

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

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Complying with regulations concerning the transparency of event funding and to guarantee accuracy of scientific contents, this disclosure certifies that in the past 2 years:

❑ I have collaborated with the following company, which have commercial interests in the healthcare area:

Medical research consultation and protocols design – for Hikkonu Ltd (Direx Group member), developer of the device

❑ I have no commercial interests

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UROLOGIST

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ENERGY BASED DEVICES (EBD)

VARIOUS MECHANICAL DEVICES WHICH APPLY ENERGY IN VARIOUS FORMS (E.G. LASER, SOUND, SHOCKWAVES, OR RADIO FREQUENCY) TO DIFFERENT TISSUES (E.G. VAGINAL EPITHELIUM, CAVERNOUS BODIES, NERVES)

Siegal A, Chubak BM. Urol Clin N Am 2021; 28: 478.

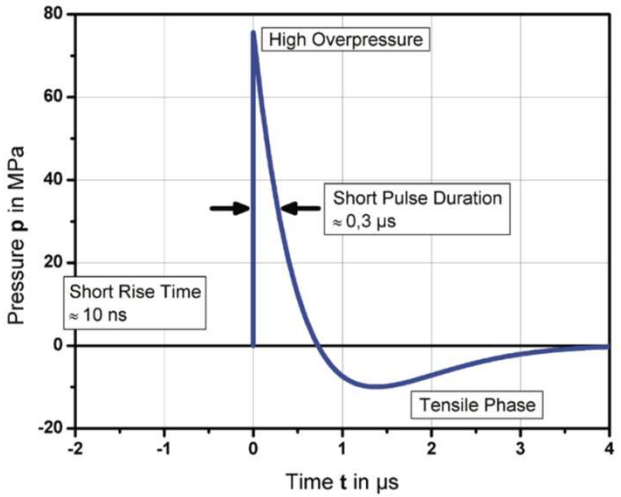
Energy Based Devices in Urogynecology

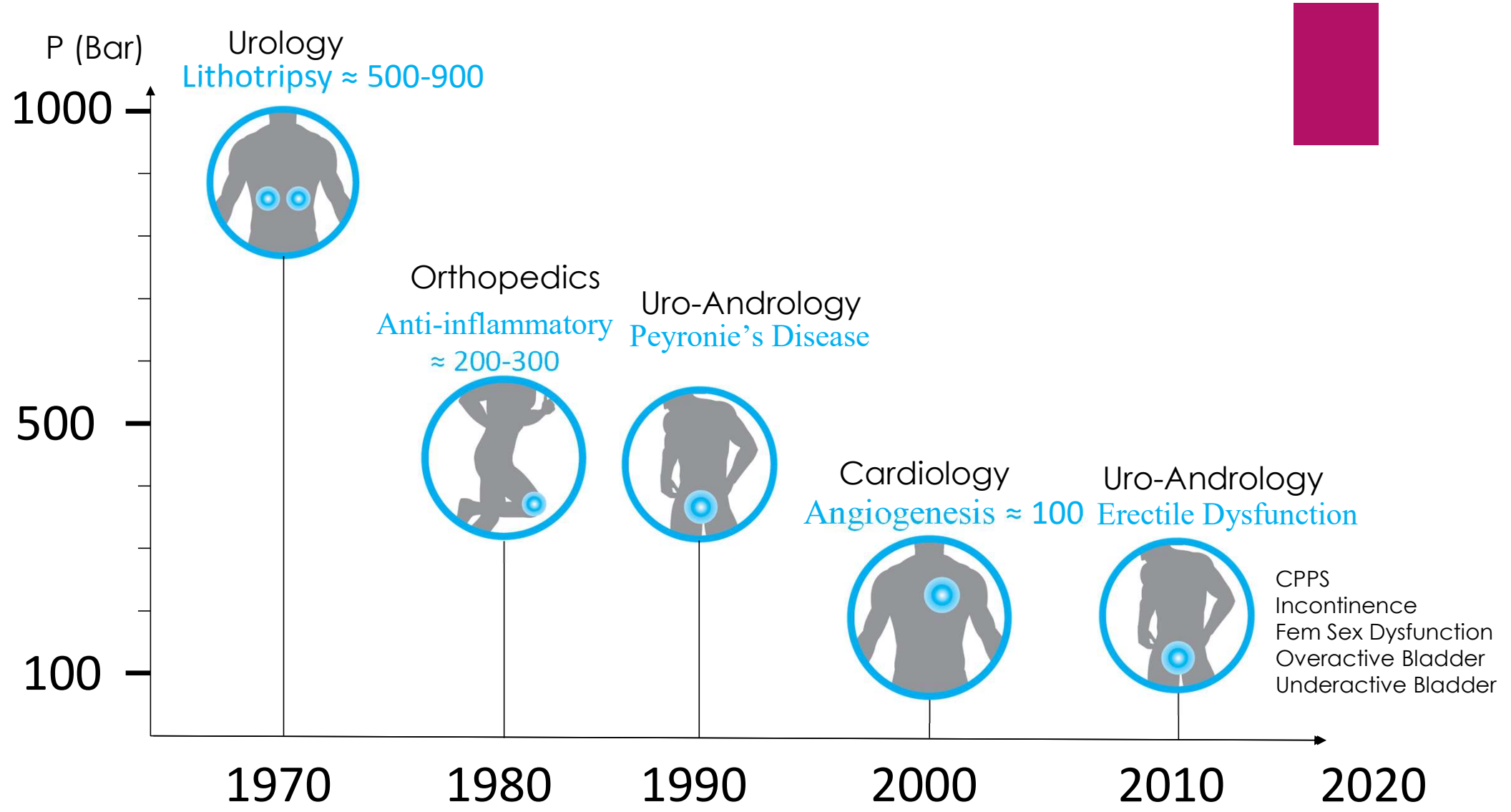
- Lasers (microablative fractional CO_2, non-ablative Er:YAG, hybrid fractional).
- Radiofrequency (RF) devices.
- Neuromodulation (sacral, percutaneous tibial nerve stimulation, vagal nerve stimulation).
- **Low-intensity extracorporeal shockwave therapy (LI-ESWT)**
  - Application on the external genitalia – using available probes
  - **Transvaginal application (TVST).**



Shockwave physics

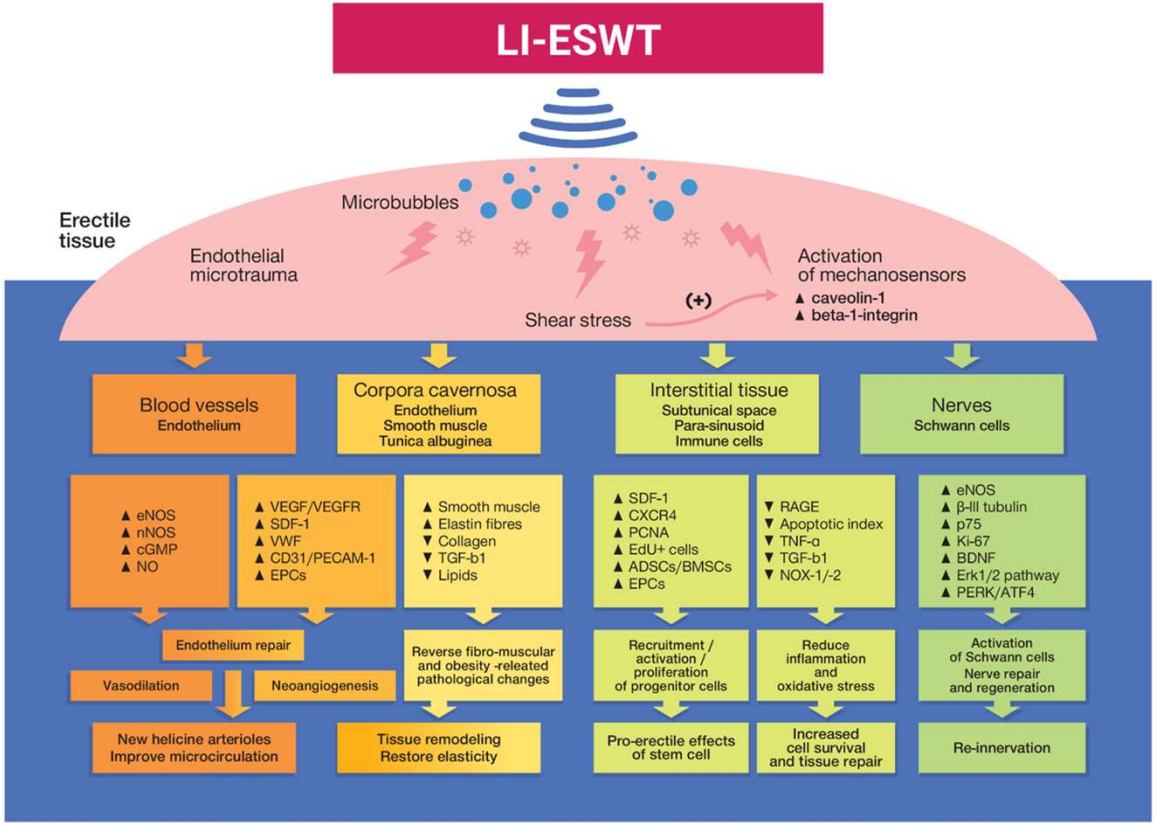
- Strong, intermittent acoustic pulses.
- Frequency: 150kHz up to 100 MHz.
- Characteristics:
  - ✓ **Short rise time (<several hundred nsec)**
  - ✓ **High pressure increase (10-150 MPa)**
  - ✓ **Short pulse duration (<10 microsec)**
  - ✓ **Gradual underpressure (-4 to -25 Mpa)**




