

Men's power-pressure wave erectile regeneration-therapy: an early assessment

Abstract

Introduction: Low intensity extracorporeal shockwave therapy for erectile dysfunction (LISWT) has been well researched as a treatment for Erectile Dysfunction (ED) and used as a first line treatment in many parts of the world as a viable alternative to oral, on-demand, phosphodiesterase type 5 inhibitors (PDE5i). Though effective, these drugs have limitations and are associated with significant non-compliance, side effects and do not reverse the underlying pathology.¹⁻³ Non-invasive low intensity shockwave therapy (LISWT) has been shown to significantly improve erectile function in men previously PDE5i dependent.

Materials and methods: Vaughan Medical LLC based in Fort Lauderdale, USA purchased the STORZ Medical D-ACTOR 100 to treat patients with ED with the C-15 Ceramic Grey Tip at 15 Hertz and 2.6 Bar with 500 pulses per 1.5 cm on top of the shaft and 1,000 pulses right side then 1,000 left side just below the shaft on the pelvis/corporal bundle. Each patient had 6 treatments either two treatments per week for three weeks or one treatment per week for six weeks randomized by patient preference and/or to fit in with clinic schedules.⁴⁻⁷

Results: Men's PoWER Therapy using the STORZ Medical D-ACTOR 100 (LISWT) has shown in this early experience to be an effective treatment paradigm for erectile dysfunction. All patients completed the treatment regime and all gained an improvement in their SHIM score with an average improvement from Moderate ED to Mild-Moderate after 6 treatments. It appears from this early experience that the optimal treatment regime is six (6) treatments at two treatments per week for three weeks.⁸⁻¹¹ The same energy settings were used for all patients of 15 Hertz and 2.6 bars with 500 pulses per 1.5 cm on top of the shaft and 1,000 pulses right side then 1,000 left sides just below the shaft on the pelvis/corporal bundle.

Conclusion: The early experience of LISWT has shown an improvement in the sexual function of patients and a treatment regime of two treatments per week for three weeks appears optimal but further research is required.¹²⁻¹⁵

Keywords: men's power therapy, low intensity extracorporeal shockwave therapy, erectile dysfunction

Volume 4 Issue 4 - 2017

Jason Perelman and Vaughan Daniels Hepnar
Cambridge University, UK

Correspondence: Vaughan Daniels Hepnar, EMEA Holmium Clinical Manager at Lumenis LTD, Lumenis LTD, Strickland House Independant, The Henley College, Gloucester CAT, Cambridge University Teddington, Greater London, UK, Tel +1 -954 439 8764, Tel +44 7557655523, Email bjorn.danielshepna@icloud.com, www.vmedical.us

Received: January 13, 2017 | **Published:** April 10, 2017

Abbreviations: LISWT, low intensity extracorporeal shockwave therapy for erectile dysfunction; ED, erectile dysfunction; PDE5i, phosphodiesterase type 5 inhibitors; PDE5, phosphodiesterase type 5

Introduction

Used in medicine since the 1980s, shockwave therapy involves the aiming of shockwaves-energy waves that travel faster than the speed of sound-toward treatment areas from outside the body. The approach is sometimes used to break up kidney stones and treat conditions like joint pain, bursitis, and tendinitis. More recently, scientists have examined its use in the treatment of ED, with encouraging results. Low-intensity extracorporeal shock wave therapy (LIESWT) to the penis has recently emerged as a new and promising modality in the treatment of erectile dysfunction (ED). Shock waves are acoustic waves that generate a pressure impulse and that carry energy when propagating through a medium.^{16,17} The degree of focus can be modulated noninvasively, resulting in variable concentration of energy at a desired location. When shock waves are applied to an

organ, the focused waves interact with the targeted deep tissues and act as transient micromechanical forces that initiate several biological changes.¹⁸

This initial study focused on the first initial experience of the LISWT procedure known under the name Men's PoWER Therapy with 22 patients with ED who did not have success with phosphodiesterase type 5 (PDE5) inhibitors or required spontaneous erections. Many patients found the medications are not suitable and some they don't respond to them. Some participants also had vascular risk factors that could contribute to ED, such as diabetes, high lipid levels, high blood pressure, and possible coronary artery disease. For three to six weeks, the men participated in either twice weekly or once weekly PoWER Therapy sessions lasting just a few minutes.¹⁹⁻²¹ Six sessions in all with the STORZ Medical D-ACTOR 100 D with the C-15 Ceramic Grey Tip at 15 Hertz and 2.6 Bar with 500 pulses per 1.5 cm on top of the shaft and 1,000 pulses right side then 1,000 left side just below the shaft on the pelvis/corporal bundle with topical Lidocaine offered and used at patient discretion. At each appointment, shockwaves were applied to the penis and the perineum (the area between the anus and

the scrotum). The men completed a SHIM score at start and post last treatment.^{22,23}

