Review Article
Male sexual health and dysfunction

pISSN: 2287-4208 / eISSN: 2287-4690
World J Mens Health 2024 Apr 42(2): 283-289
https://doi.org/10.5534/wjmh.230105

The World Journal of MEN's HEALTH

Variations in Low Intensity Shockwave Treatment Protocols for Erectile Dysfunction: A Review of the Literature and Guide to Offering Treatment

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Low-intensity shockwave therapy (LiSWT) for erectile dysfunction (ED) continues to gain popularity in both clinical practice and the academic literature. The majority of trials and meta-analysis studies have shown LiSWT to be low risk with a trend toward positive improvements in International Index of Erectile Function (IIEF) scores. However, there is still debate over the clinical utility of LiSWT and there is no agreed upon optimal treatment protocol. In this review article we summarize published meta-analysis studies of LiSWT for ED, and review the treatment protocols from randomized sham-control trials published in the last 10 years. We found the most common device settings were an energy of 0.09 mJ/mm^2 and a frequency of 5 Hz. Shock number and location varied, but the most common protocol was 1,500 shocks per session, with 900 shocks to the penis (shaft, base, or hilum) and 600 shocks to the proximal corpora/crura. Protocols ranged from 4 to 12 treatment sessions. We also describe our institutional experience with LiSWT, including patient counseling and treatment protocol.

Keywords: Erectile dysfunction; Hypertension; Phosphodiesterase inhibitors; Sexual dysfunction, physiological

INTRODUCTION

Erectile dysfunction (ED) is a common urologic complaint. Prevalence ranges from 10% to 78% in healthy individuals, with age and patient comorbidities increasing the likelihood of the condition [1]. Men's health providers are expected to be up to date with treatment options and management strategies, including risks, benefits, costs, and efficacy of each option. Phosphodiesterase 5 inhibitors (PDE5i) continue to be the main stay of ED treatment, and are now more cost effective due to generic formulations and cost-saving pharmacy programs [2]. Still, PDE5i and other non-surgical ED treatments such as intracavernosal injections (ICI), intraurethral suppositories, or vacuum erection devices (VED) focus only on symptom management. Historically "restorative therapies" have been less well studied, although data is evolving for treatments such as stem cell therapy, platelet rich plasma, and low-intensity shockwave therapy (LiSWT). The Sexual Medicine of North America (SMSNA) has been guarded in their view of these therapies, citing a paucity of data in a 2021 position statement. However, this document specifically notes that LiSWT is an established and safe

Received: Apr 16, 2023 **Revised:** May 12, 2023 **Accepted:** Jun 7, 2023 **Published online** Sep 26, 2023
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intervention, with the "cumulative results of the trials suggesting a promising degree of efficacy" [3].

LiSWT was introduced into the Men's Health arena in 2010 when Vardi et al [4] published their first series treating patients with ED. Since that time there has been a growing body of evidence regarding ED and LiSWT, but there is still debate over the clinical utility of LiSWT and no agreed upon optimal treatment protocol. In this article we summarize meta-analysis studies, report treatment protocols from published randomized sham-controlled trials, and review the treatment pathway at our institution.

MAIN BODY

1. Background

Shockwave therapy is a clinical intervention which uses sound waves to generate and transmit a positive pressure force onto a treatment area. In the urologic literature, shockwave was first used in the treatment of nephrolithiasis, but has now emerged as a popular treatment for other conditions in urology and other medical specialties [4,5]. A shockwave is produced when a wave moves through a surrounding material faster than the spend of sound [6]. Shock waves are created using one of three types of generators: piezoelectric, electromagnetic, or electrohydraulic. Briefly, piezoelectric devices generate a current across piezo crystals, causing them to rapidly expand and contract. This leads to a pressure pulse that is transmitted through water to create a shock wave. Electromagnetic generators use two conflicting magnetic fields to create a wave and an acoustic lens to focus the resulting shockwave. Finally, electrohydraulic devices use a high voltage across a capacitor to create a gas bubble. This propagates through the surrounding water and leads to a shockwave that is focused using an acoustic lens [5-8].