P (Bar)
1000
500
100
Urology
Lithotripsy ≈ 500-900
Orthopedics
Anti-inflammatory
≈ 200-300
Uro-Andrology
Peyronie's Disease
Cardiology
Angiogenesis ≈ 100
Uro-Andrology
Erectile Dysfunction
CPPS
Incontinence
Fem Sex Dysfunction
Overactive Bladder
Underactive Bladder
1970
1980
1990
2000
2010
2020

Main biologic actions of low-intensity shockwaves

- Neo-angiogenesis
- Vasodilation
- Elastogenesis
- Collagenolysis
- Stem-cell recruitment and activation
- Cellular proliferation
- Anti-inflammation
- Re-innervation



Sokolakis I, et al. J Sex Med 2019

Emerging indications of LI-ESWT in Urogynecology

- Female Sexual Dysfunction (FSD).
- Stress Urinary Incontinence (SUI).
- Overactive Bladder - Urge incontinence.
- Hypoactive bladder.
- Vaginal laxity.

Material & methods - I

- N=15 women with self-reported sexual dysfunction.
- 1 pt aborted (due to personal issues).
- Mean age: 52.7 yrs.
- 78.6 % post-menopausal.
- Large-Area low intensity shockwave therapy with **MoreNova™** device – enables transvaginal application
  - Maximal energy setting tolerated by the patient
  - 400 pulses per site
  - 6 sites (labia minora, labia majora, anterior vaginal wall at 11 & 1 o' clock)
- No significant pain or side effects.



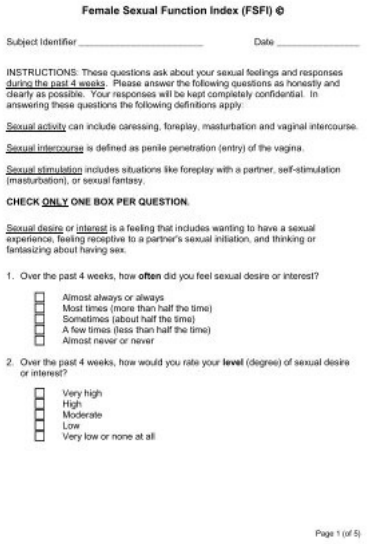
Material & methods - II

- Female Sexual Function Index (FSFI) questionnaire
  - Baseline
  - 1 month post treatment
  - 3 month post treatment
- Secondary incontinence questionnaire (ICIQ-UI SF)
  - Baseline
  - 1 month post treatment
  - 3 month post treatment



