



Evaluation of Radial Extracorporeal Shock Wave Therapy in the Treatment of Erectile Dysfunction

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Objective: Erectile dysfunction is a common problem in men, especially in 40-70 years of age. There are several ways in the treatment of this topic. One of these ways is a non-invasive non-pharmacological treatment due to the use of extracorporeal shock wave therapy (ESWT). There are a few devices and technologies for the ESWT. The aim of the study is to evaluate the effectiveness of radial shock wave therapy (RSWT) in treatment of erectile dysfunction by using the device BTL – 6000 SWT. It is a radial shock wave therapy device enabling the application of therapy by using handheld pneumatic applicator (Pic 1). One of the main effects of the application is a neovascularisation. The application of shock waves stimulates the soft tissues which results in significant increase of the growth factors, such as the eNOS, VEGF, PCNA and BMP expression. These processes stimulate the growth and remodeling of new arterioles (Pic 2)

Methods: A prospective single-center, open label clinical study of the radial shockwave therapy system (BTL-6000 SWT, manufacturer: BTL Industries, Ltd.) in therapy of the patients with erectile dysfunction, who were the responders to PDE5is. We enrolled 22 men with vasculogenic ED with good or decreasing respond to PDE5is. The patients are enrolled to the study according to the following inclusion criteria: erectile dysfunction existing for more than 6 months and/or one or more from the next criteria: metabolic syndrome, hypercholesterolemia, hypertension, diabetes, and atherosclerosis.

Assessment of erectile function was performed at screening, after the last treatment, and at the 3 month follow-up examinations by using the five items International Index of Erectile Function (IIEF-5) (Pic3).

Patients mean baseline of IIEF-5 domain score was 14,09 after a 1-month PDE5is washout period. RSWT was applied to the penile shaft and crura at five sites. The therapy was administered in contact manner using direct application above the target area. The application pressure was set from the 1,5 bars to 2 bars, depending on how well the patient tolerated the treatment. The application frequency was 12 Hz. Patients underwent 4 treatments every 7 days. The therapy was performed in 5 consequent areas, 3 on the dorsum of shaft of penis and one on the left and one on the right side of shaft, with 600 pulses applied to each area (Pic4)

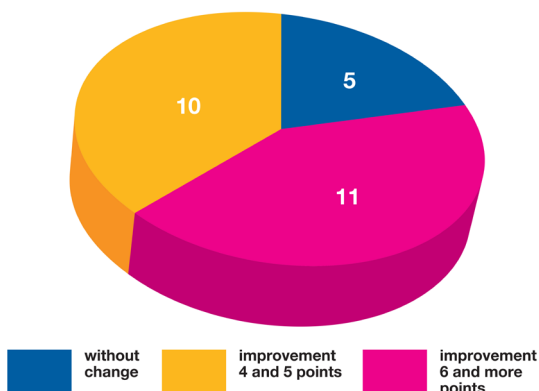
Results: We treated 22 men with vasculogenic ED, average age $52,6 \pm 9,3$ years. After the last treatment, significant increases in IIEF-5 domain scores were recorded in 21 men, 1 man had a score without change. However, this one man had a good response to PDE5is in the past, but a very low response before treatment actually. After the last treatment he had a good response to PDE5is again. The mean of the domain score in IIEF-5 after the treatment was significantly higher, average 21,36 vs. 14,09. The minimum of improvement was 4 points (4 patients), 5 points of improvement had 6 patients, and improvement from 6 to 10 points was noted in 11 patients (Pic 5). These results remained unchanged at 90-day examination. Patient tolerance of the treatment was excellent, none of the subjects reported treatment-associated pain during or after the treatment.

Conclusion: RSWT represents a new, effective, non-surgical, non-pharmacological, and well tolerated treatment for men with erectile dysfunction, who previously responded to pharmacotherapy. The therapy is painless and safe. RSWT is a new treatment option for erectile dysfunction, enabling the patient to achieve and maintain sufficient and dependable erections.

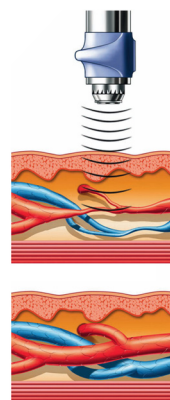
Pic 3

	Very low	Low	Moderate	High	Very high
1. How do you rate your confidence that you could get and keep an erection?	1	2	3	4	5
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	Almost never / never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always / always
3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	1	2	3	4	5
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult
5. When you attempted sexual intercourse, how often was it satisfactory for you?	1	2	3	4	5

Pic 4



Pic 5



Pic 6