The exact shockwave properties are variable depending on the source, but the overall result is a wave that has a sharp onset of peak pressure. There is then a slow decline in the wave amplitude, and a period of negative pressure before the next wave begins (Fig. 1) [6]. The cavitation bubble produced by the wave, along with mechanical stress from the wave itself, transmits force onto the treated tissue [9]. For the purposes of ED treatment, this force is applied to the distal and proximal corpora. Although the exact mechanism of action for ED treatment is not known, it is thought that shockwaves cause sheer stress on the corporal endothelium, possibly leading to neo-angiogenesis, vasodilation, and recruitment of stems cells [7].

This article will focus on LiSWT for ED only, with specific attention to the varying treatment protocols used in the literature. We have excluded other urologic uses for LiSWT such as penile pain or Peyronie's disease from this article. Furthermore we will report on LiSWT, and not radial wave therapy, as the type of waves differ and the evidence regarding radial wave therapy is less promising [6,10].

2. Summary of evidence

There are undoubtedly differences in opinion about the utility of LiSWT for ED [3]. However, over the last several years there has been growing evidence on the safety and efficacy of the treatment, resulting in LiSWT being mentioned in the American and European urology guidelines. The 2021 update on Male Sexual Dysfunction from the European Association of Urology (EAU) suggests that LiSWT is a potential treatment options for patients with vasculogenic ED. Caveats include a thorough discussion about the efficacy of the treatment, which is still being established [11]. The 2018

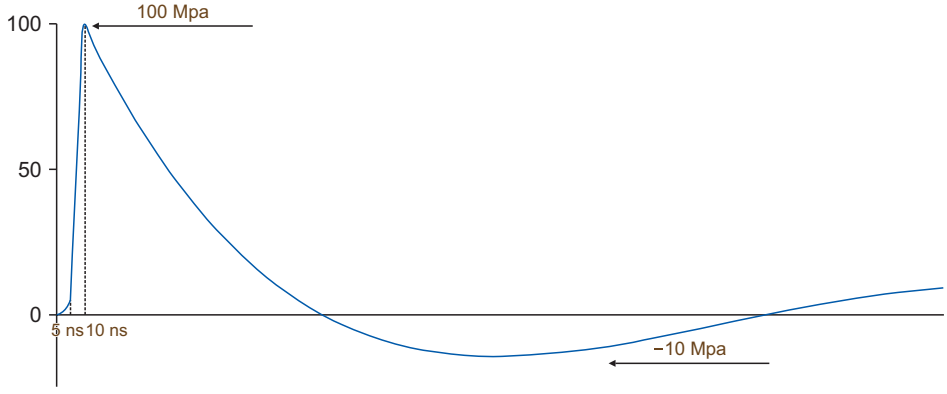

Fig. 1. An idealized pressure *versus* time plot of a shockwave. Reproduced from the article of Katz et al (Sex Med Rev. 2020;8:100-5) [6] with original copyright holder's permission.

American Urological Association (AUA) guidelines on ED take a different approach, stating that LiSWT should only be offered under an experimental context, citing limited efficacy evidence [12]. However, given the preponderance of studies on LiSWT published since the guideline was created, it will be interesting to see if these guidelines change with the next update, as clinical practice patterns of many urologist and men's health professionals have adapted since its publication.

Critics of LiSWT for ED have pointed to the difficulty in summarizing the data in the field. Most randomized control trials (RCTs) have different protocols, patient populations, sham mechanisms, outcome definitions/measurements, and follow up. In an attempt to answer questions about the utility of LiSWT for ED there have been a large number of RCTs published in the last 10 years, as well as approximately 10 meta-analysis studies in about the last 7 years [13-22].

One of the first prominent meta-analysis studies was published in 2017, evaluating 14 studies from 2005 to 2015. Interpretation of the data was limited due to variable treatment protocols. 3 studies reported International Index of Erectile Function (IIEF) outcomes 3 months after treatment, and found that the IIEF scores increased significantly with LiSWT (mean difference: 2.71, 95% confidence interval [CI]: 1.51–3.91; p<0.0001), however the two studies that evaluated IIEF outcomes at 1 month did not show significantly increased IIEF scores [13].

