



urogold100[®] SparkWave[®] Therapy

for patients with Erectile Dysfunction,
CPPS and IPP



MTS Medical UG

About MTS Medical UG:

- Development, manufacture & distribution of Spark Wave™ therapy systems for
 - orthopedics/ traumatology
 - wound care
 - urology
- Location: Konstanz, Germany
- Active: Global player - internationally registered
- CEO: Nikolaus Hopfenzitz



ESWL
MADE IN
GERMANY

Treatment of ED with urogold100®



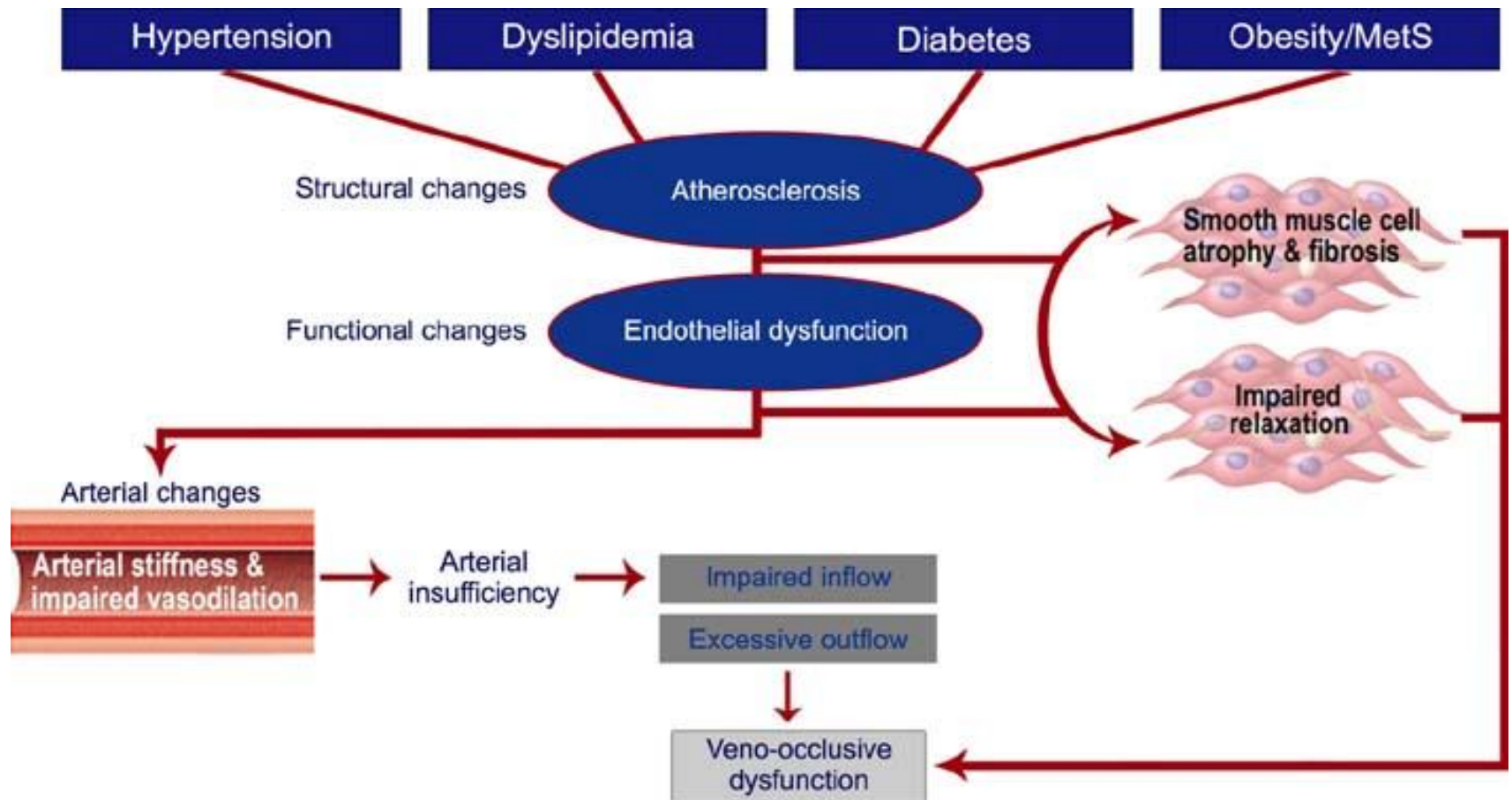
- Design: light – compact – mobile Transportable device for therapeutic Spark Wave™ treatment
- Handling: Comfortable in handling while operating with touchscreen
- Combinable with **3 applicators**:
 - unfocused
 - focused
 - soft-focused

for the treatment of:

