LSWT
Linear Shockwave Therapy for Erectile Dysfunction
Clinical Data and Reports

October 2014
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Safety and Efficient Duration of Linear Focused Shockwave Treatment for Erectile Dysfunction – A 12 months Follow-up Pilot Study

Y. Reisman
Men's Health Clinic, Bovenij Hospital, Amsterdam, The Netherlands

Objective
The aim of this pilot study was to assess the safety, effectiveness and sustainable results of the Linear Focused Shockwave system Renova, for the treatment of Vascular Erectile Dysfunction patients.

Material and methods
Renova is a system that uses a Linear Low Intensity Shockwave technology. We have treated 20 patients with Vasculogenic ED; with an averaged International Index of Erectile Function (IIEF-EF) score of 12.35±3.16 (Range 7-18). The protocol consisted of 4 weekly sessions, in which a total of 3600 shockwaves were applied, divided into 4 areas; right and left crura, and right and left corpus cavernosum, 900 shockwaves in each site. The following questionnaires were used: IIEF-EF, Sexual Encounter Profile (SEP) and Global Assessment Question (GAQ), at baseline visit and 1, 3, 6 and 12 months post treatment. Success was defined as an increase in score from baseline to the 6 months post treatment follow-up, according to Minimal Clinical Improvement Criteria (Rosen et al.).

Results
At the 6 months follow-up, 18 patients out of 20 showed success (90%). Out of these 90%, 83.3% (15 patients) sustained the positive outcome for a period longer than 12 months after the end of treatment. The average IIEF-EF increased significantly from 12.35±3.16 at baseline to 20.65±2.64 at 6 months post treatment, and was 18.65±2.56 at the 12 month
follow-up. Four patients (20%) who were non-responsive to Phosphodiesterase type 5 Inhibitors (PDE5i) at baseline became responsive after the treatment, and 2 patients (10%) successfully stopped using PDE5i. All 20 patients completed the last follow-up with an average of 14.5±1.08 months duration from the end of treatment. Among the successful patients, the average IIEF-EF score increase was 8.3 points. No side effects were reported.

Conclusions
With a success rate of 90% after 6 months, and an 83.3% sustainable positive effect after 1 year, the results of this pilot study suggest that this treatment is probably effective for at least 1 year. No anaesthesia or analgesia was needed, and no adverse effects were recorded, making it a potential good alternative for current available treatments.

The above paper abstract was presented at the 16th World Meeting on Sexual Medicine, on October 11th 2014, Sao-Paulo, Brazil.
Initial Clinical Experience of Linear Focused, Low Intensity Shockwave for Treatment of ED Patients with Different Severity Symptoms

N. Cruz¹, A. Morales²

¹Clinica Andromedi Sevilla, ²Instituto de Urología Málaga

Objective

The aim of this clinical experience was to assess the feasibility of the application of Linear Focused Low Intensity Shockwaves (Renova Direx Group) as an alternative or complementary treatment for Vascular ED patients with different degrees of symptom severity.

Material and methods

The treatment was offered in a routine natural way in 2 medical centers: 46 patients in Malaga (series A), and 35 in Sevilla (Series B). The treatment was composed of 4 weekly sessions, in which shockwaves were applied into 4 areas: right and left crura, and right and left corpus cavernosum, with 900 shockwaves in each site (Total 14400). No need for anesthesia, sedation or painkillers and each session's treatment time was 20 minutes. The evaluation was done using the IIEF-EF, SEP and GAQ questionnaires, at baseline visit, 1 month and 3 months post treatment.

Results

The average IIEF-EF increased significantly from 19.94 and 14.03 at baseline to 23.92 and 18.53 at 3 months post treatment. A number of patients stopped using PDE5-i; 30.77% and 23.53% respectively. SEP 2 increased from 88.89% and 43.48% to 100% and 66.67%. The SEP 3 increased from 38.89% and 27.59% to 78.75% and 57.89%.
At baseline, the use of PDE5-i for sexual intercourses was needed by 77.78% and 85.19% of patients, and was reduced to 53.85% and 35.29% at 3 months post treatment. No side effects were recorded.

