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

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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

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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.

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