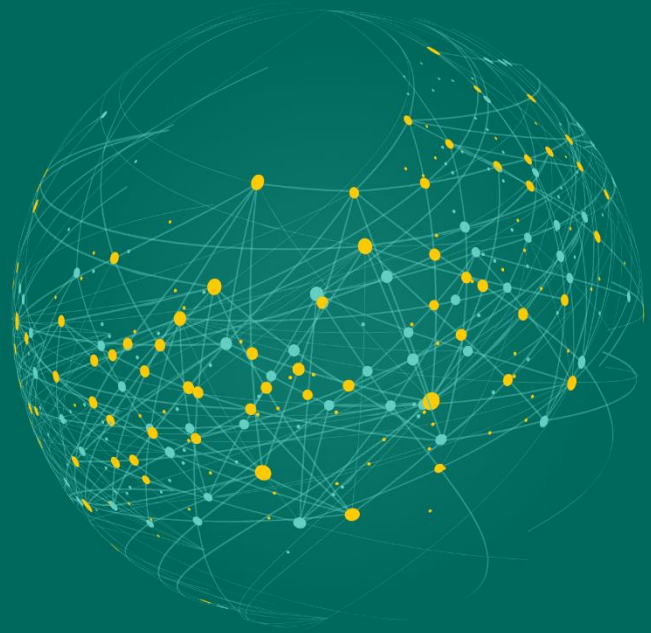
Large Area Low Intensity Shockwave Therapy (LALIS) for treating Women's Sexual Dysfunction and Stress Urinary Incontinence

Dr. Olga Majaj, Red Crescent Hospital



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Affiliations to disclose†:

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

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Our study's aim

- Prevalence of vaginal atrophy/G.S.M and their associated symptoms are well documented
- Minimally invasive treatment options for women suffering from symptoms such as vaginal pain, sexual dysfunction and/or stress incontinence remain limited
- Our aim was to evaluate a new energy-based treatment option with a potentially high safety profile for women suffering from SUI and/or Sexual Dysfunction
- Our study involved the administration of low intensity shockwaves - applied both topically and transvaginal
- Safety, patient comfort, side effects and clinical benefit were monitored

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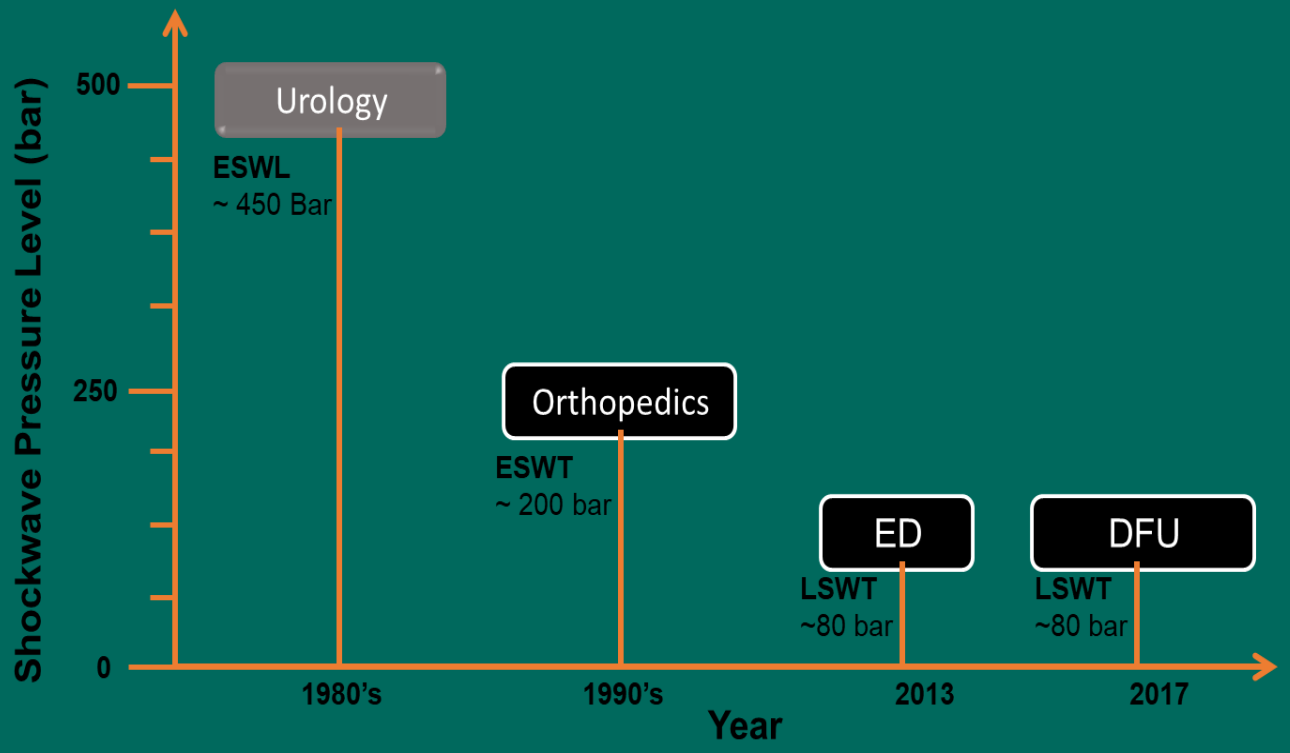
Shockwaves in medicine



