

# First Report for Unfocused Low Intensity SoftWave<sup>®</sup> Therapy (uESWT ) for Nocturia and Erectile Dysfunction (ED)

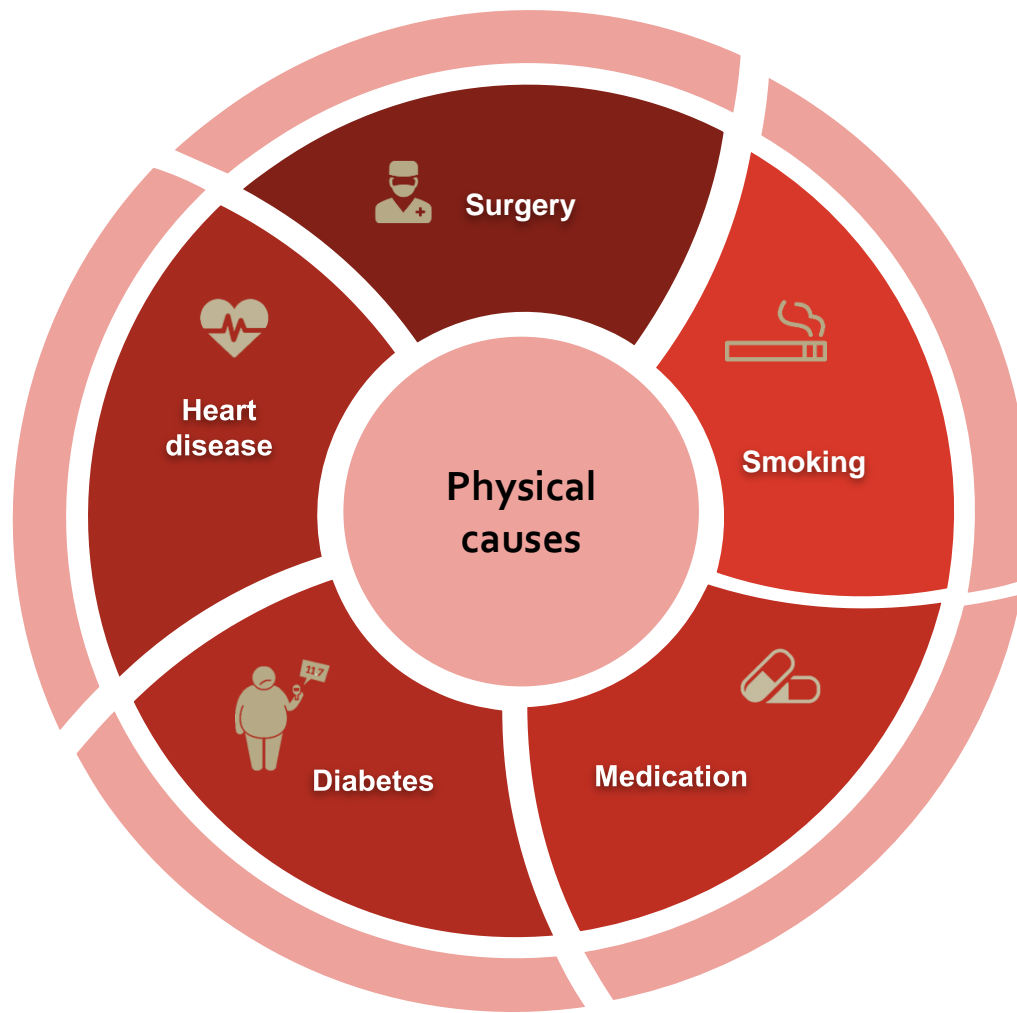
Brent Sharpe, MD

Phil Lavin, PHD

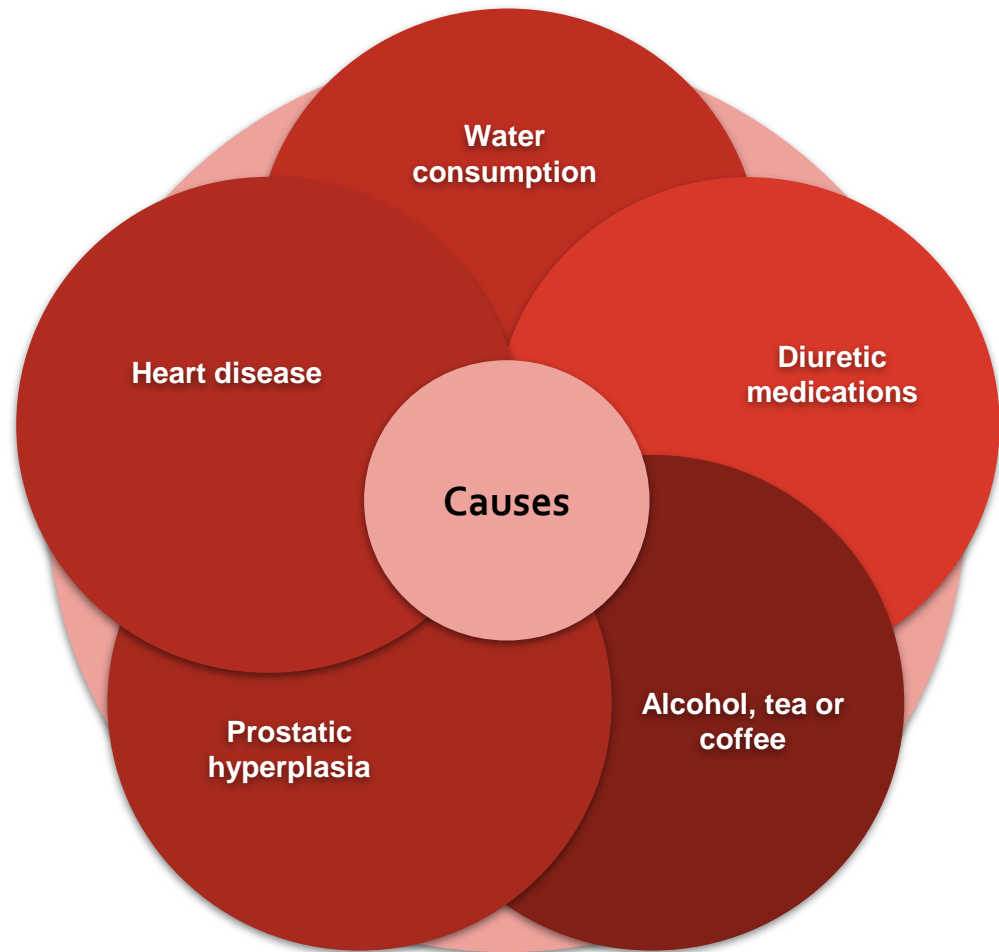
IRB study at Georgia Urology, Atlanta, USA



