New Technologies for Treatment of Premature Ejaculation

Dr. Arik Shechter, M.D.
Sexual Medicine Clinic
Neurourology Unit
Rambam Healthcare Campus, Haifa, Israel
No innovative technological treatments for over 20 years
Erotic Literature
For Premature Eyaculators.

Chapter I

She looked at him.

The end.
**clinicaltrials.gov Search for ‘device for Treatment of Premature Ejaculation’**

<table>
<thead>
<tr>
<th>No.</th>
<th>Status</th>
<th>Study Title</th>
<th>Conditions</th>
<th>Interventions</th>
<th>Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Recruiting</td>
<td>Evaluation of the Safety and Effectiveness of the vPatch Device</td>
<td>• Premature Ejaculation</td>
<td>• Device: Active Device (vPatch)</td>
<td>• Sexual Dysfunction Clinic, Rambam Medical Center, Haifa, Israel</td>
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<td></td>
<td></td>
<td></td>
<td>• Premature Ejaculation</td>
<td>• Device: Sham Device (vPatch)</td>
<td>• Urologia, Casa di Cura “Villa Donatello”, Sesto Fiorentino, Firenze, Italy</td>
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<td></td>
<td></td>
<td></td>
<td>• Premature Ejaculation</td>
<td></td>
<td>• U.O.C. Urologia e Centro di litotrasia urinaria D.A.I. Nefrologia, urologia e chirurgia generale e dei transplant di rene, anestesia e rianimazione, A.O.U. “Federico II” di Napoli, Napoli, Italy</td>
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<tr>
<td>2</td>
<td>Completed</td>
<td>Efficacy of a New Behavioral Treatment for Premature Ejaculation Using a Masturbation Aid Device Star-Stop 3.0</td>
<td>• Premature Ejaculation</td>
<td>• Device: Exercise Programme + device + lubricant</td>
<td>Jesús Rodríguez, Murcia, Spain</td>
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<tr>
<td>3</td>
<td>Recruiting</td>
<td>Cases Series App + Electronic Device for the Treatment of Premature Ejaculation</td>
<td>• Premature Ejaculation</td>
<td>• Device: Sphincter Control Training (SCT)</td>
<td>Jesús Rodríguez, Murcia, Spain</td>
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<tr>
<td>4</td>
<td>Completed</td>
<td>A New Treatment for Premature Ejaculation?</td>
<td>• Premature Ejaculation</td>
<td>• Device: FLIP HOLE</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Unknown</td>
<td>Safety Demonstration of Increasing Intensities of Electrical Stimulation Delivered to The Bulbospongiosus Muscle</td>
<td>• Premature Ejaculation</td>
<td>• Device: TENS Stimulator</td>
<td>Rambam Health Care Campus, Haifa, Israel</td>
</tr>
</tbody>
</table>
RECENT PUBLISHED WORKS ON TECHNOLOGIES for PE

• Israel - Transcutaneous Perineal Electrical Stimulation.

• China - Selective Dorsal Neurectomy.

• Spain - Sphincter Control Training (SCT), a new cognitive behavioral approach.
TRANSCUTANEOUS PERINEAL ELECTRICAL STIMULATION
In the Treatment of Premature Ejaculation

Medical Hypotheses
Volume 109, November 2017, Pages 181-183

Transcutaneous neuromuscular electrical stimulation may be beneficial in the treatment of premature ejaculation

Ilan Gruenwald a, Ege Can Serenoglu b, Tal Gollan c, Shmuel Springer d, Gideon Meiry e, Boaz Appel a, Arik Shechter a, e, g, m
Transcutaneous functional electrical stimulation—a novel therapy for premature ejaculation: results of a proof of concept study

Arik Shechter¹,² · E. C. Serefoğlu³ · Tal Gollan⁴ · Shmuel Springer⁵ · Gideon Meiry⁴ · Boaz Appel¹ · Ilan Gruenwald¹

Disclosure:
• Arik Shechter served as an Investigator and consultant at Virility Medical Ltd.
• Ilan Gruenwald served as Principal Investigator at Virility Medical Ltd.
• Study was sponsored by Virility Medical Ltd.
Introduction and Method (1)

Objectives:

To evaluate the safety and efficacy of Transcutaneous functional electrical stimulation (TFES) for the treatment of Premature Ejaculation (PE).