- **Erectile dysfunction (ED)**
- **Chronic pelvic pain (CPP) / *chronic prostatitis***
- **Peyronie's disease (IPP)**



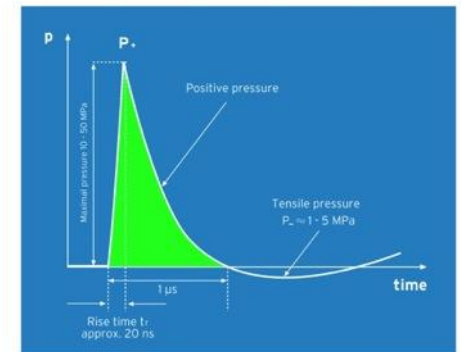
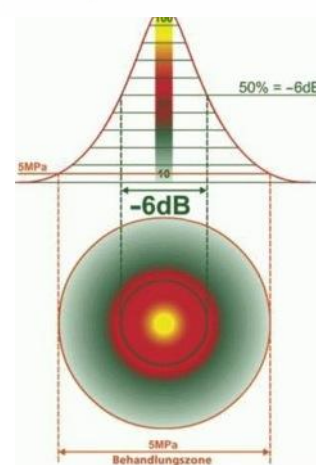
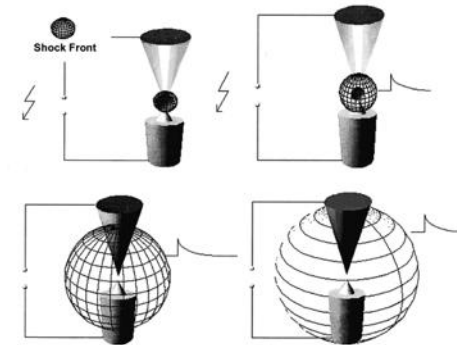
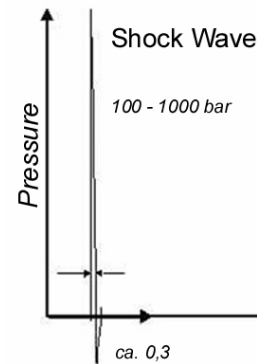
Pathophysiology of Vasculogenic Erectile Dysfunction: Endothelial Dysfunction





What are Spark Waves™?

- **Spark Waves™**
highly effective shock waves that initiate biological regeneration processes on cellular level
- **Generating principle**
spark gap in water quench
- **Spark Wave™ characteristics:**
 - High peak pressure (up to 100MPa)
 - Fast pressure rise (<10ns)
 - Short lifecycle (<10ms)
 - Positive and negative pressure phase

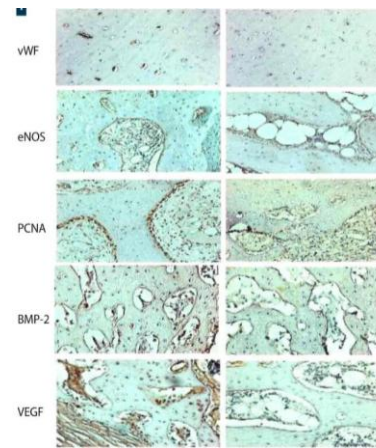




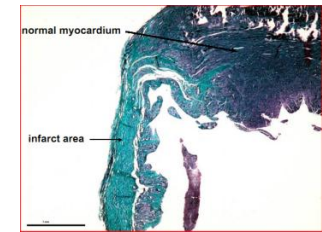
How do Spark Waves™ work?

Stimulation of healing process on cellular level by:

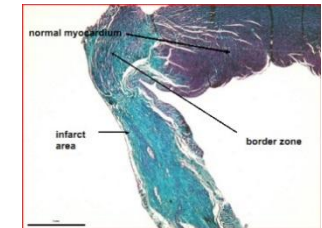
- Promotion of body's own production of **growth factors** (VEGF, eNOS, PCNA etc.)
- Promotion of development of **new blood vessels** (angiogenesis)
- Migration of **stem cells**
- Promotion of **blood circulation**
- Bactericidal effect (in vitro)
- Reduction of inflammation processes
- Bioengineering & **Tissue Regeneration**