- Being used since the 1980s – for fragmenting urinary tract stones
- Used for orthopedics (anti-inflammatory and for non-union fractures)
- Low intensity shockwaves were introduced almost 10 years ago for treating vasculogenic ED

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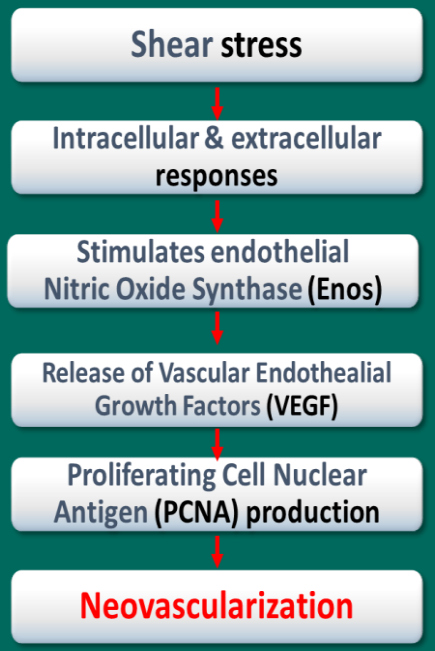
Low intensity shockwaves



- The known biological responses include angiogenesis, as well as the possible activation of progenitor/stem cells. Studies in-vitro and in-vivo have confirmed that low-intensity shockwaves enhance growth factors (TGF-β1) and collagen (types I and III), as well as increase nitric oxide (NO) release and activation of vascular endothelial growth factor (VEGF)

- The use of low intensity shockwaves for female and gynecological indications is still in its infancy.

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Published data – treating SUI with shockwaves

Original Article

Treatment of stress urinary incontinence with low-intensity extracorporeal shock wave therapy in a vaginal balloon dilation induced rat model

Alex K. Wu, Xiaoyu Zhang, Jianwen Wang, Hongxiu Ning, Uwais Zaid, Jaqueline D. Villalta, Guifang Wang, Lia Banie, Guiting Lin, Tom F. Lue