Materials and methods:

- Prospective, single-blinded, self-controlled study, (n=23) aged 20-60 self-reporting PE patients.

- On the first visit, we alternately delivered either TEFS or sham treatment to the perineum, based on enrollment order.

- For stimulation, we used a commercial neuro-muscular electrical stimulation device.
Materials and methods (cont.):

- The alternating second treatment was given to the same subject after a minimal period of one week.

- In order to determine the intensity threshold for muscle contraction, we gradually increased TEFS intensity by 0.5 mA, until reaching the patient’s first sensation of convenient muscle contraction in the stimulated area. Maximal intensity was limited to 25mA max.

- After defining the individual intensity-threshold during the pre-study test, the patient was left alone in the room to self-stimulate.
Materials and methods (cont.):

- Using a stopwatch, the patient measured the time-interval between full erection and ejaculation, namely his individual ‘Masturbating Ejaculatory Latency Time’ (MELT).
- All MELT results were recorded from both visits.
- The patients filled-out safety related questionnaires after each visit and on each of the three following days after stimulation.
Twenty patients completed the study.

Self-controlled ejaculation latency time was compared.

In 17 out of the 20 patients (85%), TFES considerably prolonged MELT.

### Safety

<table>
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<tr>
<th>% of patients</th>
<th>No AE</th>
<th>Minor AE</th>
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<tr>
<td>95%</td>
<td></td>
<td>5%</td>
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</table>
Results (2)

- Significant improvement compared with shams in 17 patients (85%). Overall MELT increased by 3.5-fold ($p<0.001$) and by 4.5-fold in responders.

**Baseline (sham):**
Av: 92.9 (SD=72.91) sec
Median: 60.0 sec

**Treatment:**
Av: 325.2 (SD=254.55) sec
Median: 261.0 sec

![Graph showing efficacy comparison between Baseline and Treatment](chart.png)
Discussions & Conclusions

1. 85% responded to the treatment.

2. Using Transcutaneous Functional Electrical Stimulation, we demonstrated a significant increase in Masturbating Ejaculatory Latency Time (X3.5 over all x 4.5-fold in responders)

- Main limitations: Masturbation- not Coitus, Uncomfortable device
- Conclusion: Miniaturized perineal on-demand stimulation device which can be used in a home setting during sexual intercourse, has the potential to become the first-line treatment for PE.
Solution - The vPatch

- Wearable, discrete and non-painful
- Immediate effect
- Drug free
- Single-use & disposable
Usability-on demand during intercourse

Apply

Remove liner and apply the patch. Device can be worn even hours before activation.

Ready

Press On button. Intensity will automatically ramp up. No additional attention is required.

Done

Remove and discard of the patch.
35 PE patients

Cognitive behavioral therapy with and without masturbation aid device (Tenga Egg)

Two treatment groups completed training over 7 weeks.

The training consists of four different exercises and an educational session.

The objective was to provide patients with greater control of the external urethral sphincter.
Results: 

- Group with the device (n=18) mean = 166.63 (SD = 106.54).
  Less than 3 minutes (SD almost two minutes)

- Group without the device (n=17) mean = 86.99 (SD = 59.98).

Significance: p = 0.008

- No SHAM control group
PAST PUBLISHED WORKS

Usability-Training aid-NOT during intercourse-NOT on demand

Pelvic-floor muscle rehabilitation

Transrectal pudendal nerve stimulation


Transcutaneous Posterior Tibial nerve stimulation (2019) – Ahead of print: 11 men, thirty six 30 min sessions of stimulation, 6 men reached goal (X3 increase in IELT)

Transdermal, Penile wearable device using local neuromodulation to delay ejaculation
22nd CONGRESS
OF THE EUROPEAN SOCIETY FOR SEXUAL MEDICINE
A grow from basic science to clinical practice
January 23–25, 2020
Prague, Czech Republic
www.essm.org

Hosted by:
Society for Sexual Medicine of Czech Republic (CSSM)