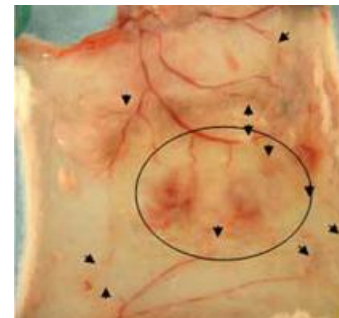
Growth factors



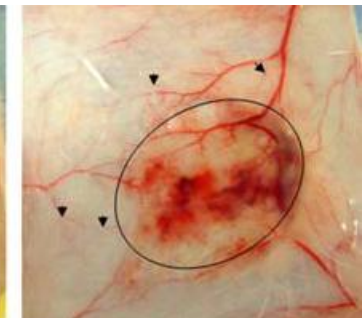
Myocardium stem cell migration



Results of 8 weeks after Spark Waves



Before ESWT



7 days after ESWT

SparkWave[®] Therapy - experimental studies



Author, publication	Title	MTS Reference center
<p>1. <i>Xuefeng Qiu, MD, Tom F. Lue, published in J Sex Med. 2013 Mar; 10(3): 738–746</i></p>	<p><i>Effects of low-energy SWT on the erectile function and tissue of a diabetic rat model</i></p>	<p>University of California, San Francisco</p>
<p>2. <i>Li, H., Lue, T. et al., published in J. Sex. Med. 13, 22–32 (2016)</i></p>	<p><i>Low-energy Shock Wave Therapy Ameliorates Erectile Dysfunction in a Pelvic Neurovascular Injuries Rat Model</i></p>	<p>University of California, San Francisco</p>

Spark Wave® therapy for ED - experimental studies



Study University of California, San Francisco

Qiu et al. „Effects of low-energy SWT on the erectile function and tissue of a diabetic rat model“ (2013)

Methods:

- 24 male rats, 3 groups: control group, DM-induces group & DM-induced group that received trice per week for two weeks Spark Wave™ therapy
- After 4 weeks all rats were evaluated for erectile function & penile tissues were examined by histology

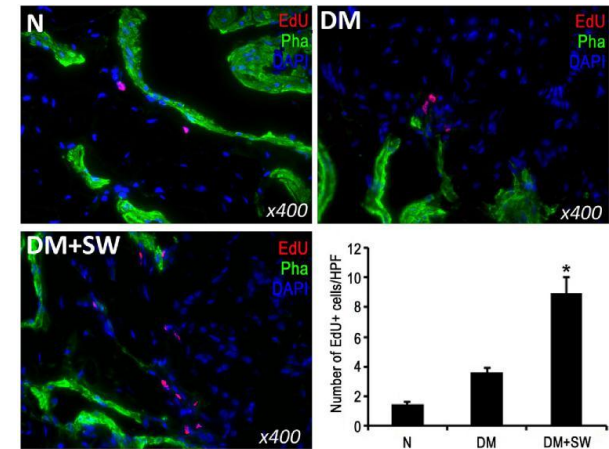


Spark Wave® therapy for ED - experimental studies



Qiu et al. „Effects of low-energy SWT on the erectile function and tissue of a diabetic rat model“ (2013)

- **Results:** DM-associated deficits (decrease in erectile function, reduction of nNOS-positives nerves and endothelial & reduction of smooth muscle contents) were significantly reversed by Spark Wave™ therapy
- **Conclusion:** Spark Wave™ therapy ameliorates DM-associated erectile dysfunction



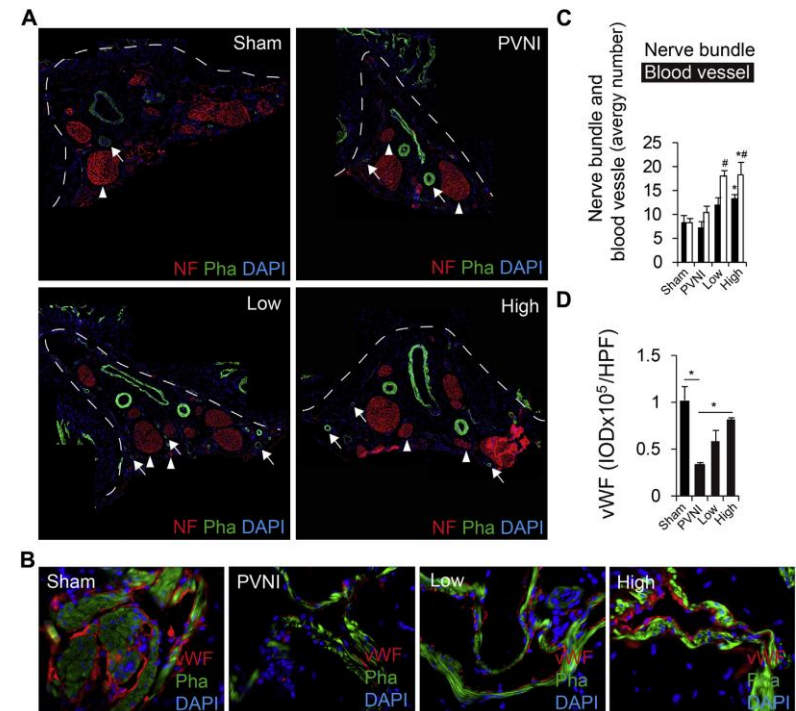


Spark Wave® therapy for ED

- experimental studies

Lue T. et al.: Low-energy Shock Wave Therapy Ameliorates Erectile Dysfunction in a Pelvic Neurovascular Injuries Rat Model. J Sex Med 2016