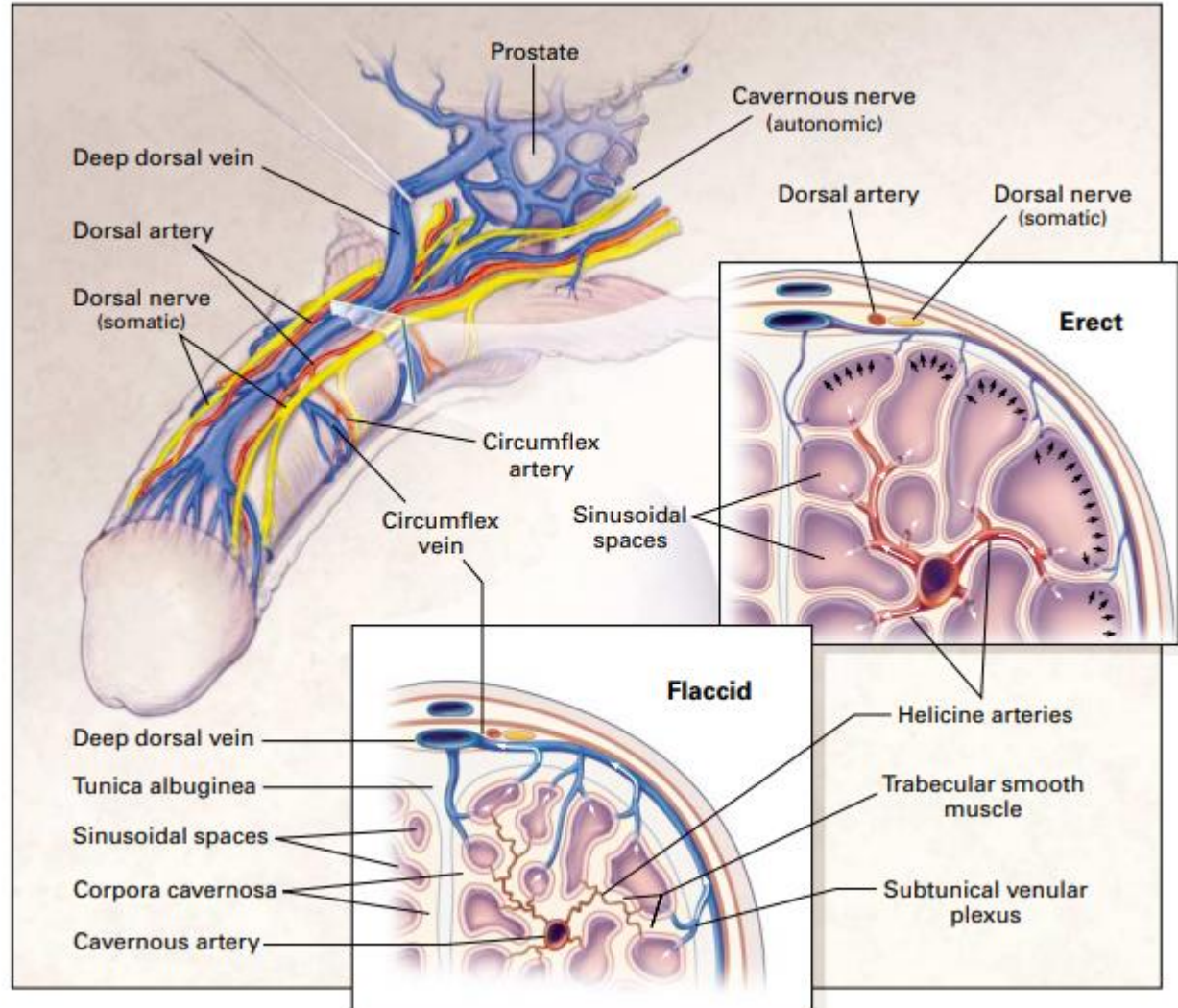
# Causes of Erectile Dysfunction (ED)



# Causes of Nocturia (night urination)



# Mechanism of a penile erection



## SWT in the US for ED

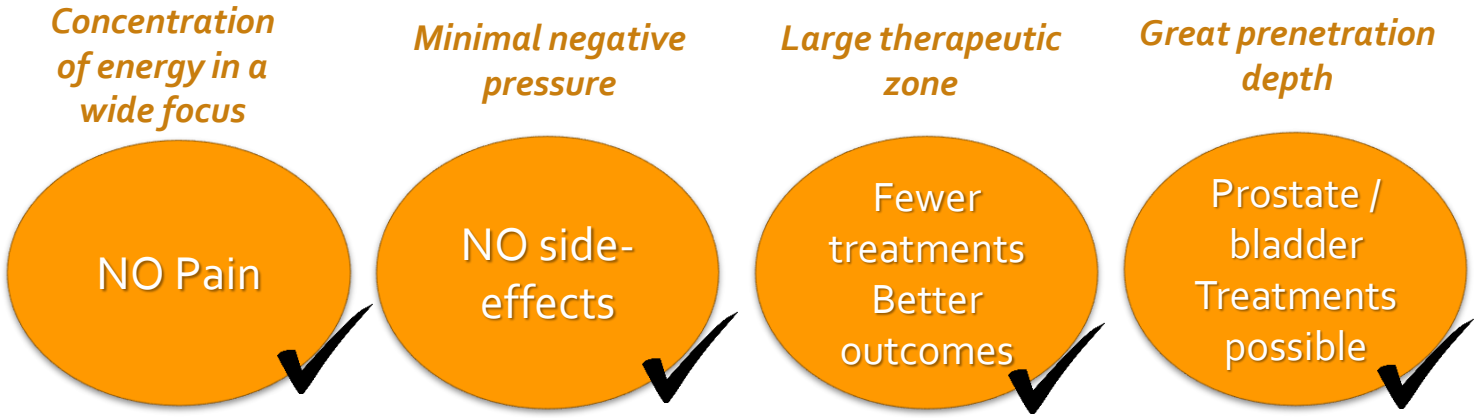
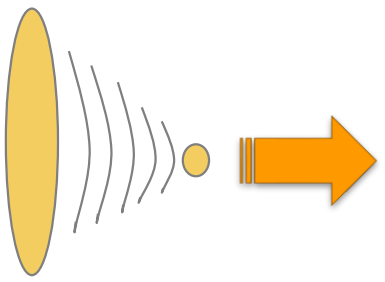