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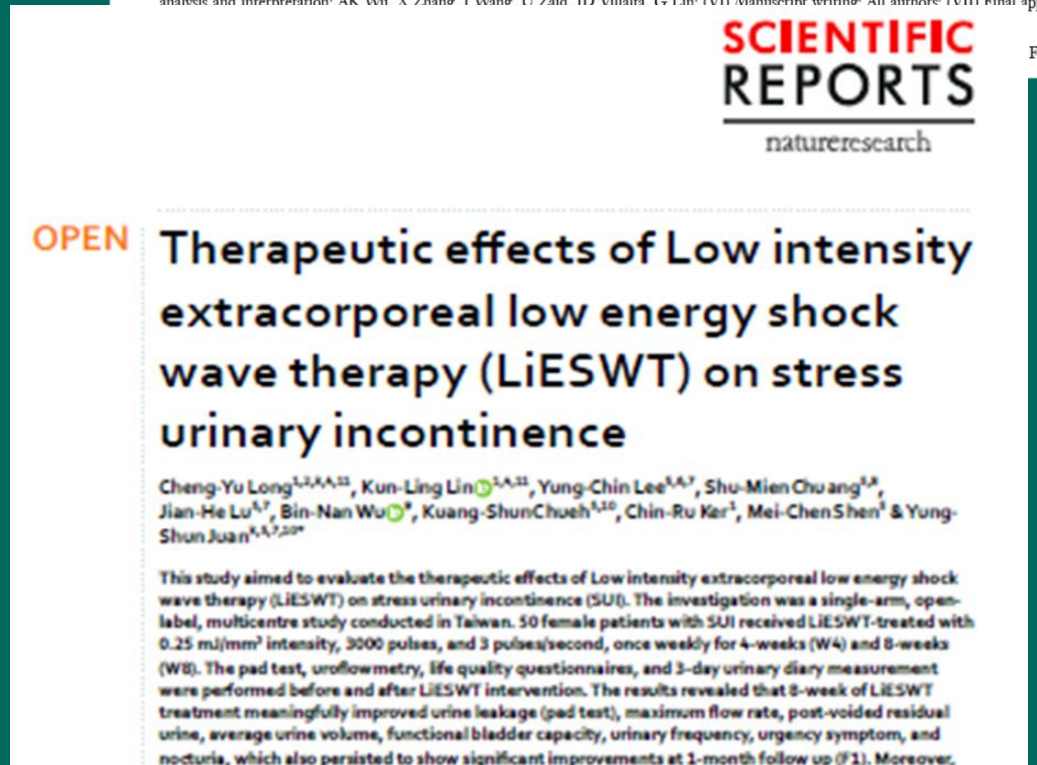
Contributions: (I) Conception and design: TF Lue, G Lin; (II) Administrative support: TF Lue, L Banie, G Lin; (III) Provision of study material or patients: TF Lue, AK Wu, G Lin; (IV) Collection and assembly of data: AK Wu, X Zhang, J Wang, H Ning, U Zaid, JD Villalta, G Wang ; (V) Data analysis and interpretation: AK Wu, X Zhang, J Wang, U Zaid, JD Villalta, G Lin; (VI) Manuscript writing: All authors; (VII) Final approval of

Francisco,



SCIENTIFIC REPORTS

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Therapeutic effects of Low intensity extracorporeal low energy shock wave therapy (LiESWT) on stress urinary incontinence

Cheng-Yu Long[1,2,3,4,11], Kun-Ling Lin[1,4,11], Yung-Chin Lee[5,6,7], Shu-Mien Chuang[3,8], Jian-He Lu[5,7], Bin-Nan Wu[9*], Kuang-ShunChueh[3,10], Chin-Ru Ker[1], Mei-Chen Shen[1] & Yung-Shun Juan[1,4,7,10*]

This study aimed to evaluate the therapeutic effects of Low intensity extracorporeal low energy shock wave therapy (LiESWT) on stress urinary incontinence (SUI). The investigation was a single-arm, open-label, multicentre study conducted in Taiwan. 50 female patients with SUI received LiESWT-treated with 0.25 mJ/mm² intensity, 3000 pulses, and 3 pulses/second, once weekly for 4-weeks (W4) and 8-weeks (W8). The pad test, uroflowmetry, life quality questionnaires, and 3-day urinary diary measurement were performed before and after LiESWT intervention. The results revealed that 8-week of LiESWT treatment meaningfully improved urine leakage (pad test), maximum flow rate, post-voided residual urine, average urine volume, functional bladder capacity, urinary frequency, urgency symptom, and nocturia, which also persisted to show significant improvements at 1-month follow up (F1). Moreover,

- A rat model introduced by a research team at UCSF (Lue et al) demonstrated that low intensity shockwaves ameliorated SUI by promoting angiogenesis and urethral sphincter regeneration
- Clinical trial from Taiwan (Long et al) was the first human SUI study – by applying shockwaves by suprapubic application

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Our study design

- We used a novel shockwave therapy device: *MoreNova* (__) capable of transvaginal applications due to its unique shockwave transducers that enable precise targeting of different shaped organs
- Shockwave energy used was 0.09mJoule/mm2 and applied simultaneously to large areas of tissue
- 21 patients suffering from SUI or sexual dysfunction or both participated in our pilot study

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Our study design

- Six applications: labia minora (bilateral), labia majora (bilateral) and two transvaginal applications; towards each side of the urethra
- A total of 2100 shocks per session that lasted approx. 20 minutes
- 6 sessions per patient, 3 weeks
- Undesirable events and patient complaints were recorded
- Clinical results were assessed with FSFI and ICIQ-UI questionnaires