Before treatment, and again at last treatment point, the men's erectile function was assessed using the SHIM score measurements, which is often used in medical studies of ED. The patients were all treated by one of two practitioners. All twenty two (22) of the men (average age: 57.78 years) completed the treatment regime so we calculated the results based on data from this group. We found that 95% of the men had improved erections based on the SHIM Score measurement tool at last treatment. None of the men had side effects from treatment. The men's age and the length of time with ED did not affect the results. We acknowledge several limitations, including the lack of a placebo group and to date no long term follow up.²³⁻²⁵

We stress the need for further research to determine long term benefit and how many LISWT sessions would be most effective and over what period of time (treatment regime) and which men are the best candidates for this therapy. The patients (Table 1) were selected randomly into two groups by patient preference and/or to fit in with clinic schedules between two treatments per week and one treatment session per week. In the two treatment sessions a week group an 8 point average increase in SHIM score was noted from 9.17 to 17.17 average with an average age of 63.33 years (Table 2) where in the one treatment per week group an average increase on 3 point score was noted from 7.5 to 10.5 with an average age of 55.69 years (Table 3). It is worth noting that the ED score was severe in the one treatment per week group and only moderate in the two treatment sessions a week group (Figure 1-3).²⁶⁻³¹

Table 1 Patient group-an early assessment

N = 22	Median	Range
Age Years	40.5	(39 – 80)
IIEF-5 Questionnaire (SHIM) at start	7.05	3 - 20
IIEF-5 Questionnaire (SHIM) after last treatment	10.5	5 - 22

Table 2 Two treatments per week cohort

N = 6	Median	Range
Age Years	63.33	(53 – 75)
IIEF-5 Questionnaire (SHIM) at start	9.17	5 - 18
IIEF-5 Questionnaire (SHIM) after last treatment	17.17	6 - 22

Table 3 One treatment per week cohort

N = 16	Median	Range
Age Years	55.69	(39 – 80)
IIEF-5 Questionnaire (SHIM) at start	7.05	3 - 20
IIEF-5 Questionnaire (SHIM) after last treatment	10.5	5 - 22



Figure 1 The D-ACTOR 100



Figure 2 The treatment head

The IIEF-5 Questionnaire (SHIM) Please Encircle the Response that Best Describes you for the Following Five Questions:					
Over the past 6 month: 1. How do you rate your confidence that you could get and keep an erection?	Very low 1	Low-2	Moderate 3	High 4	Very High 5
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5
3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated your partner?	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5

Figure continues

The IIEF-5 Questionnaire (SHIM) Please Encircle the Response that Best Describes you for the Following Five Questions:					
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	Extremely difficult 1	Very difficult 2	Difficult 3	Slightly difficult 4	Not difficult 5
5. When you attempted sexual intercourse, how often was it satisfactory for you?	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5

Figure 3 SHIM Score Form

Total score: _____

1-7: Severe ED 8-11: Moderate ED 12-16: Mild-moderate ED 17-21: Mild ED 22-25: No ED