A 2019 study focused on 7 RCTs that specifically looked at LiSWT for ED. They found that 1 month after treatment the mean difference in IIEF scores from baseline was significantly higher in the LiSWT group compared to the sham group 4.23 (p=0.012) [15]. Similarly, a 2019 meta-analysis of 10 sham controlled RCTs specifically for ED also revealed a 3.97 improvement in IIEF scores (95% CI: 2.09–5.84; p<0.0001), with an improved objective measure of peak systolic velocity on penile Doppler ultrasound [17].

Specific patient populations have been evaluated via a meta-analysis approach, with a 2022 study reporting on the effects of LiSWT on ED for post-prostatectomy patients. The meta-analysis showed that in the 4 studies reporting IIEF scores at 3 months, there was a weighted mean difference of 2.04 (95% CI: –3.72 to –0.35; p=0.02) favoring the treatment group [20].

The most recent meta-analysis was published in 2022 by Yao et al [19]. This meta-analysis encompassed 16 RCTs, of which 8 reported IIEF scores at 3 months. The mean difference in IIEF scores was 3.2 (95% CI: 2.49, 3.92; p<0.00001) favoring the treatment arm over the placebo arm.

There has even been a review published recently that attempts to summarize the large number of meta-analysis studies. Again, the overall trend was toward positive treatment effects on IIEF, erection hardness score, and peak systolic velocity scores. However, despite all of these positive trials, the data was limited due to significant heterogenicity in patient populations, comorbidities, causes of ED, treatment protocols, and assessment measures. For this reason, the paper by Yuan et al [23] concluded that nearly all of the recent meta-analysis and systematic reviews are of "critically low" evidence quality, with only one study by Dong et al [22] rated as "low quality" evidence.

3. Treatment protocols

Due to the low risk of treatment and the general trend toward positive results, many providers have started to offer LiSWT as an alternative ED treatment for select patients. However, when offering LiSWT, one of the biggest questions in delivering LiSWT is which protocol to use. Given the lack of consensus of a "best" treatment protocol, we reviewed the literature for randomized, sham-controlled trials of LiSWT for ED published in the last 10 years. Table 1 [24-37] -summarizes the treatment protocols used, specifically distinguishing device settings, shock number, treatment sessions, and shock location (a practical variable not reported in prior LiSWT reviews). We included studies regardless of patient population, origin of ED, or concurrent medication use. Studies that did not report shock location or have a randomized sham-control methodology were excluded. In the studies reviewed, there was an overall trend was toward positive treatment effects. The most common settings were an energy of 0.09 mJ/mm^2 and a frequency of 5 Hz. Shock number and location varied, but the most common protocol was 1,500 shocks per session, with 900 shocks to the penis (shaft, base, or hilum) and 600 shocks to the proximal corpora/crura. The number of sessions ranged from 4 to 12, with variable time intervals between treatments.

https://doi.org/10.5534/wjmh.230105

Table 1. Treatment protocols from randomized sham-controlled trials of low-intensity shockwave therapy for erectile dysfunction