- Since 2007 at least 250.000 ED patients have been treated with shock wave therapy (SWT). The majority of them treated with radial / ballistic SWT devices by non-urologists (Source: TRT)
- The average success rate of SWT for ED is estimated at 50 % (Source: Mayo Clinic, presented at the ISSM Congress in Lisbon, Portugal, 2018)
- Demand for SWT by affected patients is growing rapidly

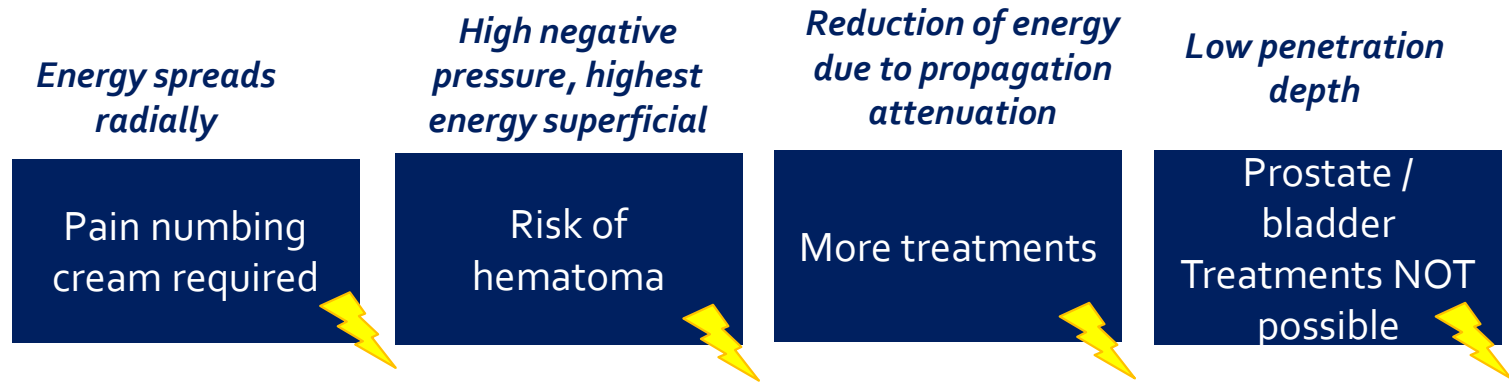
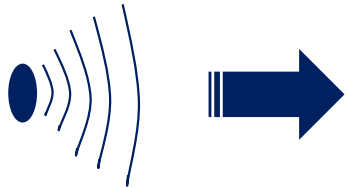


# SoftWave® Technology: Unfocused Applicator OP155

## TRT Soft Focus Spark Wave® Technology



## Radial Wave



SoftWave<sup>®</sup>  
Therapy for  
ED –  
case series of  
an effective  
protocol

## Case series of weekly low intensity shock wave (LiSW) therapy for erectile dysfunction

- **Methods:** Men with diagnosis of ED for at least 6 months were treated 4x weekly with low intensity shock wave at 6 treatment sites: one at each crus of the penis and 2 on the shaft bilaterally with about 500 shocks each for a total of 3000 shocks. Energy flux was 0.13 mJ / mm<sup>2</sup> and frequency was 4 Hz using the soft wide focused applicator
- **Results:** Eight men with a mean age of 56.8 and median duration of 36 months. Overall, SHIM score improved from 11.0 ± 3.6 to 17.2 ± 5.2 (p= 0.01). The treatments were painless and there were no side effects. SHIM was unchanged in 2 patients (25 %), mildly improved in 1 patient but not sufficiently for intercourse and significantly improved with erection sufficient for intercourse in 5 patients (62.5 %). Two of these 5 men required a PDE5i for optimal erections however both had failed PDE5i in the past
- **Conclusion:** Once weekly low intensity shock wave lithotripsy improved erections sufficient for intercourse in 62.5 % of our patients without side effects

SoftWave<sup>®</sup>  
Therapy for  
ED –  
case series of  
an effective  
protocol

## Effectiveness of shock wave therapy: implementation of a soft wide focus applicator in patients with erectile dysfunction

