

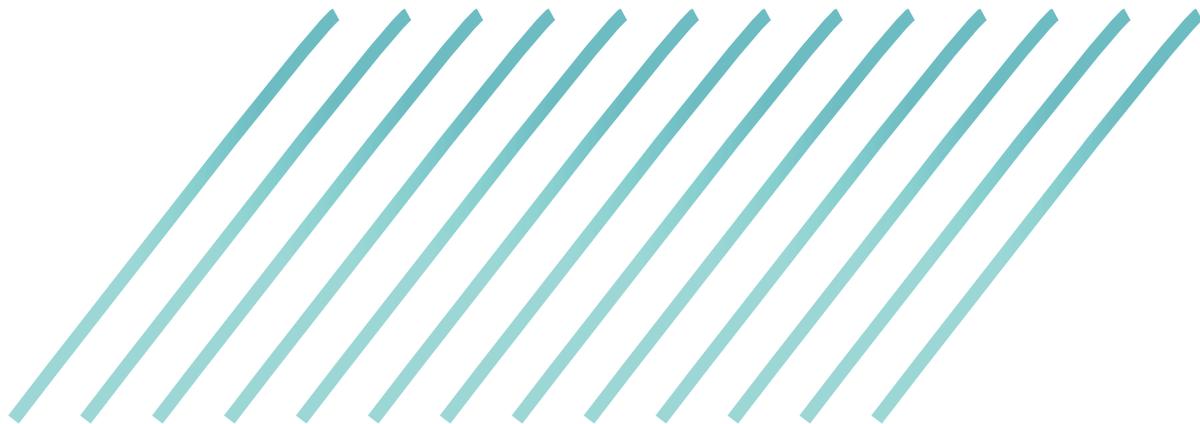


**MORENOVA<sup>FEM</sup>**

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**LINEAR TECHNOLOGY  
IN GYNECOLOGY**

**CLINICAL COMPENDIUM**



## Executive Summary

MoreNova\* is unique and purposefully designed to provide hands free, heat free and simple treatments for improved female health, quality of life and well being.

Patented Large Area Shockwave Technology (also referred to as LAST) is a non-invasive, anesthesia-free and pain-free solution providing significant improvement for indications such as sexual dysfunction, vaginal treatment, Stress Urinary Incontinence and GSM.

Exclusive LAST treatment reduces inflammation, generates new blood vessels for improved blood flow, , alleviates pain and activates stem cells resulting in improved Female Sexual Function Index (FSFI) and Sexual Distress Scale (SDS)

MoreNova treatment places its emphasis on a short, effective, simple and comfortably seated experience.

Results from clinical publications demonstrates safe, effective treatment and high patient satisfaction.

MoreNova system is a safe and effective regenerative alternative to Laser and other heat-based devices, surgical and hormonal options.

\* MoreNova is FDA registered for medical purposes such as minor aches and pains only.

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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.

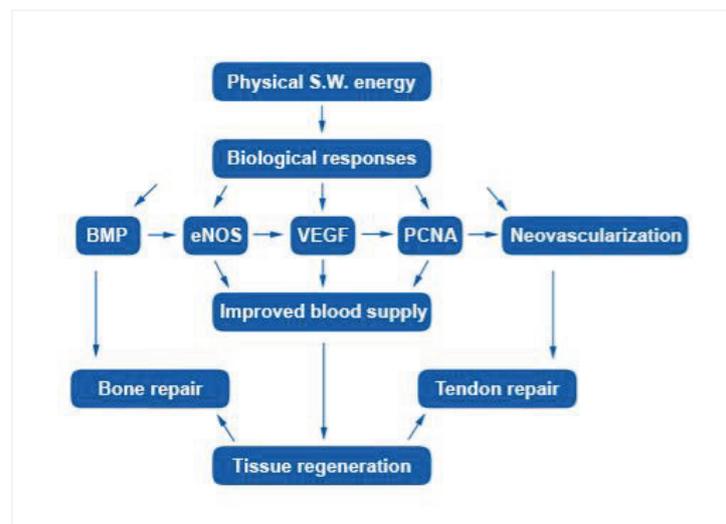
- ◆ We hold ourselves to a high standard when it comes to accumulating clinical evidence
- ◆ We are committed to extending research opportunities to medical professionals worldwide
- ◆ We strive to engage the professional community to explore existing guidelines in order to reach knowledge-based consensus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



