Efficacy and Safety of Linear Focused Shockwaves for Erectile Dysfunction (RENOVA) – A Second Generation Technology

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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 restoration of erectile function at diabetic rats. The present study evaluates the therapeutic effect of a 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 significant change was seen between the 4 arms. 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.

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