References

- Hatzichristou D, d'Anzeo G, Porst H, et al. Tadalafil 5 mg once daily for the treatment of erectile dysfunction during a 6-month observational study (EDATE): impact of patient characteristics and comorbidities. *BMC Urol.* 2015;15:111.
- Rassweiler JJ, Knoll T, Köhrmann KU, et al. Shock wave technology and application: an update. *Eur Urol.* 2011;59(5):784–796.
- Hazan-Molina H, Reznick AZ, Kaufman H, et al. Periodontal cytokines profile under orthodontic force and extracorporeal shock wave stimuli in a rat model. *J Periodontol Res.* 2015;50(3):389–396.
- Becker M, Goetzenich A, Roehl AB, et al. Myocardial effects of local shock wave therapy in a Langendorff model. *Ultrasonics.* 2014;54(1):131–136.
- Hayashi D, Kawakami K, Ito K, et al. Low-energy extracorporeal shock wave therapy enhances skin wound healing in diabetic mice: a critical role of endothelial nitric oxide synthase. *Wound Repair Regen.* 2012;20(6):887–895.
- Abu-Ghanem Y, Kitrey ND, Gruenwald I, et al. Penile low-intensity shock wave therapy: a promising novel modality for erectile dysfunction. *Korean J Urol.* 2014;55(5):295–299.
- Chung E, Cartmill R. Evaluation of clinical efficacy, safety and patient satisfaction rate after low-intensity extracorporeal shockwave therapy for the treatment of male erectile dysfunction: an Australian first open-label single-arm prospective clinical trial. *BJU Int.* 2015;115(Suppl 5):46–49.
- Pelayo-Nieto M, Linden-Castro E, Alias-Melgar A, et al. Linear shock wave therapy in the treatment of erectile dysfunction. *Actas Urol Esp.* 2015;39(7):456–459.
- Frey A, Sønksen J, Fode M. Low-intensity extracorporeal shockwave therapy in the treatment of postprostatectomy erectile dysfunction: a pilot study. *Scand J Urol.* 2016;50(2):123–127.
- Palmieri A, Imbimbo C, Creta M, et al. Tadalafil once daily and extracorporeal shock wave therapy in the management of patients with Peyronie's disease and erectile dysfunction: results from a prospective randomized trial. *Int J Androl.* 2012;35(2):190–195.
- Chitale S, Morse M, Swift L, et al. Limited shock wave therapy vs sham treatment in men with Peyronie's disease: results of a prospective randomized controlled double-blind trial. *BJU Int.* 2010;106(9):1352–1356.
- Poulakis V, Skriapas K, de Vries R, et al. Extracorporeal shockwave therapy for Peyronie's disease: an alternative treatment?. *Asian J Androl.* 2006;8(3):361–366.
- Skolarikos A, Alargof E, Rigas A, et al. Shockwave therapy as first-line treatment for Peyronie's disease: a prospective study. *J Endourol.* 2005;19(1):11–14.
- Zimmermann R, Cumanas A, Miclea F, et al. Extracorporeal shock wave therapy for the treatment of chronic pelvic pain syndrome in males: a randomised, double-blind, placebo-controlled study. *Eur Urol.* 2009;56(3):418–424.
- Bechara A, Casabé A, De Bonis W, et al. Effectiveness of low-intensity extracorporeal shock wave therapy on patients with erectile dysfunction (ED) who have failed to respond to PDE5i therapy. A pilot study. *Arch Esp Urol.* 2015;68(2):152–160.
- Srini VS, Reddy RK, Shultz T, et al. Low intensity extracorporeal shockwave therapy for erectile dysfunction: a study in an Indian population. *Can J Urol.* 2015;22(1):7614–7622.
- Vardi Y, Appel B, Kilchevsky A, et al. Does low intensity extracorporeal shock wave therapy have a physiological effect on erectile function? Short-term results of a randomized, double-blind, sham controlled study. *J Urol.* 2012;187:1769–1775.
- Yee CH, Chan ES, Hou SS, et al. Extracorporeal shockwave therapy in the treatment of erectile dysfunction: a prospective, randomized, double-blinded, placebo controlled study. *Int J Urol.* 2014;21(10):1041–1045.
- Olsen AB, Persiani M, Boie S, et al. Can low-intensity extracorporeal shockwave therapy improve erectile dysfunction? A prospective, randomized, double-blind, placebo-controlled study. *Scand J Urol.* 2015;49(4):329–333.
- Rosen RC, Allen KR, Ni X, et al. Minimal clinically important differences in the erectile function domain of the International Index of Erectile Function scale. *Eur Urol.* 2011;60(5):1010–1016.
- Goertz O, Lauer H, Hirsch T, et al. Extracorporeal shock waves improve angiogenesis after full thickness burn. *Burns.* 2012;38(7):1010–1018.
- Abe Y, Ito K, Hao K, et al. Extracorporeal low-energy shock-wave therapy exerts anti-inflammatory effects in a rat model of acute myocardial infarction. *Circ J.* 2014;78(12):2915–2925.
- Tara S, Miyamoto M, Takagi G, et al. Low-energy extracorporeal shock wave therapy improves microcirculation blood flow of ischemic limbs in patients with peripheral arterial disease: pilot study. *J Nippon Med Sch.* 2014;81(1):19–27.
- Ioppolo F, Rompe JD, Furia JP, et al. Clinical application of shock wave therapy (SWT) in musculoskeletal disorders. *Eur J Phys Rehabil Med.* 2014;50(2):217–230.
- Kim JH, Kim JY, Choi CM, et al. The dose-related effects of extracorporeal shock wave therapy for knee osteoarthritis. *Ann Rehabil Med.* 2015;39(4):616–623.

26. Delius M, Denk R, Berding C, et al. Biological effects of shock waves: cavitation by shock waves in piglet liver. *Ultrasound Med Biol.* 1990;16(5):467–472.
27. Li H, Matheu MP, Sun F, et al. Low-energy shock wave therapy ameliorates erectile dysfunction in a pelvic neurovascular injuries rat model. *J Sex Med.* 2016;13(1):22–32.
28. Qiu X, Lin G, Xin Z, et al. Effects of low-energy shockwave therapy on the erectile function and tissue of a diabetic rat model. *J Sex Med.* 2013;10(3):738–746.
29. Liu J, Zhou F, Li GY, et al. Evaluation of the effect of different doses of low energy shock wave therapy on the erectile function of streptozotocin (STZ)-induced diabetic rats. *Int J Mol Sci.* 2013;14(5):10661–10673.
30. Mense S, Hoheisel U. Shock wave treatment improves nerve regeneration in the rat. *Muscle Nerve.* 2013;47(5):702–710.
31. Ilan Gruenwalda, Ofer Shenfeldb, Juza Chenc, et al. Positive effect of counseling and dose adjustment in patients with erectile dysfunction who failed treatment with sildenafil. *Eur Urol.* 2006;50(1):134–140.