- Methods:** 32 rats injected with 5-ethynyl-20-deoxyuridine (EdU) at newborn were divided into 4 groups: sham surgery (Sham), after pelvic neurovascular injury treated with LESW at low energy. in vitro studies were conducted.
- Conclusion:** LESW-induced endogenous progenitor cell recruitment and Schwann cell activation coincides with angiogenesis, tissue, and nerve generation in a rat model of pelvic neurovascular injuries.



SparkWave[®] Therapy for ED

- clinical studies



Author, publication	Title	MTS Reference center
<p>1. Curbelo et al., published at the 20th ISMST congress in San Sebastian 2017</p>	<p>Penile low-intensity shock wave therapy for PDE5i non-responders suffering from vasculogenic erectile dysfunction since 2-10 years: A prospective, randomized, placebo-controlled study (2016)</p>	<p>Fundació Puigvert, Barcelona</p>
<p>2. Saffón et al., published at the 23rd WAS congress in Prague 2017</p>	<p>Effectiveness of shock wave therapy: implementation of a soft wide focus applicator in patients with erectile dysfunction</p>	<p>Boston Medical Group, Colombia</p>
<p>2. Shoskes et al., published at the 20th ISMST congress in San Sebastian 2017</p>	<p>Case series of weekly low intensity shock wave (LiSW) therapy for erectile dysfunction</p>	<p>Cleveland clinic, Glickman Urological and Kidney Institute</p>
<p>2. Ramon et al., published at the 20th ISMST congress in San Sebastian 2017</p>	<p>Efficacy of extracorporeal shockwave therapy (ESWT) for male chronic pelvic pain syndrome: a phase III, randomized, double blind controlled with placebo study</p>	<p>Quiron Hospital, Barcelona</p>

SparkWave[®] Therapy for ED - PDE5i – non-responder



Curbelo et al., Fundació Puigvert, Barcelona

Penile low intensity shock wave therapy for PDE5i non-responders suffering from vasculogenic Erectile Dysfunction since 2 to 10 years: A prospective, randomized, placebo-controlled study (2016)

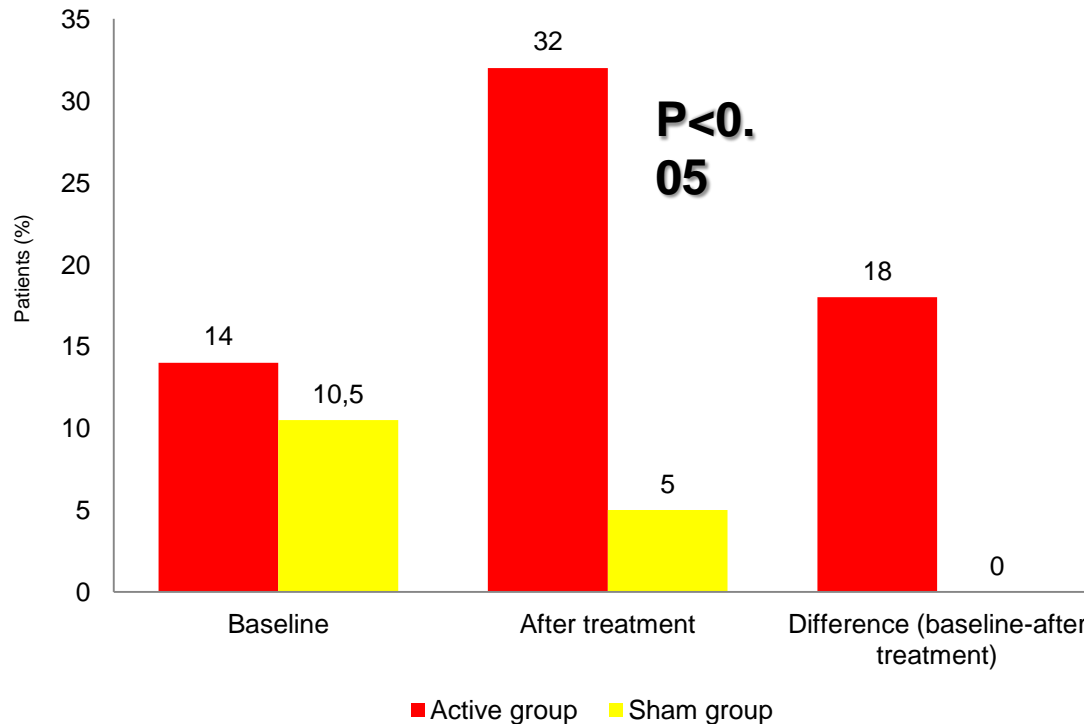
- **Methods:** In total 58 patients with vasculogenic erectile dysfunction refractory to PDE5i were randomized into two groups. 30 were treated with electrohydraulic low intensity shock waves (1 session/week for 6 weeks; 1,500 pulses of 0.10 mJ/mm² at 5 Hz, urogold100® MTS) and 28 were treated with a sham probe.
- **Results:** 22 active-treated patients and 19 sham-treated patients, suffering from ED since 2-10 years were analyzed. One month after treatment IIEF-5 scores mean changes from baseline, in the active and placebo group, were 2.2 ± 4.9 and 0.25 ± 4.4 , respectively ($p= 0.2$). SEP 3 positive responders increased by 33% in the active group (7 of 22) and even decreased in the placebo group to 5% (1 of 19) ($p=0.03$) after LIST.