## 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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23<sup>rd</sup> CONGRESS  
OF THE EUROPEAN SOCIETY  
FOR SEXUAL MEDICINE

FEBRUARY 17-19 2022, ROTTERDAM, THE NETHERLANDS

## A Novel Treatment Modality for Premenopause Female Sexual Dysfunction

Kornya L

The 23<sup>rd</sup> 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/mm<sup>2</sup>) 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

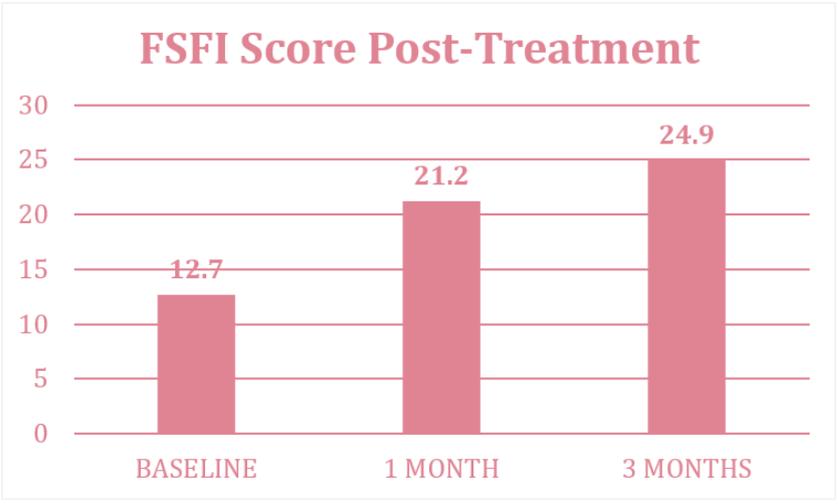
We interviewed the patients before the treatment and at 4 weeks and 12 weeks post treatments and used the Female Sexual Function Index (FSFI) questionnaire for assessing the clinical impact. All 15 patients concluded the treatment and 14 patients are cooperating fully with the follow up visits.

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.





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

Zoumpos I

The 14<sup>th</sup> EUGA Annual Congress | European Urogynaecological Association (EUGA) | DEC 2021

