A Novel Treatment Modality for Premenopause Female Sexual Dysfunction





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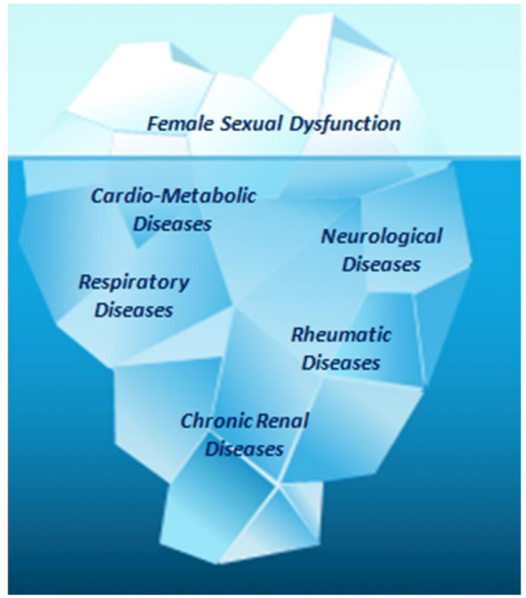
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FSD – NOT ONLY IN MIDDLE-AGED WOMEN

- High (**43%**) overall prevalence of FSD in reproductive-age women worldwide[1]
- **55%** of women partners of men with ED[2]
- **4/10** students show a risk of having FSD[3]

FSD as a warning sign?



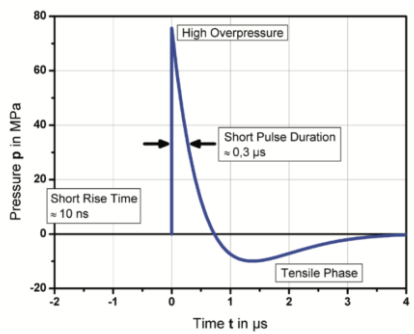
FSD as the tip of the iceberg of many common chronic diseases[4]

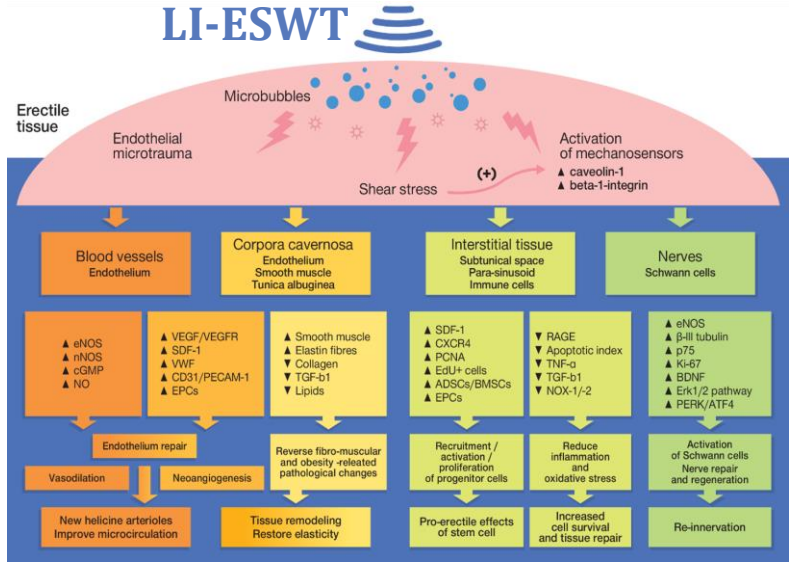
1. McCool-Myers M, Theurich M, Zuelke A, Knuettel H, Apfelbacher C. BMC Womens Health. 2018 Jun 22;18(1):108.
2. Greenstein A, Abramov L, Matzkin H, Chen J. Int J Impot Res. 2006 Jan-Feb;18(1):44-6.
3. Halle-Ekane GE, Timti LF, Tanue EA, Ekukole CM MD, Yenshu EV. Sex Med. 2021;9(5):100402.
4. Di Stasi, V., Verde, N., Maseroli, E. et al. Curr Sex Health Rep 11, 307–319 (2019).