SparkWave[®] Therapy for ED - PDE5i – non-responder

Variation of SEP-3 values: Basal vs. after one month of treatment


Results



SEP-Q3: Did your erection last long enough for you to have successful intercourse?

SparkWave® Therapy for ED – Poster presentations





Case Series of Weekly Low Intensity Shock Wave Therapy for Erectile Dysfunction

Daniel A Shoskes MD, Nic Tadros MD, Brandon Mooney PA
All Cleveland Clinic, Department of Urology, Glickman Urological and Kidney Institute

Introduction

Low Intensity Shock Wave (LISW) has emerged as a therapy for vasculogenic erectile dysfunction (ED). Mechanism may be related to angiogenesis, release of growth factors and/or recruitment of stem cells.

Several sham controlled studies have shown improvement in peak arterial velocity and efficacy in the 60-65% range depending on the definition.

The initial protocol of twice weekly treatments for 3 weeks with a rest period and repeat has remained the standard, although this can be very inconvenient for patients. We wished to study the efficacy and safety of LISW using a modified protocol of 4 weekly treatments.

Methods

Men were enrolled in this IRB approved study provided they had a diagnosis of ED for at least 6 months and were able to return for weekly treatments. Low Intensity Shockwave was delivered with the Urologid 100 machine (Tissue Regenerator Technologies, Woodstock, GA) using the soft wide focused applicator probe (figure 1). There were 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/mm² and frequency was 4 Hz yielding a biologic energy density of 1560.

ED severity was measured with the Sexual Health Inventory for Men (SHIM) score at baseline and 1 month following the 4 weekly treatments. Pre and post SHIM values were compared with the paired t test with significance set at p<0.05.

Results

Eight men enrolled with a mean age of 56.8 years (range 26-70) and median duration of 36 months (range 12-120). Five had previously tried PDE5 inhibitor (PDE5i) oral medications without adequate success. One patient stopped after 3 treatments but was included for an intent to treat analysis. The treatments were painless and there were no side effects.

Overall, SHIM score improved from 11.0±3.6 to 17.2±5.2 (p=0.01). SHIM was unchanged in 2 patients (25%), mildly improved in 1 patient but not sufficient for intercourse and significantly improved with erection sufficient for intercourse in 5 patients (62.5%) (figure 2). Two of these 5 men required a PDE5i for optimal erections however both had failed PDE5i in the past.




Figure 1: Urologid 100 device used in this study

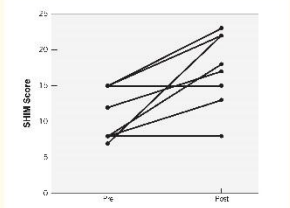


Figure 2: Change in SHIM score in individual subjects before and after therapy

Discussion

Low Intensity Shockwave Lithotripsy with the Urologid 100 using a once a week protocol produced a similar success rate to previously published twice weekly protocols. One of the treatment failures had psychogenic ED suggesting that inclusion criteria should focus on men with an arteriogenic etiology.

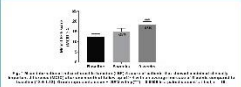
Whether this once weekly therapy remains durable will await longer term follow up. Since in the United States this device is not approved by the FDA and patients will need to pay cash for therapy, a protocol that minimizes time away from work and out of pocket expense is highly desirable.