### 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.

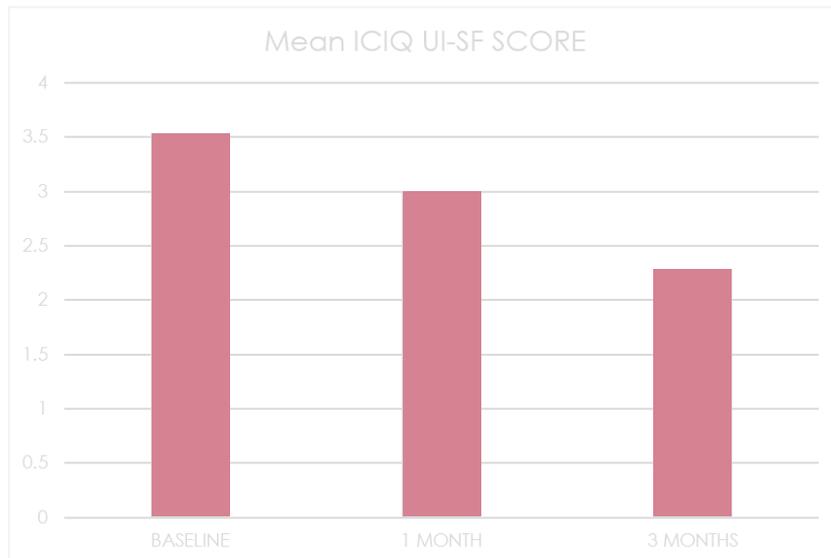
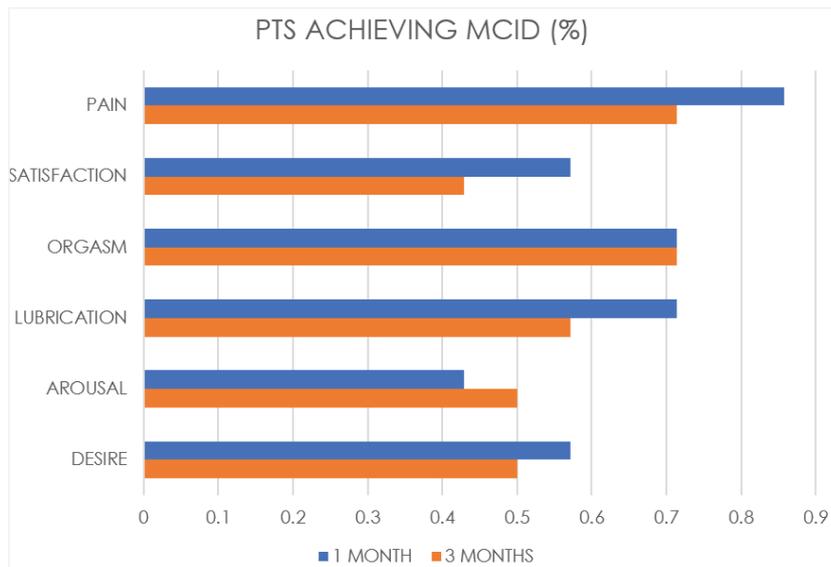
### MATERIALS & METHODS

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.



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

Majaj O

The 51<sup>st</sup> 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

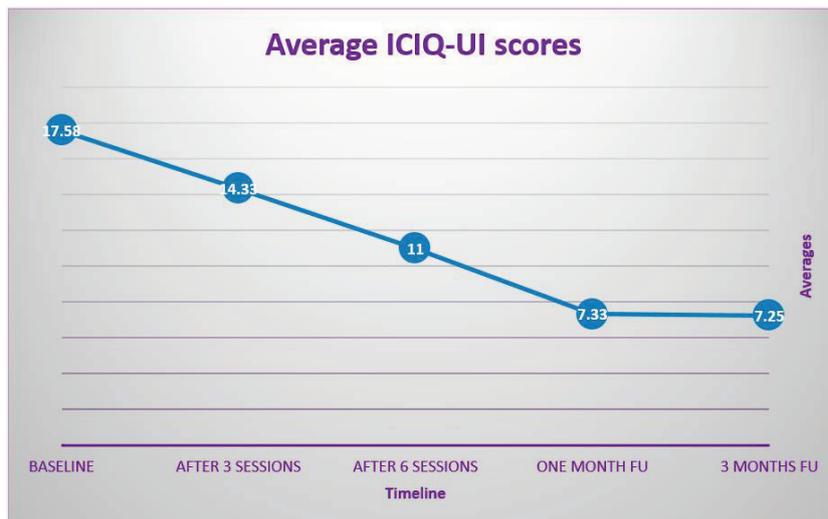
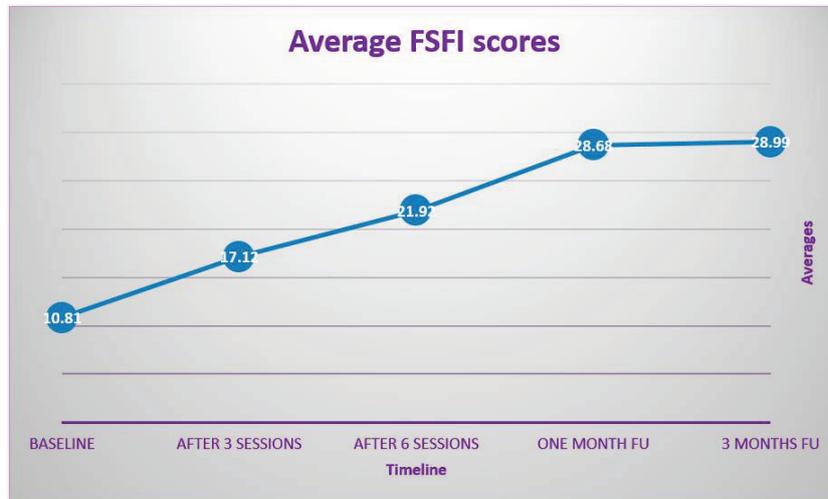
The study was a triple-arm pilot study whereas 21 female patients with sexual dysfunction and stress urinary incontinence were treated with 0.09 mJ/mm<sup>2</sup> energy density, 2100 shocks at 2 shocks/second, twice weekly for three weeks, totalling 6 treatment sessions and 12,600 shocks administered 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.