EMERGING INDICATIONS OF LI-ESWT IN UROGYNECOLOGY

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)





LI-ESWT in Urogynecology

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

1. Sokolakis I, Dimitriadis F, Teo P, Hatzichristodoulou G, Hatzichristou D, Giuliano F. J Sex Med. 2019 Feb;16(2):168-194.

MORENOVA™ LI-ESWT FOR PREMENOPAUSAL WOMEN

- N = 15 premenopause female patients with self-reported sexual dysfunction
- Patients' age: 30-46 yrs
- Large-Area LI-ESWT with **MoreNova™** device for transvaginal treatment
  - Energy density: 0.09 mJoule/mm^2
  - Treated areas: vaginal wall, labium minora & majora
  - Protocol: 6 sessions (~20 min each); 2 sessions/week



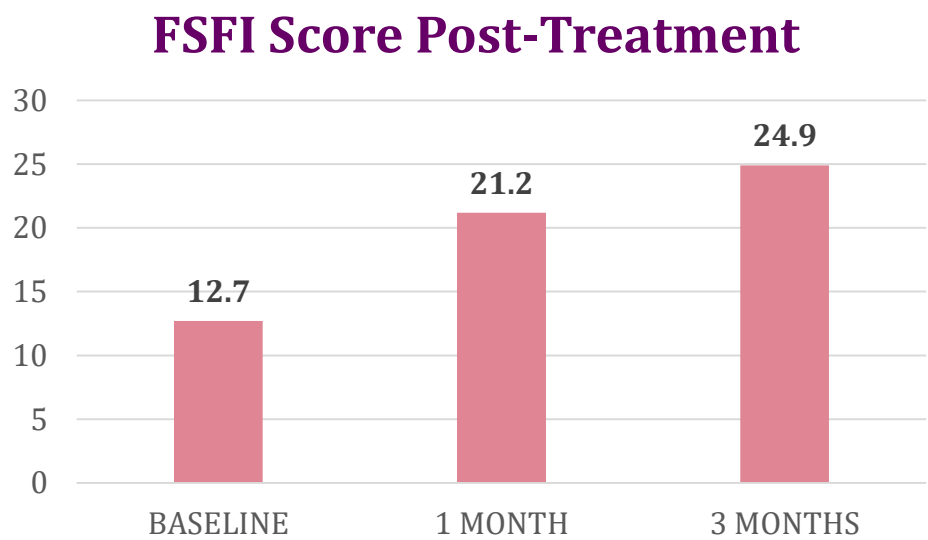
SIGNIFICANT INCREASE IN FSFI SCORES

- All 15 patients concluded the treatment
  - 14 patients are cooperating fully with the follow up visits









MoreNova™ – a Promising Solution for FSD

- ✓ Safe without any complications
- ✓ Very well tolerated by all patients
- ✓ Efficient, significant improvement in all aspects of FSD in short-term follow-up
  - Significant increase in FSFI scores at 3 months
- ✓ Longer follow-up in larger patient populations is required
  - FSD is highly common among women of menopause age, but also of younger ages; further clinical research should be performed in treatment of both pre and post menopause women suffering from GSM related FSD

LI-ESWT IN FUTURE PREVENTION STRATEGIES

- FSD affects millions of women worldwide
  - The high prevalence signals the importance of integrating **early-stage non-surgical and non-pharmacological solutions**, that could result in a reversal and prevention of symptoms, if addressed appropriately
- Times appear to be changing
  - Clinical and academic interest in FSD lately increased (though overlooked for many years[1])
  - More women seek medical attention
- LI-ESWT seems to be a value-based solution for FSD care

1. Sobecki JN, Curlin FA, Rasinski KA, Lindau ST. J Sex Med. 2012 May;9(5):1285-94.

DISCLOSURE

- 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 (DirexGroup member), developer of the device
  - I have no commercial interests



Thank You!