffering from vaginal atrophy and sexual dysfunction symptoms. The safety profile and initial data from this study, although limited in their scope, support the need for additional, larger scale studies utilizing also control groups. Furthermore, initial data suggests the need for separate studies focused on patients suffering from urinary incontinence.





Large Area Low Intensity Shockwave Therapy (LALIS) for Treating Women's Sexual Dysfunction and Stress Urinary Incontinence

Majaj O

The 51st ICS Annual Meeting | International Continence Society (ICS) | OCT 2021

OBJECTIVE

This study's purpose was to evaluate the therapeutic effects and safety of low intensity shockwaves, when utilizing a novel large area transducer (LALIS) designed to transfer therapeutic shockwaves both topically, as well as trans-vaginal.

DESIGN

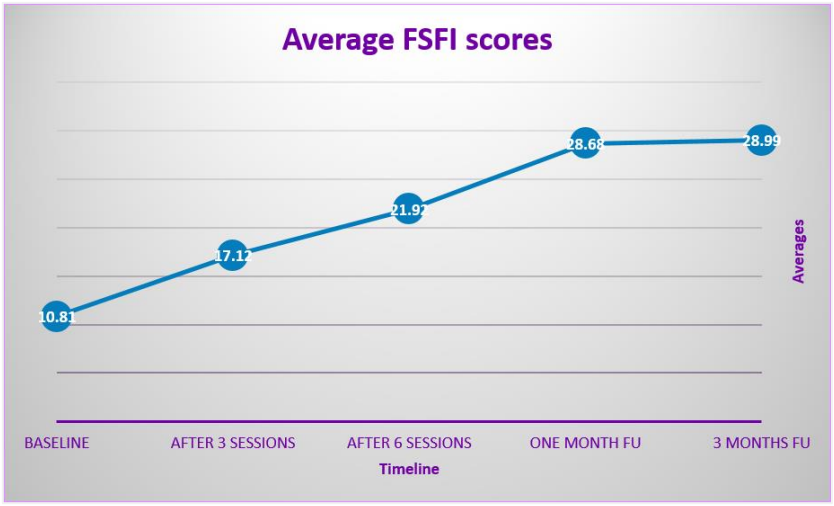
The study was a triple-arm pilot study whereas 21 female patients with sexual dysfunction and stress urinary incontinence were treated with 0.09 mJ/mm2 energy density, 2100 shocks at 2 shocks/second, twice weekly for three weeks, totalling 6 treatment sessions and 12,600 shocks administered per patient. FSFI and ICIQ-UI patient questionnaires were completed before treatment, during and following LALIS treatment, as well as a follow up period.

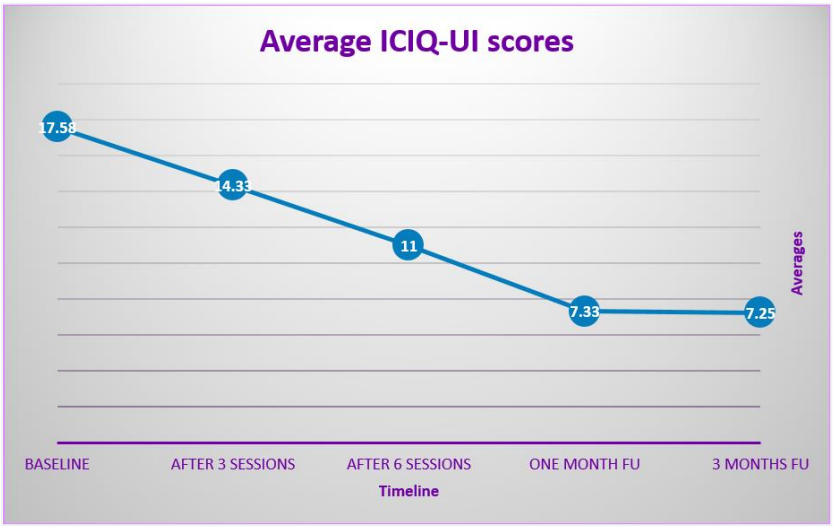
RESULTS

Results indicated a significant improvement in both sexual dysfunction and stress urinary incontinence symptoms, while safety issues were not experienced and patient discomfort or side effects were not reported.

CONCLUSIONS

There is a great demand for new interventions for vaginal atrophy symptoms, especially for women who are contra-indicated to hormonal therapy such as women suffering from breast cancer. Treatment with large area – low intensity shockwaves seem to be a safe and efficient new treatment option for women suffering from sexual dysfunction or stress urinary incontinence or both. The data, although limited in its scope, supports the need for larger scale and controlled studies, ideally targeting each of the clinical indications separately. Another parameter to be further investigated is the prospect of providing patients with severe conditions a longer treatment regimen, including more treatment sessions. The safety and tolerability of this treatment option make it, potentially, a preferred treatment option compared to other energy-based devices, such as lasers and RF treatment systems.


Average FSFI scores
10.81
17.12
21.92
28.68
28.99
Averages
BASELINE
AFTER 3 SESSIONS
AFTER 6 SESSIONS
ONE MONTH FU
3 MONTHS FU
Timeline


Average ICIQ-UI scores
17.58
14.33
11
7.33
7.25
Averages
BASELINE
AFTER 3 SESSIONS
AFTER 6 SESSIONS
ONE MONTH FU
3 MONTHS FU
Timeline

Comparison of Current Vaginal Treatment Options

	1. Shockwave Systems	2. Laser Systems
Pros	♦ Non-surgical, non-pharmacological ♦ No tissue ablation or heating ♦ clinically validated regenerative effect ♦ High safety and efficacy	♦ Non-surgical, non-pharmacological ♦ Widely used for aesthetic indication
Cons	♦ Limited efficacy for moderate-severe cases	♦ Downtime in sexual intimacy 3 days ♦ Introital pain with high energy levels ♦ Limited efficacy for mild-severe cases

	3. RF Systems	1. Surgical Procedures
Pros	♦ Non-surgical, non-pharmacological ♦ Widely used for aesthetic indication	♦ 90% success rate ♦ Recommended for mild-severe symptoms
Cons	♦ 80-85% success rate ♦ Minimal experience treating vaginal canal ♦ Introital pain with preheated rings ♦ Limited efficacy for mild-severe cases	♦ Surgery-associated risks and complications, e.g., infection, permanent changes in sensation, ongoing pain, scarring

	5. Pharmacotherapy	6. Physical Therapy
Pros	♦ Non-invasive ♦ Effective in relief of menopausal symptoms	♦ Non-invasive ♦ Effective in ease of discomfort and pain symptoms during sex
Cons	♦ Limited efficacy for urinary symptoms ♦ Temporary solution, high maintenance ♦ Side effects, including monthly bleeding ♦ Increased risk of serious conditions, e.g., heart disease, stroke, blood clots, breast cancer	♦ Poor adherence, <50%

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