Conclusion

Once weekly low intensity shock wave lithotripsy improved erections sufficient for intercourse in 62.5% of our patients without side effects

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

José Pablo SAFFON 1, Juan Manuel MARTÍNEZ 1, Carolina SANDOVAL 2, Héctor A. CORREDOR 3 MD, Clinical Sexology, Universidad Javeriana, Bogotá, Colombia; 2 Epidemiologist, Universidad El Bosque, Bogotá, Colombia; 3MD, Specialist in Urology, Universidad Nacional de Colombia, Bogotá, Colombia.



INTRODUCTION

Low-intensity extracorporeal shock wave therapy (LI-SWT) is of great clinical interest for the treatment of erectile dysfunction (ED), chronic pelvic pain (CPP) and Peyronie's disease. Extensive research in animal and human studies showed that the beneficial effect of LI-SWT is due to its angiogenic properties. It is thought to stimulate neovascularization by inducing the expression of angiogenic- and growth-related factors, like for example eNOS, VEGF and PDGF, although the precise underlying mechanisms are not entirely clear yet. Therapy LI-SWT can increase peak blood flow and endothelial function and represents a new, sustainable therapeutic strategy to restore erectile function, independent of, or supporting the conventional pharmacological treatment. [1][2][3]

OBJECTIVE

Report progression of LI-SWT in the treatment of vascular ED using a SWFA (soft wide focused applicator) hardware for a cohort of patients in a clinical center in Bogotá, Colombia.

METHODS

Clinical records of patients treated in a Boston Medical Group centre in Bogotá were reviewed during the first half of 2016, with diagnosis of vascular ED. Patients underwent a protocol of LI-SWT once a week for 5 weeks, energy flux density 0.15mJ and 3000 pulses per session, with the MTS unipolarTM and applicator OP155. Outcome measurements: Erection hardness Score (EHS), International Index of Erectile Function-5 (mean version IIEF-5).


RESULTS

20 patients with a mean age of 53.1 ± 12.1 years were included. At admission, 70% of patients had mild / moderate (n=4), 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 seven 35% (n=7) of patients showed a clinical important difference (defined as an increase of ≥4 points) in the IIEF score with an average increase of 5 points (18 ±4.4).


Assessing the EHS, 55.5% of patients at baseline (mean EHS: 3 ±0.6) had an erection insufficient to penetrate to this proportionally decreased significantly to 20% after therapy (mean EHS: 4 ±0.7), a beneficial effect that was still persisting after one month follow-up (mean EHS: 4 ±0.7).

Conclusions


The preliminary results of LI-SWT in the treatment of ED with the MTS unipolarTM and applicator OP155 are promising and indicate a clinically significant improvement in both the IIEF and EHS by this technology. Studies with a larger group of patients, a longer follow-up and a comparative shock wave protocol setup are necessary to further define the clinical significance and efficacy of this improvement in erectile function upon LI-SWT.



shock wave therapy



MTS_MDOC_PPT-Treatment-of-ED-with-Spark-Wave-therapy_E_170714





urogold100[®]

... Effective

... Highly tolerated

... Long-term solution

... NO pain and no side-effects

... Supporting spontaneity in Sex-Life

... Treating the cause, not only the symptoms



Treatment of ED with uro**gold**100[®]



Benefits using the urogold**100[®] for the treatment of erectile dysfunction:**

- Unique biological SparkWave[™] effects for successful therapy of ED
- Safe alternative to ingestive medical treatment
- No side effects
- Regaining the spontaneity in sexual intercourse
- Easy adjustment of penetration depth on touch-screen
- 3 different applicators for effective treatment