Conclusions
The results of both series at 3 months show a consistent and global improvement in IIEF-EF, SEP 2 and SEP 3 parameters. Since the baseline symptoms severity of patients in series B was much higher compared to series A, the end results obtained in series B are consistently lower compared to series A.

This would imply that the outcome of the treatment is related to the baseline symptoms severity, meaning that in average, patients with more severe ED symptoms will improve, but will not reach the final level of improvement that can be obtained by mild to moderate patients. In our experience the Linear-Focused Low Intensity Shockwave treatment is a valid alternative or complement to current available treatments.

The above paper abstract was presented at the 16th World Meeting on Sexual Medicine, on October 11th 2014, Sao-Paulo, Brazil.
Efficacy and Safety of Linear Focused Shockwaves for Erectile Dysfunction (RENOVA) – A Second Generation Technology

Y. Reisman¹, A. Hind², A. Varaneckas³, I. Motil⁴

¹Men's Health Clinic, Bovenij Hospital, Amsterdam, The Netherlands, ²Urology and Andrology Center, Red Crescent Hospital (RCH), Ramallah, Palestine,³Amber Clinic, Klaipėda, Lithuania,⁴Uroclinic Brno, Brno, Czech Republic

Introduction
Recent studies have demonstrated that low intensity shockwaves have a therapeutic effect on ED of vascular origin.

Objective
The present study was aimed to assess the efficacy and safety of a dedicated shockwave device, Renova, which was designed to achieve substantially superior organ coverage.

Material and Methods
52 patients with mild to severe ED were treated by Renova as part of a multi-center, open-label, prospective pilot study, conducted at 4 sites. Patients underwent 4 weekly treatment sessions by a Renova that generates line focused shockwaves. Patients' erectile function was assessed by the IIEF-EF, SEP and GAQ questionnaires at baseline and at 1 and 3 months post treatment. Success was defined as an increase of IIEF-EF score from baseline to the second follow up according to the severity of the symptoms at baseline.
Results
The average IIEF-EF greatly increased from 14.7 at baseline to 21.4 at 1 month and 3 months post treatment. **Out of 52 patients, 41 (79%) had a successful treatment.** No adverse events were reported during the treatment and the follow-up duration. Main outcomes are presented in the following table:

<table>
<thead>
<tr>
<th>Age</th>
<th>Baseline IIEF-EF</th>
<th>Improvement in IIEF-EF</th>
<th>P value</th>
<th>% Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>57.2 ± 10.1</td>
<td>14.7 ± 4.9</td>
<td>6.8</td>
<td>&lt;0.0001</td>
<td>78.8%</td>
</tr>
</tbody>
</table>

Conclusions
The results of this study indicate success of the second generation technology for treating ED with linear low-intensity shockwaves. Initial follow up data demonstrate a therapeutic success in almost 80% of patients. No side effects have been recorded, demonstrating the suitability of this treatment in an office setting.

The above paper abstract was presented at the 12th Congress of the Latin American Society for Sexual Medicine, on August 29th 2013, Cancun, Mexico.
Low intensity shock wave (LISW) treatment (Renova) to improve male sexual function: A preliminary data on 42 patients

F. Iacono, A. Ruffo, D. Prezioso, G. Romeo, E. Illiano, L. Romis, G. Di Lauro
Centro Urolab, Napoli, Italy

Objective
The aim of our study is to investigate the safety and efficacy of Low intensity Extracorporeal shock wave therapy LI-ESWT (Renova) in the treatment of erectile dysfunction.