# Presentations

- ◆ New Treatment Approach for Female Sexual Dysfunction by Transvaginal Shockwave Therapy (TVST)

Zoumpos I

The 23<sup>rd</sup> Annual Fall Scientific Meeting of SMSNA  
23<sup>rd</sup> ISSM Scientific Meeting I October 27 - 30 2022.

## New Treatment Approach for Female Sexual Dysfunction by Transvaginal Shockwave Therapy (TVST)

DR. IOANNIS ZOUPOS, MD, PHD, FEBU  
UROLOGIST  
THESSALONIKI - GREECE

## Introduction

- ▶ Female Sexual Dysfunction (FSD) is a prevalent condition, especially among midlife women.

## Objective - Methods

- ▶ To assess safety and clinical efficacy of TVST mainly for FSD and also incontinence.
- ▶ N=15 women with self-reported sexual dysfunction
  - ▶ 7 women (46,7%) also reported urinary incontinence.
  - ▶ 1 pt aborted (unrelated to treatment).
- ▶ Mean age was 52.7 years, 78.6 % were post-menopausal.
- ▶ Clinical assessments at baseline, 1 and 3 months post treatment using FSFI and ICIQ UI-SF.
- ▶ Statistical analysis was performed using student's t-test (paired, one-tail, p<0.05).



used devices (EBD), such as lasers and radiofrequencies, intended for vaginal rejuvenation and FSD treatment.

Shockwave therapy (LIST) has emerged as a novel therapeutic option for female genital dysfunction and may also hold promise for FSD.

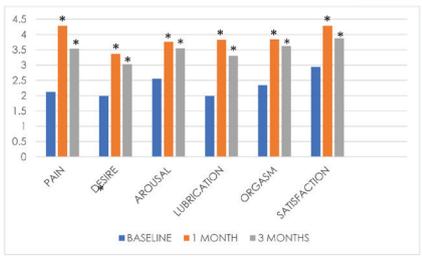
Treatment of FSD can be performed by:

• **External:** energy is applied to the external genitalia and distal urethra.

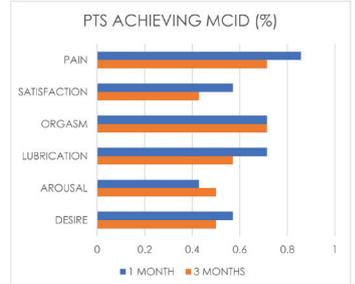
• **Internal (Transvaginal Shockwave Therapy, TVST):** energy is applied to the internal urethra in combination with conventional application

## Results

### FSFI Domain Score Changes



\* significance at p<0.05, paired t-test



# Poster Publications

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

Zoumpos I

The 2<sup>nd</sup> Women's Health Innovations & Inventions (WHII) Congress | JUL 2022

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

Dr. Ioannis Zoumpos, MD, PhD  
Urologist, Thessaloniki, Greece



### 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 (Hikokou Ltd., Israel) low-intensity shockwave system and a novel transvaginal treatment probe. Patients were treated by application of shockwaves (energy density = 0.09mJoule/mm<sup>2</sup>) 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/mm<sup>2</sup>
  - 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 incontinence 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.

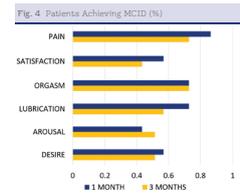
### Results

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





# MORENOVA<sup>FEM</sup>

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