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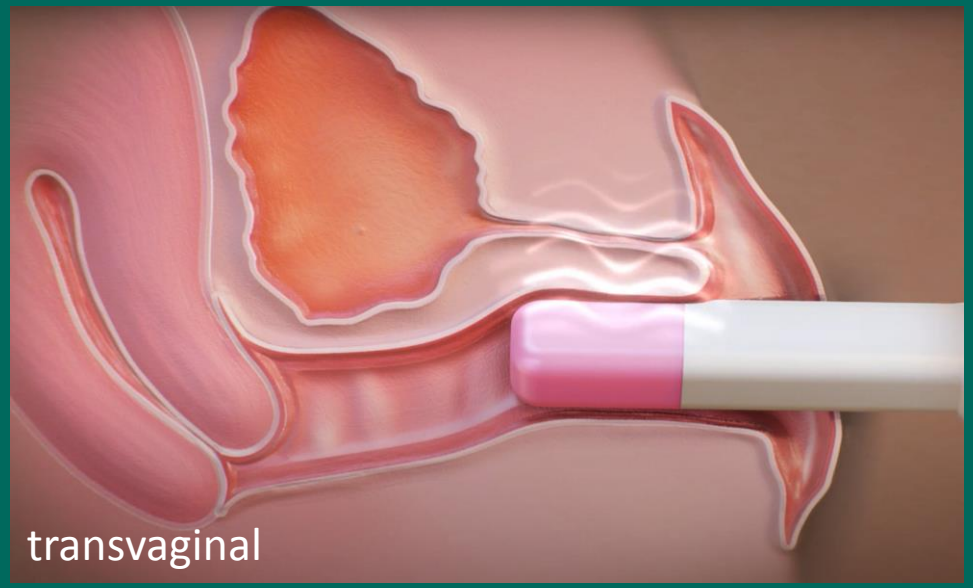
Clinical assumptions



- Low intensity shockwaves stimulate the release of growth factors in vaginal tissue, resulting in the generation of new blood vessels
- This would enhance sensitivity in the vagina and improve sensation
- This would increase natural lubrication production
- This would tighten tissue in the vaginal canal and strengthen muscles to improve continence

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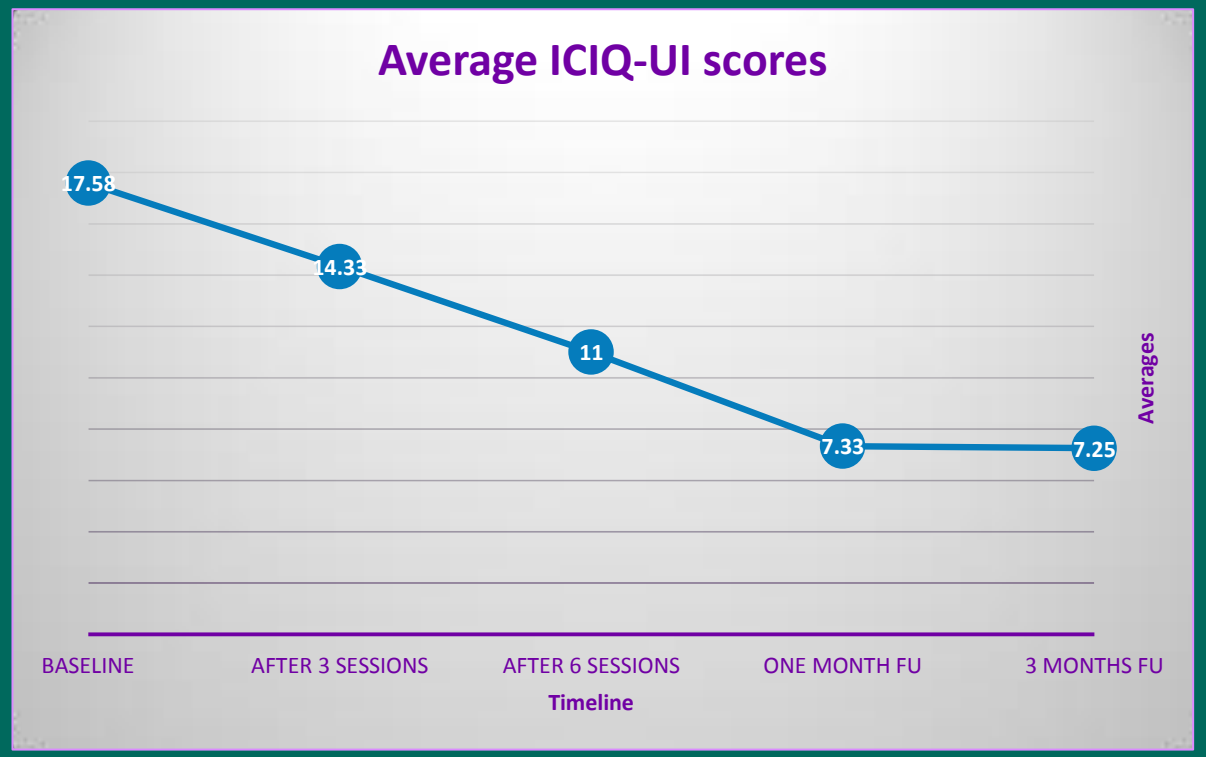
Study results