Methods
We enrolled 47 patients with erectile dysfunction (ED). They underwent four weekly sessions using a dedicated device (Renova) for the management of erectile dysfunction. The treatment included four weekly sessions. During each treatment session, LI-ESWT was applied at four different anatomical areas, right and left corpus cavernosum and right and left crus penis (900 shocks, 0.09 mJ/mm² intensity at 240 shocks/min at each site for a total of 3600 shocks). Patients were followed at one month after treatment. Two self-administered questionnaires: International Index of Erectile Function-Erectile Function (IIEF-ED), Sexual Encounter Profile (SEP- Questions 2 and 3) were given to patients to assess their sexual function pre and post treatment.

Results
Five patients dropped out of treatment, so forty-two patients (mean age was 59.2 years) were evaluated. At one month follow-up, we noticed a statistically significant improvement in IIEF-ED domain scores in treated patients (from a mean of 12+-4.8 at baseline to 23.5+-5.3,
p<0.05). **SEP-Q2** and **SEP-Q3** success rates improved from 57% to 84% and from 24% to 76% respectively. No side effects were reported.

**Conclusion**

(LI) ESWT improves male sexual function inducing neovascularization in the treated tissues by stimulating the expression of angiogenesis-related growth factors, such as endothelial nitric oxide synthase, vascular endothelial growth factor, and endothelial cell proliferation factors, such as proliferating cell nuclear antigen. This therapy shows a statistically significant clinical improvement of erectile function without any side effect or contraindication. In our opinion further studies are needed even to assess the possibility to repeat the treatment cyclically or in association with PDE5-i or with nutraceutical composite.

The above paper abstract was presented at the 16th Congress of the European Society for Sexual Medicine (ESSM), on February 1st 2014, Istanbul.
Low Intensity Linear Focused Shockwave Therapy: a New Treatment to Improve the Quality of Life of Vascular Erectile Dysfunction Patients

P. Puppo, A. Casarico
Montallegro Clinic, Genova, Italy

Objective
Erectile dysfunction is a common medical disorder that primarily affects men older than 40 years of age. Phosphodiesterase type 5 inhibitors (PDE5i) are considered as first-line therapy as they increase arterial blood flow leading to smooth muscle relaxation, vasodilatation and penile erection. The limitation in the efficacy of PDE5 inhibitors is that a 'critical amount' of NO is necessary for these drugs to work. Therefore, in cases of impairment in NO synthesize or release or in cases of destruction of NO, PDE5 inhibitors cannot cure erectile dysfunction (ED) symptoms.

The correlation between potency and quality of life was established by a study on 1680 men seeking medical attention in a free screening program at three different locations in the USA. Unsurprisingly, it was reported that potent men have a better quality of life than impotent men.

Lately, studies have started to evaluate the effect of low intensity shockwave (LISW) to treat ED on PDE5i responders and non-responders patients.

The current study evaluated how the therapy by a new device ('RENOVA', Initia Ltd, Israel) using low-intensity linear focused shockwave affects the quality of life of patients who suffer from ED of vascular origin and experience full, partial or no response at all to PDE5 inhibitors.

Methods and results
This study was conducted in an outpatient clinic over a period of 10 months. Eligible patients were those who have been suffering from Vasculogenic ED for at least 6 months, and their
International Index of Erectile Function score in the erectile function domain (IIEF-EF) was between 9 and 25. Patients who had hormonal, neurological or psychological pathology or have undergone radical prostatectomy were excluded.

The treatment consisted of 4 weekly sessions; in each session 4 areas were treated consecutively: left and right sides of the Crura and the Corpora Cavernosa. Shockwaves were delivered with a maximum energy of 0.09mJ/mm²; therefore, no anesthesia was required. During the treatment period (22 days) and 3 weeks prior it, no phosphodiesterase type 5 inhibitors (PDE5-I) were used.

Erectile function was evaluated by means of IIEF-EF, questions 2-3 of the Sexual Encounter Profile (SEP), questions 1-2 of the Global Assessment Questions (GAQ) and the Erection Hardness Score (EHS), at baseline and at 1, 3 and 6 months post treatment. Success was defined as positive answer to both SEP and GAQ questions, EHS of 3 or higher and an increase of IIEF-EF score from baseline to the third follow up (6 months post treatment) according to the severity of the symptoms.