Conduct of treatment for ED with urogold100®

Spark Wave therapy is applied on penile shaft and corpus

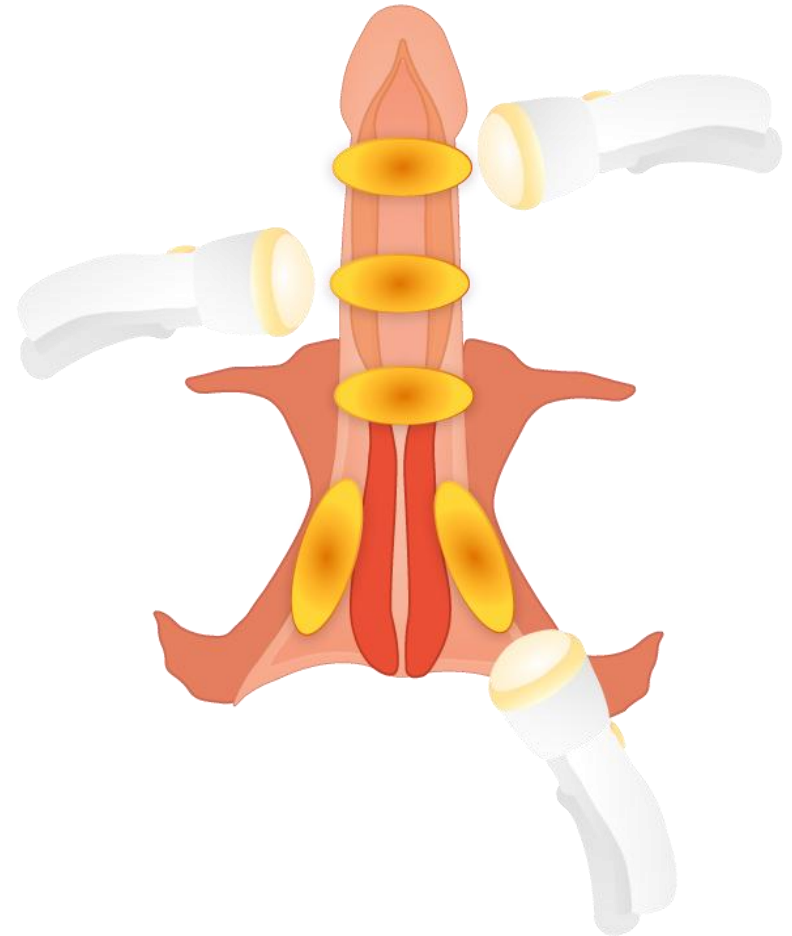
The following regions are treated:

Penis shaft

- Distal, mid and proximal

Crus of penis shaft

- Left and right-hand



Conduct of treatment for ED with uro**gold**100[®]

Treatment protocol for ED therapy with uro**gold**100[®]:

- Total: 6 weeks
- Interval: 1x per week **or** 1x every 14 days
- Repetition: **if necessary** after 4 weeks

Per patient:



6 treatments

5 treatment zones

300 shocks per zone

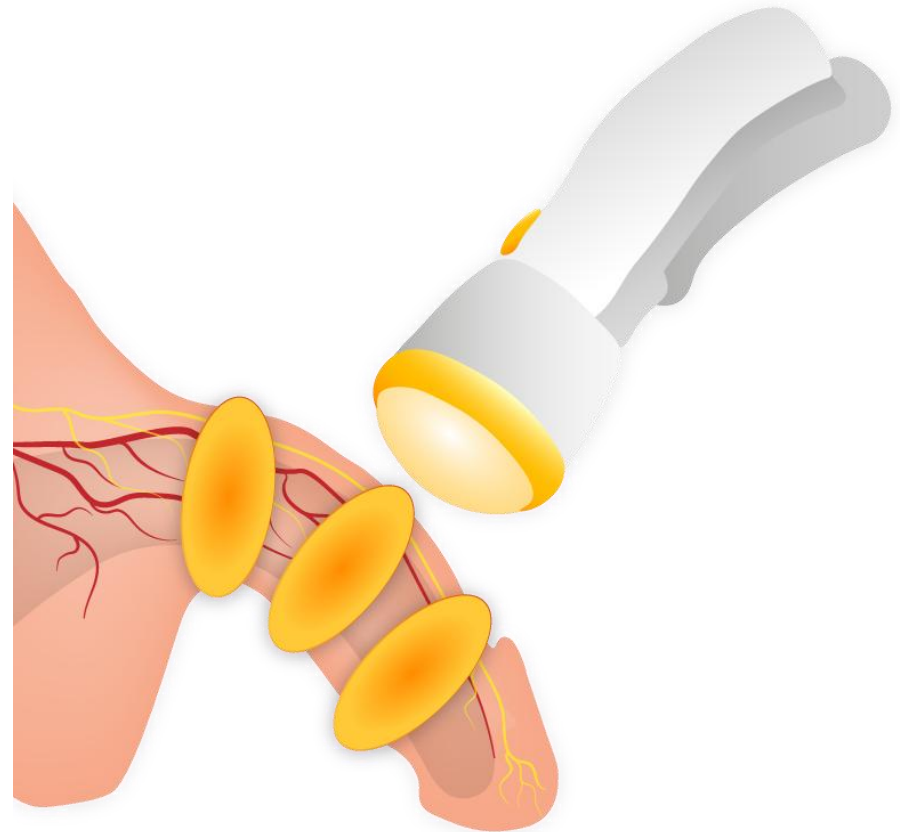
Only 9000 shocks in total for significant improvement of erectile function



Conduct of treatment for ED with urogold100®

Treatment of the shaft:

1. Stretch the penis
2. Bring applicator in firm contact to treatment location perpendicular to shaft
3. Apply 300 shocks each at distal, mid and proximal penile shaft (900 shocks in total)
4. Use generous amount of coupling ultrasound gel
(Before treatment, please clean skin in the treatment area and remove hair)

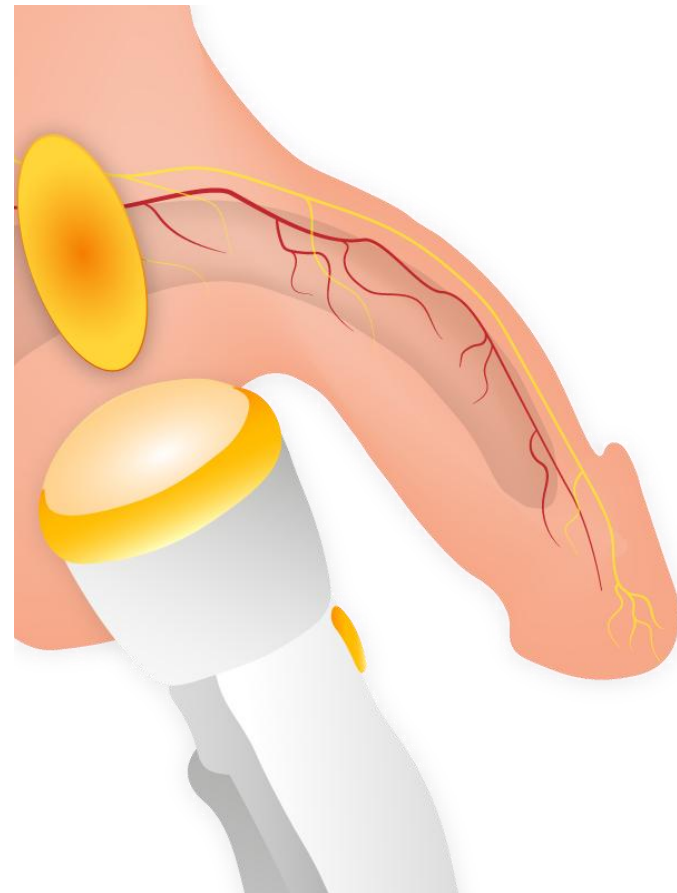


Conduct of treatment for ED with urogold100[®]



Treatment of the crus of penis:

1. Locate pubic bone of patient
2. Deliver 300 shocks beneath the pubic bone toward the crus as indicated on picture
3. Repeat procedure on the other side with further 300 shocks (600 shocks in total)
4. Use generous amount of coupling ultrasound gel



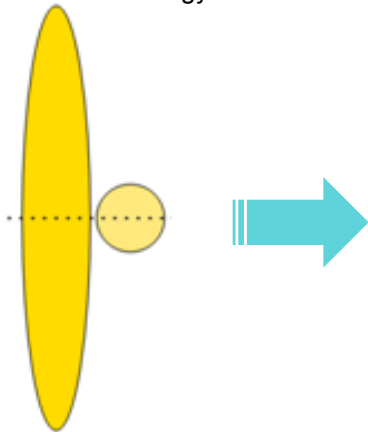


Unique SparkWave™ Technology

Unfocused applicator OP155

MTS Focus

SparkWave™ Technology



Large volume of positive energy



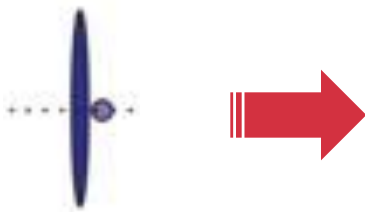
No negative / tensile pressure



Covers more surface



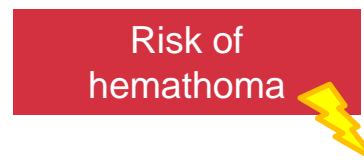
Standard Focus



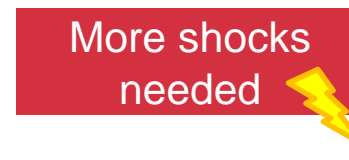
Energy concentrated to small area



Negative / tensile pressure



Covers less surface





Take home message

- ✓ Spark Wave™ therapy is effective long-term and highly tolerated solution for patients with ED to restore sexual spontaneity
- ✓ Innovative, safe and effective therapy for ED and other urogenital disorders to avoid problems in sexual intercourse
- ✓ Unique biological Spark Wave™ effects for successful therapy of urogenital disorders, such as ED
- ✓ Safe alternative to ingestive medical treatment of ED without the side effects of the latter
- ✓ Even suitable for ED-patients that did not respond to medication



Thank you very much for your attention!



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