- **Methods:** Patients with diagnosis of vascular ED underwent a protocol of LI-ESWT once a week for 5 weeks, energy flux density 0.15 mJ and 3000 pulses per session
- **Results:** 20 patients with a mean age of 53.1 years. At admission, 70 % of patients had mild / moderate (n = 14), 20 % (n = 4) moderate and 10 % (n = 2) severe ED according to the IIEF-5 scale. After five sessions 25 % (n = 5), and after one month follow-up even 45 % (n = 9) of patients showed a clinical important difference (defined as an increase of  $\geq 4$  points) in the IIEF score with an average increase of 5 points ( $18 \pm 4.4$ ,  $p = 0.001$ ). Assessing the EHS, 55.5 % of patients at baseline (mean EHS:  $3 \pm 0.6$ ) had an erection insufficient to penetrate, this proportion decreased significantly to 28 % after therapy (mean EHS:  $4 \pm 0.7$ ,  $p = 0.05$ ), a beneficial effect that was still persisting after one month follow-up (mean EHS:  $4 \pm 0.7$ ,  $p = 0.04$ )
- **Conclusion:** The preliminary results of LI-ESWT in the treatment of ED indicate a clinically significant improvement in both, the IIEF and EHS by this technology



# Penile low intensity shock wave therapy for PDE5i non responders suffering long-term vasculogenic erectile dysfunction: A prospective, randomized, placebo-controlled study

SoftWave<sup>®</sup>  
Therapy for  
ED –  
case series of  
an effective  
protocol

- **Methods:** Prospective, randomized, simple-blind, sham-controlled study. In total 58 patients with vasculogenic erectile dysfunction refractory to PDE5i were randomized into two groups. 30 were treated with electrohydraulic low intensity shock waves (1 session/week for 6 weeks; 1.500 pulses of 0.10 mJ / mm<sup>2</sup> at 5 Hz, urogold100<sup>®</sup> MTS) and 28 were treated with a sham probe. Eleven patients withdrew from the study and were lost to follow-up. All patients were evaluated at baseline and 1 month after the end of treatment using validated erectile dysfunction questionnaires like the International Index of Erectile Function (IIEF-5) and the Sexual Encounter Profile (SEP). Demographic and clinical characteristics were recorded. Forty-one patients presented ED for 2-10 years; 22 in the active group and 19 in the sham group
- **Results:** 22 active-treated patients and 19 sham-treated patients, suffering from ED for 2-10 years were analyzed. There was no significant difference between the two groups in baseline characteristics. Baseline five-item version of the IIEF mean scores, in the active and sham groups, were  $10.0 \pm 4$  and  $9.9 \pm 4.6$ , respectively ( $p = 0.94$ ). At baseline, 14 % of patients in the active group (3 of 22) and 10.5 % of patients in the placebo group (2 of 19) had a positive answer to the SEP<sub>3</sub> question ( $p = 0.8$ ). One month after treatment IIEF-5 scores mean changes from baseline, in the active and placebo group, were  $2.2 \pm 4.9$  and  $0.25 \pm 4.4$ , respectively ( $p = 0.2$ ). After LIST, SEP<sub>3</sub> positive responders increased by 33 % in the active group (7 of 22) and decreased by 5 % the placebo group (1 of 19) ( $p = 0.03$ )
- **Conclusion:** In this prospective study, a six week treatment with a moderate protocol of penile LIST led to partial recovery of erectile function at one-month follow up. SEP<sub>3</sub> positive responders significantly increased in the active treated group when compared to the placebo group. More studies with larger sample size and longer follow-up, comparing different lithotripters and shock wave protocols, are imperative to define the real role of LIST in the treatment of erectile dysfunction

## Objective

Evaluate the effectiveness and safety of unfocused, electrohydraulic uESWT for ED and Nocturia

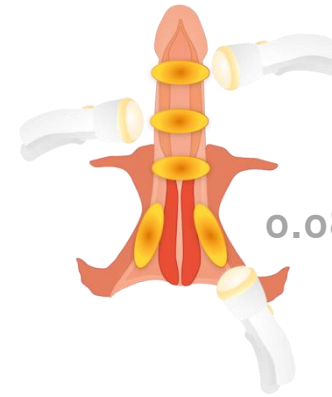
# Methods

**n= 15**  
With ED

- 11 with nocturia
- 10 with weak urine flow



Age 54 to 80  
(64 average)