Out of 25 patients who were enrolled to this study, 24 have finished the full treatment series. The mean age of these patients was 62.58 ± 8.32 (45-74) years and the mean duration of their ED was 4.84 ± 4.46 (1-20) years. 52% were smokers, 26% had diabetes, 58% had high cholesterol levels, 37% had a cardiovascular disease and 47% had hypertension. 74% of the patients had a positive response to PDE5 inhibitors.

All patients were instructed to use PDE5 inhibitors during the 4 weeks prior baseline evaluation. At the end of the treatment and during the follow-up period patients were using PDE5 inhibitors as needed.

At the most recent follow-up of each patient, 40% of the PDE5i non-responders and 78% of the responders achieved positive outcomes at all 4 evaluation questionnaires. 42.8% of the responders stopped using PDE5 inhibitors at 6 month follow-up. Out of these patients, 83% achieved positive outcomes at all 4 evaluation questionnaires. The overall percentage of patients who achieved positive outcomes at all 4 evaluation questionnaires was 70%.

None of the patients have reported on pain during or after treatment. No adverse events were reported.

Discussion
This pilot study was designed for assessing the efficacy of a novel device dedicated for the treatment of erectile dysfunction and based on an original technology that enables the delivery of low-intensity shockwaves onto a long focal area. The subjects in this study included also
patients with multiple co-morbidities, different degrees of response to PDE5 inhibitors and wide range of ED severities. The results of this study demonstrate a possible alternative treatment for some of the patients who did not respond to first-line oral pharmacotherapy and thanks to this treatment may avoid turning to other therapy options which are less convenient to use. In parallel, these data imply on a potential mean to eliminate the need for PDE5 inhibitors which may significantly improve patients’ quality of life. In order to establish the overall effect of this treatment on the quality of life of ED patients, a larger study with longer follow-up duration is required.

The above paper abstract was presented at the 21^{st} National Congress of the Italian Urology Association, on June 2014, Rome, Italy.
Linear Low Intensity Shockwaves Treatment of Vasculogenic ED – First Results

Motil¹, T. Šramkova²
¹Urology Ajem, Brno, Czech Republic, ²Department of Sexology, Brno University Hospital, Czech Republic

Introduction and Objectives
ED is significantly associated with: increased age, diabetes, cardiovascular disease, hypertension, depression, smoking, medications, and has a multifactorial etiology with physical and psychological factors.

The treatment options currently offered to patients are: drugs that reversibly inhibit penile-specific PDE5 and enhance the nitric oxide–cyclic GMP pathways of cavernous smooth muscle relaxation, vacuum constriction device, intraurethral and intracorporeal alprostadil, or surgical treatment-implantation of penile prosthesis.

Our aim was to assess the safety and efficacy of a unique Linear Shockwave Therapy for Vasculogenic ED patients in a prospective trial (PT).

Materials and Methods
22 men with vasculogenic ED completed this open-label, prospective pilot study. In order to compare our own results (22 men) we included the outputs of other 3 European LSWT centers. Finally, overall 69 (22+47) patients with mild to severe ED were treated using Renova device and evaluated.

The evaluation of success was made according to the IIEF-EF questionnaire, which was filled at baseline, and 1, 3 and 6 months post treatment.
Results
The average IIEF-EF increased significantly from 14.7 at baseline to 21.6 at 1 month and 3 months post treatment. **82% of patients had a successful treatment.** No adverse events were reported during the treatment and the follow-up duration.

Conclusions
We have been able to prove that Linear SWT is an effective therapeutic option for men with erectile dysfunction of vasculogenic origin. Moreover the efficacy of linear application of low-intensity extracorporeal shock waves is superior to former non-linear methods.

