

SAFETY AND EFFICIENT DURATION OF LINEAR FOCUSED SHOCKWAVE TREATMENT FOR ERECTILE DYSFUNCTION: A 12 MONTHS FOLLOW-UP PILOT STUDY

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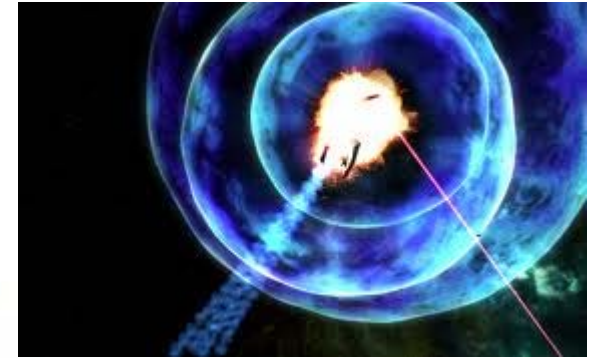
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Background



- Shockwaves are special acoustics waves that can be targeted and focused non-invasively
- Therapeutic effect is localized and precise (<2mm)
- In vitro and in-vivo data show angiogenic effect and neo-vascularization after LI-ESWT treatment

Studies have demonstrated that low intensity shockwaves have a therapeutic effect on ED of vascular origin.

Can Low-Intensity Extracorporeal Shockwave Therapy Improve Erectile Function? A 6-Month Follow-up Pilot Study in Patients with Organic Erectile Dysfunction

*Yoram Vardi *, Boaz Appel, Giris Jacob, Omar Massarwi, Ilan Gruenwald* EUROPEAN UROLOGY 58 (2010) 243–248

Does Low Intensity Extracorporeal Shock Wave Therapy Have a Physiological Effect on Erectile Function? Short-Term Results of a Randomized, Double-Blind, Sham Controlled Study

Yoram Vardi,,† Boaz Appel, Amichai Kilchevsky and Ilan Gruenwald* THE JOURNAL OF UROLOGY May 2012

Mean IIEF-EF

in the treated group increased by 6.7

in the sham group increased by 3.0 points (p= 0.0322)

Aim

- A pilot study was to assess the effectiveness and sustainable results of the Linear Focused Shockwave system (Renova) for the treatment of Vascular Erectile Dysfunction patients.
- 12 Month follow-up



Treatment Protocol

LSWT is applied to the entire penile shaft and crura (energy intensity of 0.09 mj/mm² per shock)

Treatment parameters are as follows:

Treatment frequency: 300 shocks/min

Application areas: 4

Number of shockwaves: 900 per application area

Number of treatment sessions: 4 – once a week for four weeks.

- **Assessment:**

- International Index of Erectile Function (IIEF-EF)

- Sexual Encounter Profile (SEP)

- 2.Over the past 4 weeks, were you able to insert your penis into your partner's vagina?

- 3.Over the past 4 weeks, did your erection last long enough for you to have successful intercourse?

- Global Assessment Question (GAQ)

- 1.Over the past 4 weeks, has the treatment you have been taking improved your erectile function?

- 2.Has the treatment improved your ability to engage in sexual activity over the past 4 weeks?

- At baseline and 1, 3, 6 and 12 month post treatment

Inclusion Criteria

- ED for at least 3 months.
- International Index of Erectile Function (IIEF-ED) between 10 to 24 (= mild to moderate)
- Responders and Non-Responders
 - Positive response to PDE5i (able to penetrate on demand = 'Responder')
 - Negative response to PDE5i (unable to penetrate on demand even with maximum PDE5i dosage = 'Non-responder').
- Non-hormonal, neurological or psychological pathology

Exclusion Criteria

- Psychogenic ED
- Neurological pathology
- Past radical prostatectomy
- Any unstable medical, psychiatric, spinal cord injury and penile anatomical abnormalities
- Clinically significant chronic hematological disease
- Anti-androgens, oral or injectable androgens
- Radiotherapy in pelvic region

- Success defined as increase of IIEF-EF score according to severity of symptoms by clinically importance

IIEF-EF Baseline Score	Success Factor
6-10	improvement of 7 points or more
11-16	improvement of 5 points or more
17-25	improvement of 2 points or more

Rosen RC et al. European Urology, 2011;60(5):1010-6

Results

- 20 patients
- Age: : 60.6 ± 5.7
- 55% cardiovascular disease; 40% DM
1 patients show vascular ED on doppler
- No adverse events or use of pain killers

Results at baseline, 6 and 12 months follow-up

	Baseline	6 months	12 months	p
% Success (N)		90% (18)	75% (15)	
IIEF-EF score	12,35±3,2	20,65±2,6	18,65±2,6	<0,05
SEP-Q 2 % success	50	90	90	<0,05
SEP-Q 3 % success	5	55	40	<0,05
GAQ- Q1 %success		90	80	
GAQ- Q2 %success		60	45	
PDE5i response	80%		100%	

4 PDE-5i non responders become responders; 2 stopped using PDE5-i

Conclusion

- **Promising treatment modality**
 - **75% positive effect after 1 year**
- **Safe treatment**
- **Larger randomised trials are needed**
- **More understanding of physiological effect is needed.**
- **Improvement but not cure**