- 12 patients suffering from stress incontinence symptoms
- Average ICIQ-UI baseline score – 17.58
- 3 months post treatment score – 7.25
- No complaints about pain or discomfort, no side effects experienced
- General impression: _____

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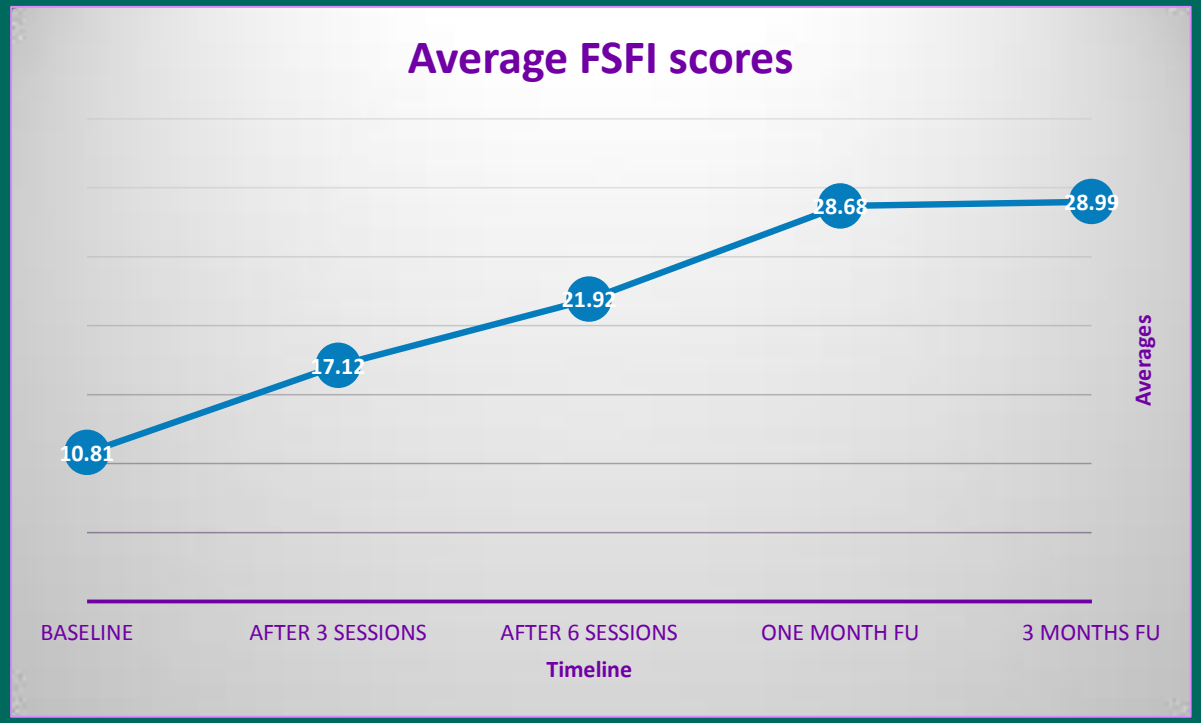
Study results



- 13 patients suffering from sexual dysfunction symptoms
- Baseline average FSFI score – 10.81
- 3 months post treatment score – 28.99
- No complaints about pain, discomfort. No side effects
- General impression: _____

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Conclusions and take-aways

Transvaginal shockwave therapy is a new and safe minimally invasive treatment option to be further investigated

Initial results from this study show promise in treatment of stress incontinence related or not related to sexual dysfunction

More elaborate studies involving control groups are required to better understand the benefit for women suffering from different types of urogynecology conditions

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Thank you

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