The above paper abstract was presented at the **102nd Annual Meeting of the Japanese Urological Association (JUA)**, on April 21st 2014, Kobe, Japan.
Efficacy and Safety of Linear Focused Shockwaves for Erectile Dysfunction (RENOVA) – A Second Generation Technology

Y. Reisman¹, A. Hind², A. Varaneckas³, I. Motil⁴

¹Men's Health Clinic, Bovenij Hospital, Amsterdam, The Netherlands, ²Urology and Andrology Center, Red Crescent Hospital (RCH), Ramallah, Palestine, ³Amber Clinic, Klaipėda, Lithuania, ⁴Uroclinic Brno, Brno, Czech Republic

Introduction
Vasculogenic erectile dysfunction (ED) which is caused by arteriosclerosis can be treated by a variety of therapies that aim at reducing ED symptoms. Low-intensity shockwaves (LISW) were discovered as an enhancing factor to angiogenesis for treating ischemic heart disease. In addition, LISW therapy demonstrated significantly the restoration of erectile function in diabetic rats. The present study evaluates the therapeutic effect of LISW produced by an innovative device on patients with erectile dysfunction.

Objective
The present study was aimed to assess the safety and efficacy of a dedicated shockwave device, 'Renova', which was designed to achieve substantially superior organ coverage.

Material and Methods
57 patients with mild to severe ED were treated by Renova as part of a multi-center, open-label, prospective pilot study, conducted at 4 sites. Patients underwent 4 weekly treatment sessions by a novel machine (Renova) that generates line focused shockwaves at 4 treated areas: right and left crus and right and left corpus cavernosum. Each treatment session lasted approximately 15 minutes, did not required anesthesia and did not cause any pain or adverse
effects. Patients' erectile function was assessed by the IIEF-EF, SEP and GAQ questionnaires at baseline and at 1 and 3 months post treatment. Success was defined as an increase of IIEF-EF score from baseline to the second follow up according to the severity of ED symptoms at baseline.

Results
The average IIEF-EF score has greatly increased from 14.7 at baseline to 21.6 at 1 month and 3 months post treatment. Out of 57 patients, 47 (82%) had a successful treatment. Among the successful patients, the average IIEF-EF score increase was 8 points. No adverse events were reported during the treatment and the follow-up duration.

Conclusions
The results of this study indicate success of the second generation technology for treating ED with linear low-intensity shockwaves. Initial follow up data from almost 60 patients demonstrate a clear therapeutic success in 82% of patients.

The above paper abstract was presented at the 2nd Biennial Meeting of the Middle East Society for Sexual Medicine, on November 2013, Dubai.
Initial Experience Using Linear Shockwave Therapy (RENOVA®) in the Treatment of Erectile Dysfunction

M. Pelayo-Nieto, E. Linden-Castro, A. Alias-Melgar, D. Espinosa-Perezgrovas
F. Bertrand-Noriega, E. Ordoñez-Campos, L. Guerra-Zepeda, R. Cortez-Betancourt, J. Morales-Covarrubias, F. Carreño-De la Rosa, E. Sánchez-Neave
Department of Urology, National Medical Center November 20, ISSSTE, Mexico, DF.

Introduction
Linear Shockwave Therapy (LSWT) is a new noninvasive therapy that uses shockwaves of low intensity to induce locally controlled angiogenesis and to significantly improve the hemodynamic function of the male sexual organ.

Objective
To report our experience (15 cases) using Linear Shockwave Therapy as a treatment for ED.

Material and Methods
This pilot, prospective, cross-sectional study included 15 sexually active men of ages 45-70 years with mild and moderate vasculogenic ED that were evaluated by the International Index of Erectile Function (IIEF-EF). The study was conducted in three stages: screening, treatment and monitoring. Patients received 4 weekly LSWT sessions (by RENOVA®); each session included 5000 shocks with an intensity of 0.09 mJ/mm². Patients’ erectile function was assessed by IIEF-EF, SEP (Sexual Encounter Profile) and GAQ (Global Assessment Questions) at one and three months post treatment.