Female Sexual Function Index (FSFI)

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  - Baseline
  - 1 month post treatment
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- Secondary incontinence questionnaire (ICIQ-UI SF)
  - Baseline
  - 1 month post treatment
  - 3 month post treatment



Female Sexual Function Index (FSFI) ©

Subject Identifier _____ Date _____

INSTRUCTIONS: These questions ask about your sexual feelings and responses during the past 4 weeks. Please answer the following questions as honestly and clearly as possible. Your responses will be kept completely confidential. In answering these questions the following definitions apply:

Sexual activity can include caressing, foreplay, masturbation and vaginal intercourse.

Sexual intercourse is defined as penile penetration (entry) of the vagina.

Sexual stimulation includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

CHECK ONLY ONE BOX PER QUESTION.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

1. Over the past 4 weeks, how **often** did you feel sexual desire or interest?

   ☐ Almost always or always
   ☐ Most times (more than half the time)
   ☐ Sometimes (about half the time)
   ☐ A few times (less than half the time)
   ☐ Almost never or never

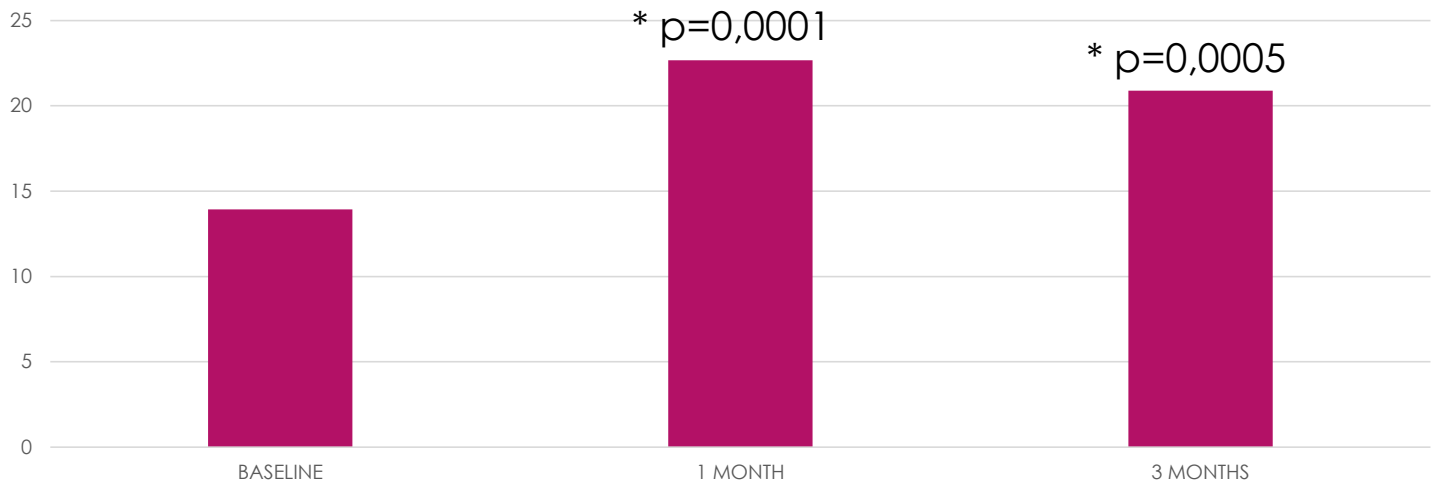
2. Over the past 4 weeks, how would you rate your **level** (degree) of sexual desire or interest?