2000 pulses -  
0.08 – 0.1 mJ / mm<sup>2</sup>

6 treatments per person at  
the shaft ,crura and  
perineum during 6-10 weeks

Ask % of improvement  
(0-100 %)



Post treatment  
questionnaire after 12  
weeks

Patients paid \$ 1500 to participate in  
the study

## Results

We report the first ever results for uESWT and Nocturia

### ED improvement relative to the baseline (n=15)

---

- **Overall all patients significantly improve 47 %** [Two-sided 95 % confidence interval for % improvement: (34.3 %, 60.3 %)] ✓
- **12 patients (80 %) significantly improve at least 40 %** [Two-sided 95 % lower confidence interval for  $\geq 40$  % improvement: 51.2 %]
- 1 patient 100 % improvement
- 1 patient 80 % improvement
- 2 patients 60 % improvement
- 5 patients 50 % improvement
- 3 patients 40 % improvement
- Nocturia improved even faster (3 weeks) than ED symptoms (10 weeks)
- **All patients reported that they wanted to continue the protocol and would pay for more treatments**

# Results

## NOCTURIA improvement relative to the baseline (n=11)

- **The average decrease in bathroom visits was 46 %** [Two-sided 95 % confidence interval for % improvement: (25 %, 67.4 %)]
- **73 % patients significantly improved at least 50 %** [Two-sided 95 % lower confidence interval for  $\geq 50$  % improvement: 39 % ] ✓
- 2 patients decreased bathroom visits from 6 to 1
- 1 patient improved 75 %
- 1 patient improved 66.7 %
- 4 patients improved 50 %
- Patients reported these improvements in the early weeks (3<sup>rd</sup> week)
- Improved urine flow

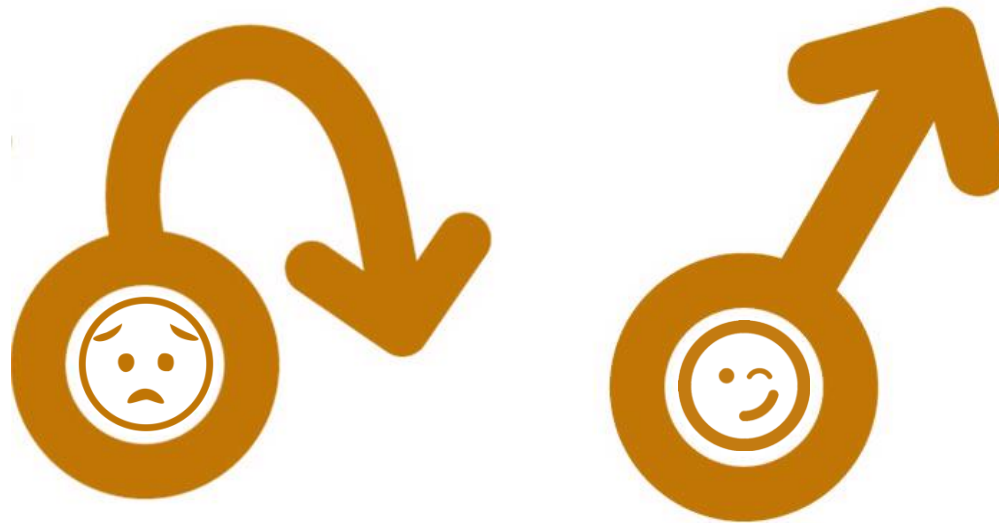
### Remarks

As early as week 2, several patients reported that they urinated less frequently at night and attributed this improvement to the uESWT

# Conclusions

- Multi-dimensional efficacy of electrohydraulic unfocused Low Intensity SoftWave<sup>®</sup> Therapy for ED and Nocturia
- Both ED and Nocturia patients showed significant improvement with the uESWT treatment
  - **ED:** Overall mean **47.3 % improvement**
  - **Nocturia:** Overall mean **46.2 % improvement**, less frequent urination at night
- Unfocused SoftWaves are an efficient, reliable and painless non-invasive therapy option to treat ED and Nocturia
- Our practice has decided to offer uESWT to our patients

Thank you for your attention!!



In cooperation with



**TRT**  
Tissue Regeneration Technologies  
(888) 862-6162