Results
13% of patients started the treatment with moderate ED, 66.6% started with mild to moderate ED and 20% with mild ED. We noted that the trend of success in our study was 80%. We
found an increase between the baseline IIEF-5 score (average 14.53 pts), the one month follow-up IIEF-5 score (average 19.60 pts) and the three month follow-up IIEF-5 score (average 19.66 pts) with distribution t of 1.7445 (p<0.013).

Conclusions

We observed that LSWT has a positive short-term clinical effect in men with Vasculogenic ED. Long term follow-up is required to show the ability of LSWT to be an effective and safe solution for the treatment of ED. The feasibility and tolerability of this treatment, and rehabilitation of tissue functionallity, make LSWT a potential new attractive treatment option for patients with Vasculogenic ED.

The above paper abstract was presented at the 21st SMU National Congress of Urology, on November 2013, Mexico.
Line Focused Shockwave for Erectile Dysfunction – A Different Technological Approach

A. Hind, O. Saleh, Y. Abu Asbeh
Urology and Andrology Center, Red Crescent Hospital (RCH), Ramallah, Palestine

Introduction
During the last 2 years a new technology was introduced to treat Erectile Dysfunction. The treatment uses Low Intensity Shockwave which was shown to produce angiogenesis in order to improve the patient erectile function for patients of Vasculogenic origin ED. The initial treatments were done with conventional orthopedic treatment shockwave devices, and although results were encouraging, they have a series of limitations.

We are presenting our initial results with a new type of Low Intensity shockwave system that was specifically developed to treat ED.

Patients and Methods
Instead of focusing the shockwave into a focal point, like in any conventional lithotripter, Renova system (DirexGroup) shockwaves focalize along a 70mm line, with a dept of 40mm. This allows a perfect coverage of the full penis shaft and the crura. We use a short protocol of 4 weekly sessions, applying 900 shocks in each of the 4 following areas: right Crus, left Crus, right Corpus Cavernosum, left Corpus Cavernosum.

We have treated 20 patients and we have a follow up of the first 12 patients, both PDE5-I Responders and non Responders.
### Results

IIEF-EF: International Index of Erectile Function – Erectile Function Domain

<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>Baseline IIEF-EF</th>
<th>IIEF-EF at 1 month</th>
<th>IIEF Difference</th>
<th>Success/Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>M I M</td>
<td>9</td>
<td>18</td>
<td>9</td>
<td>Success</td>
</tr>
<tr>
<td>H I S</td>
<td>8</td>
<td>8</td>
<td>0</td>
<td>Failure</td>
</tr>
<tr>
<td>N M M</td>
<td>8</td>
<td>8</td>
<td>0</td>
<td>Failure</td>
</tr>
<tr>
<td>J H S</td>
<td>17</td>
<td>24</td>
<td>7</td>
<td>Success</td>
</tr>
<tr>
<td>M N S</td>
<td>14</td>
<td>25</td>
<td>11</td>
<td>Success</td>
</tr>
<tr>
<td>O I S</td>
<td>19</td>
<td>25</td>
<td>6</td>
<td>Success</td>
</tr>
<tr>
<td>M M K</td>
<td>11</td>
<td>24</td>
<td>13</td>
<td>Success</td>
</tr>
<tr>
<td>A A D</td>
<td>16</td>
<td>19</td>
<td>13</td>
<td>Success</td>
</tr>
<tr>
<td>I H A</td>
<td>19</td>
<td>28</td>
<td>9</td>
<td>Success</td>
</tr>
<tr>
<td>A H</td>
<td>19</td>
<td>28</td>
<td>9</td>
<td>Success</td>
</tr>
<tr>
<td>S A</td>
<td>12</td>
<td>20</td>
<td>8</td>
<td>Success</td>
</tr>
<tr>
<td>A M H</td>
<td>17</td>
<td>24</td>
<td>7</td>
<td>Success</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>13.25</strong></td>
<td><strong>20.92</strong></td>
<td><strong>7.67</strong></td>
<td><strong>84%</strong></td>
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SEP- Sexual Encounter Profile