   ☐ Very high
   ☐ High
   ☐ Moderate
   ☐ Low
   ☐ Very low or none at all

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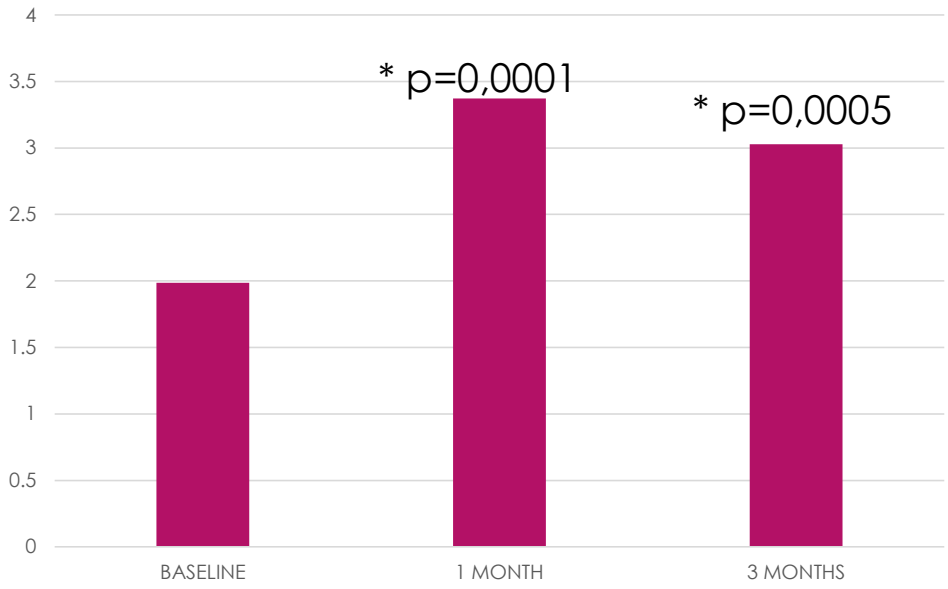
Rosen R, Brown C, Heiman J, et al. J Sex Marital Ther. 2000;26(2):191-208.

FSFI Total Score



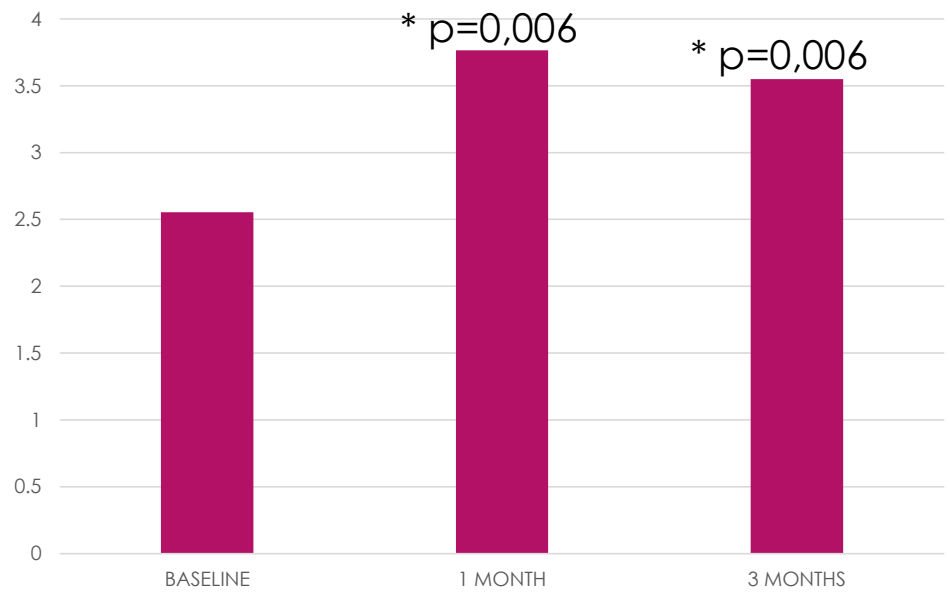
** significance at p<0,05, paired t-test*

