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

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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.

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

<table>
<thead>
<tr>
<th>IIEF-EF Baseline Score</th>
<th>Success Factor</th>
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<tbody>
<tr>
<td>6-10</td>
<td>improvement of 7 points or more</td>
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<tr>
<td>11-16</td>
<td>improvement of 5 points or more</td>
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<tr>
<td>17-25</td>
<td>improvement of 2 points or more</td>
</tr>
</tbody>
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Rosen RC et al. European Urology, 2011;60(5):1010-6
Results

- 20 patients
- Age: $60.6 \pm 5.7$
- 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

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 months</th>
<th>12 months</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td><strong>% Success (N)</strong></td>
<td></td>
<td>90% (18)</td>
<td>75% (15)</td>
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<tr>
<td>IIEF-EF score</td>
<td>12,35±3,2</td>
<td>20,65±2,6</td>
<td>18,65±2,6</td>
<td>&lt;0,05</td>
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<tr>
<td>SEP-Q 2 % success</td>
<td>50</td>
<td>90</td>
<td>90</td>
<td>&lt;0,05</td>
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<tr>
<td>SEP-Q 3 % success</td>
<td>5</td>
<td>55</td>
<td>40</td>
<td>&lt;0,05</td>
</tr>
<tr>
<td>GAQ- Q1 %success</td>
<td></td>
<td>90</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>GAQ- Q2 %success</td>
<td></td>
<td>60</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>PDE5i response</td>
<td>80%</td>
<td>100%</td>
<td></td>
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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**