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<tr>
<th>Patient Initials</th>
<th>Baseline SEP 2</th>
<th>Baseline SEP 3</th>
<th>Follow-up SEP 2</th>
<th>Follow-up SEP 3</th>
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<tr>
<td>M I M</td>
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<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>H I S</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>N M M</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>J H S</td>
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<td>I H A</td>
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**LSWT – CLINICAL DATA AND REPORTS**

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<td>11</td>
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<tr>
<td>12</td>
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<tr>
<td>Average</td>
<td></td>
<td>50%</td>
<td>33%</td>
<td>83%</td>
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</table>

Comparative follow up: 1 and 3 months

<table>
<thead>
<tr>
<th>Patients</th>
<th>Response to PDE5-I</th>
<th>IIEF Score</th>
<th>Results Comparison</th>
<th>Delta</th>
<th>Success</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline 1</td>
<td>Imonth 1</td>
<td>3 months</td>
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- Results at 1 and 3 month follow-up are essentially the same.
- Successful results are seen at 1 month post treatment.

**Conclusions**

- Initial results at 1 and 3 months show great progress in erectile function.
- Average IIEF-EF increased from 13.25 to 20.92 (57.86 % improvement).

- **84% Success according to success criteria.**
- All mild to moderate cases have succeeded.
• One severe case has improved while 2 severe cases failed.
• SEP and GAQ results have improved.
• No pain and no complications were reported.

The above paper abstract was presented at the 5th Pan Arab Congress of Sexual Health, on April 20th 2013, Dubai.
The Effect of Low Intensity Shockwave Therapy on the Erectile Function of Smokers and Non-smokers - Initial Report with a Dedicated System

P. Puppo, A. Casarico
Montallegro Clinic, Genova, Italy

Introduction and Objective

The association between cigarettes smoking and erectile dysfunction (ED) was researched in many studies so far. The strongest relationship found was an adjusted odds ratio of 1.97 for incident ED in smokers compared with nonsmokers. Smoking appears to decrease pelvic and penile vascular flow. Moreover, atherosclerosis is possibly the most important vascular consequence of cigarette smoking. It was established that the effect of smoking on erectile function is related to impairment of endothelium dependent smooth muscle relaxation which is a key process leading to the dilation of vessels in the erectile tissue and an increased blood flow required for erection.

10 years ago, a study that examined the beneficial effects of Shockwaves on ischemia-induced myocardial dysfunction was published and revealed that shockwaves at energy level of 0.09mJ/mm² enhance coronary angiogenesis.

The present study examines the effect of a treatment by a new dedicated device delivering shockwaves at the same energy level and a long focal area adjusted to the male sexual organ, on patients suffering from vascular origin ED, both smokers and non-smokers.

Materials and Methods

25 patients with Vasculogenic ED were treated by the shockwave device, 4 times, once a week. 1600 shocks were applied to each Crus and 900 shocks were applied to each Corpus Cavernosum. No PDE5 inhibitors were used during the treatment and 3 weeks prior
treatment. Erectile function was evaluated at baseline and at 1, 3 and 6 months post treatment by 4 self administered questionnaires: IIEF-6, SEP, GAQ and EHS. Success was defined as positive answers to SEP and GAQ questions, EHS≥3 and a significant increase of IIEF-6 score according to the baseline ED severity.

Results
24 men with a mean age of 62.6 have finished treatment. 53% of them were smokers. There was no significant difference between ED duration, age and baseline IIEF-6 of smokers and non-smokers. Co-morbidities rates were higher in smokers than in non-smokers. The increase in IIEF-6 from baseline to the last follow-up was twice as large in the smokers than the non-smokers. The overall success rate was 70% and 84% of patients answered "Yes" to both GAQ questions. No adverse events were reported.

Conclusions
This pilot study shows that eventually this new treatment for vascular ED could be suitable to smoking patients and patients with vascular risk factors. More research is required for confirming the efficacy of this treatment on different populations.

The above paper abstract was presented at the 30th Italian society of Andrology Congress (SIA), on May 2014, Maratea, Italy.