FSFI – Desire



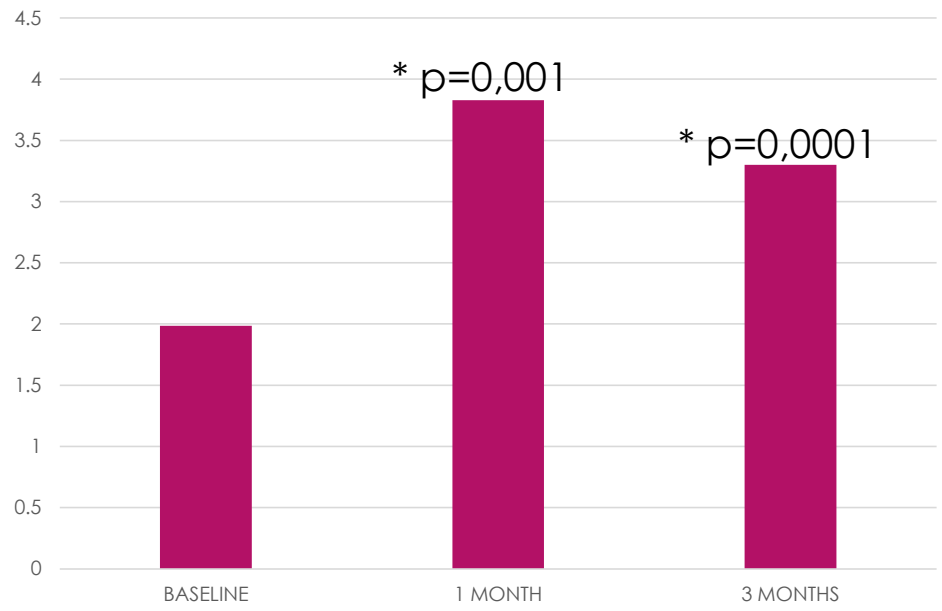
** significance at p<0,05, paired t-test*

FSFI – Arousal



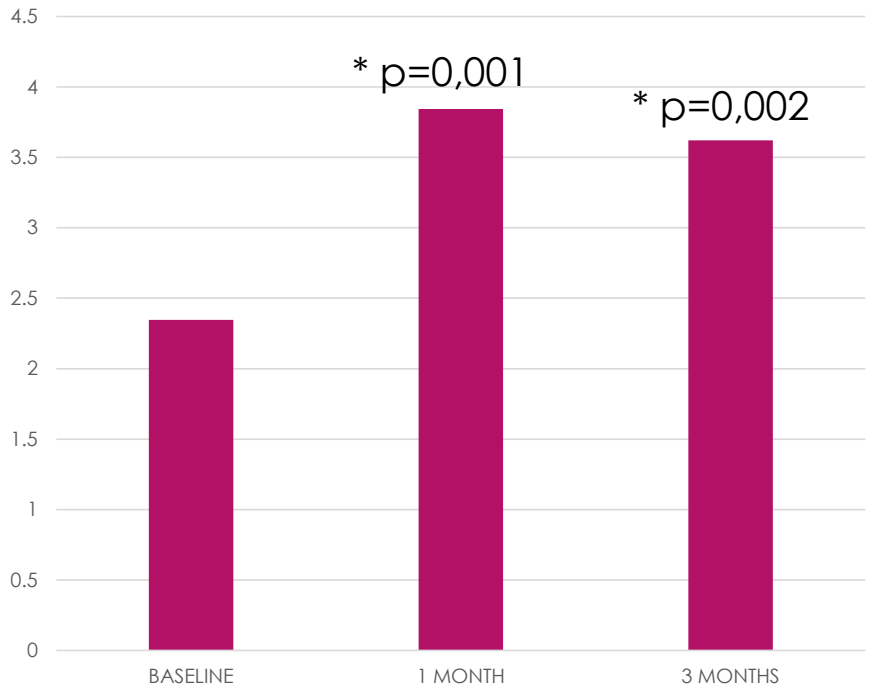
** significance at p<0,05, paired t-test*

FSFI – Lubrication



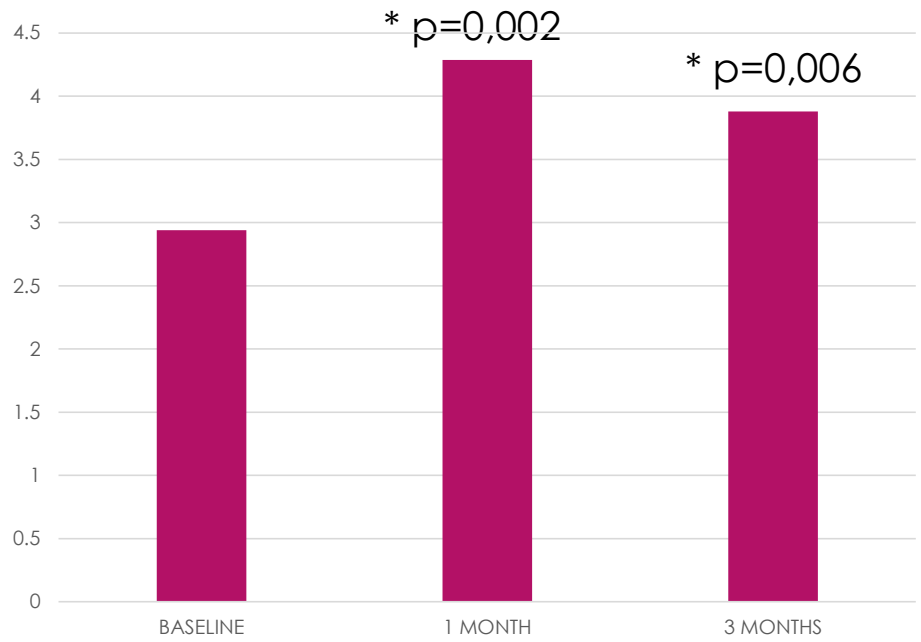
** significance at p<0,05, paired t-test*

FSFI – Orgasm



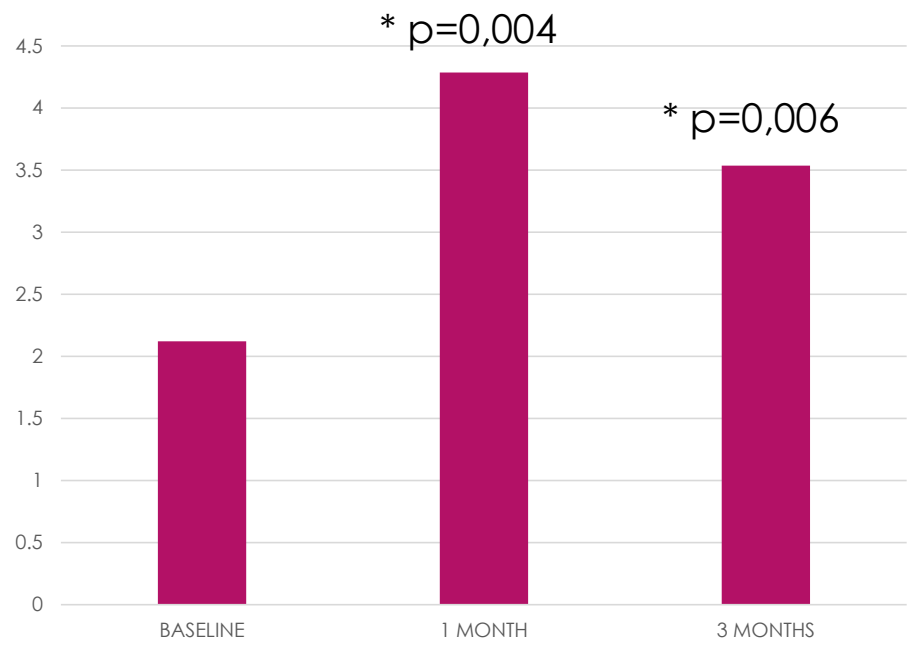
** significance at p<0,05, paired t-test*

FSFI – Satisfaction



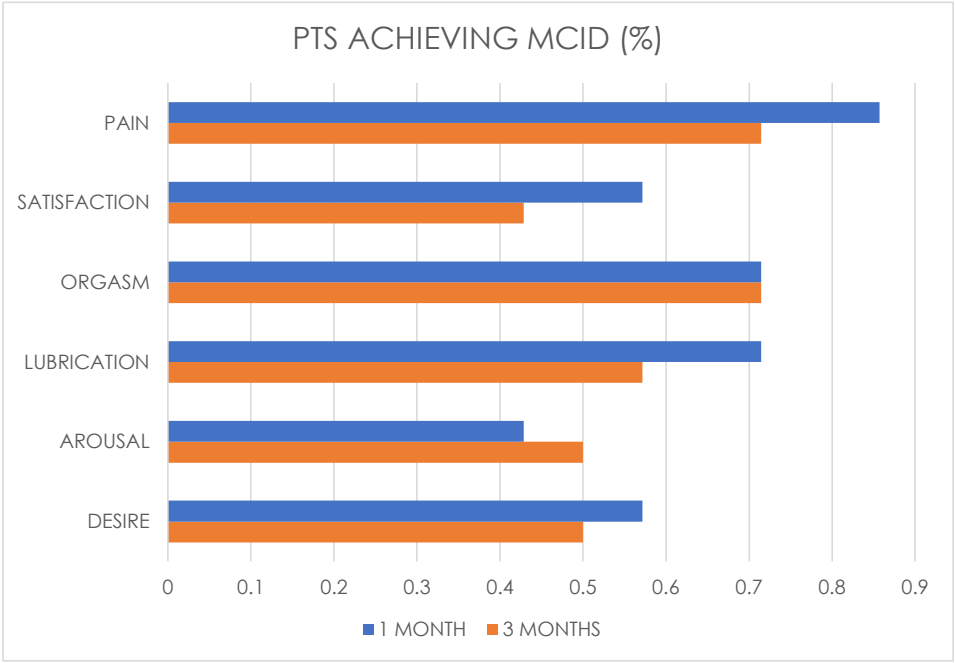
** significance at p<0,05, paired t-test*

FSFI – Pain

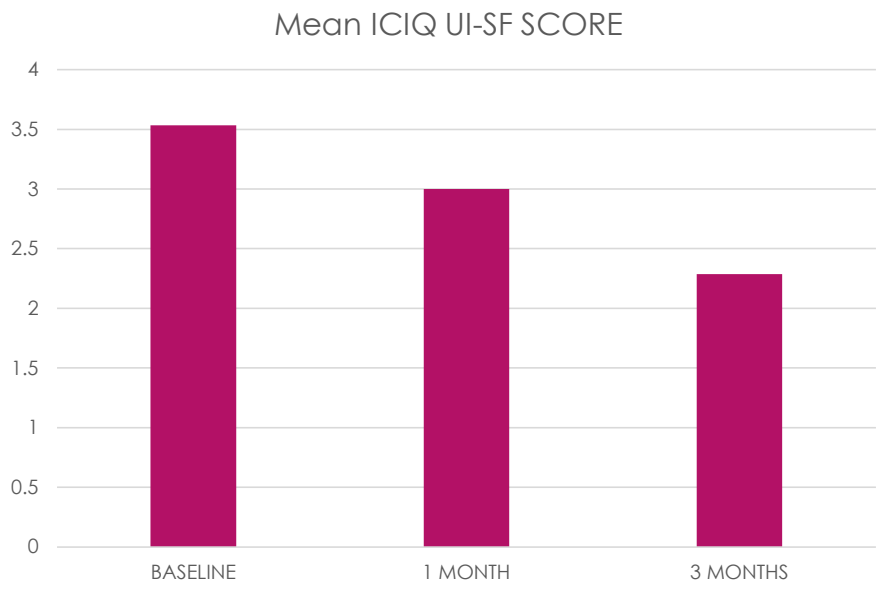


** significance at p<0,05, paired t-test*

FSFI – Minimal Clinically Important Differences



International Consultation on Incontinence Urinary Incontinence Short-Form (ICIQ UI-SF)



Conclusions

- Safe without any complications.
- Very well tolerated by all patients.
- Significant improvement in all aspects of FSD in short-term follow-up.
- Slight, but non-significant, decrease in FSFI scores at 3 months.
- Longer follow-up in larger patient populations is required. Propose to further clinical research in treatment of stress urinary incontinence