Author (Country, Year)	ED: Patient population/ PDE5i: Response status	Patient (n)	Energy (mJ/mm^2)	Pulse frequency (Hz)	Total shocks	Penile shocks (Shaft/base/hilum)	Proximal shocks (Corpora/crura)	No. of sessions	Device	Outcome
Kalyvianakis et al (Greece, 2022) [25]	ED: Mod vasculogenic PDE5i: Concurrent use	67	0.096	5	5,000	3,000	2,000	12	Aries 2 (Dornier MedTech)	IIEF: +
Motil et al (Czech, 2022) [26]	ED: Post-prostatectomy PDE5i: Unclassified	32	0.16	8	4,000	2,000	2,000	4	PiezoWave2 (Richard Wolf)	IIEF: +
Ladegaard et al (Denmark, 2021) [24]	ED: Post-prostatectomy PDE5i: Unclassified	38	0.15	5	4,000	3,000	1,000	5	Duolith SD1 (Storz Medical)	IIEF: + EHS: +
Ortac et al (Turkey, 2021) [27]	ED: Mild PDE5i: Unclassified	64	0.20	5	3,000	2,400	600	4	Duolith SD1 (Storz Medical)	IIEF: +
Shendy et al (Egypt, 2021) [28]	ED: DM2, Mild-moderate PDE5i: Unclassified	42	0.09	Not listed	3,000	1,800	1,200	12	CSW-400 (Chattanooga Intellect)	IIEF: + PSV: +
Vinay et al (Spain, 2021) [29]	ED: Vasculogenic PDE5i: Non responders	76	0.09	2	5,000	1,800	3,200	4	Renova (DIREX Group)	IIEF: + EHS:+
Kim et al (Korea, 2020) [30]	ED: Unclassified PDE5i: Non responders	81	12–20	5	3,000	2,000	1,000	12	MT 2000H (Urontech Korea)	IIEF: +
Zewin et al (Egypt, 2018) [31]	ED: Post cystectomy PDE5i: Unclassified	128	0.09	2	1,500	900	600	12	Aries device (Dornier MedTech)	IIEF: no change EHS: no change
Fojecki et al (Denmark, 2017) [32]	ED: Unclassified PDE5i: Unclassified	118	0.09	5	600	300	300	5	FBL10 (Richard -Wolf GmbH)	IIEF: no change
Kalyvianakis and Hatzichristou (Greece, 2017) [33]	ED: Vasculogenic PDE5i: Partial response	46	0.09	2.7	1,500	900	600	12	Omnispec ED1000 (Medispec Ltd)	IIEF: + PSV: +
Kitrey et al (Israel, 2016) [34]	ED: Vasculogenic PDE5i: Non responders	55	0.09	2	1,500	900	600	12	Omnispec ED1000 (Medispec)	IIEF: + EHS: +
Olsen et al (Denmark, 2015) [35]	ED: Unclassified PDE5i: Responders	103	0.15	5	3,000	3,000	-	5	Duolith SD1 (Storz Medical)	IIEF: no change EHS: +
Yee et al (China, 2014) [36]	ED: Unclassified PDE5i: Previous users	58	0.09	2	1,500	900	600	12	Omnispec ED1000 (Medispec)	IIEF: no change
Vardi et al (Israel, 2012) [37]	ED: Unclassified PDE5i: Responders	60	0.09	2	1,500	900	600	12	Omnispec ED1000 (Medispec)	IIEF: + EHS: +

ED: erectile dysfunction, PDE5i: phosphodiesterase 5 inhibitors, IIEF: International Index of Erectile Function, EHS: erection hardness score, PSV: peak systolic velocity.

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4. Our experience: patient, counseling, patient selection, and treatment protocol

1) Patient counseling

We began offering LiSWT at our institution with guarded optimism in 2022, and have had an overall positive experience with the treatment. Although the AUA and SMSNA are reserved in their evaluation of LiSWT, we believe that with appropriate counseling and selection patients can make an informed decision regarding LiSWT therapy. We counsel patients that LiSWT is an emerging treatment modality, and that although the initial data is promising, there is a lack of quality evidence regarding the efficacy and long-term durability of treatment. We explain that appropriately selected patients will likely see a clinically meaningful improvement within about 3 months, but that only about 50% of patients will maintain that benefit two years after treatment [38]. Prior to initiating LiSWT, patients are encouraged to undergo a trial of PDE5i. For those with a poor response or side effects we then counsel heavily on other forms of established ED treatment (combination PDE5i, ICI, VED etc.) prior to offering LiSWT.

2) Patient selection

Based on prior evidence and our clinical experience, we believe the ideal patient is a male with mild or moderate vasculogenic ED, as defined by an erectile function score of 5–8 on a 10-point scale. A well-selected patient does not have a history of diabetes, as this condition has been shown to be associated with less efficacious treatment outcomes [38]. We will treat patients with a history of a radical prostatectomy, but we counsel heavily that their response may not be as robust, with prior studies showing an increase in IIEF scores, but not necessarily meaningful sexual function improvement [24]. All patients are encouraged to continue use of other ED therapies during their treatment course. This does cause heterogenicity in our initial treatment cohort, and although we are not able to track results between patients, specific patient reported erectile function scores are followed closely and reviewed during the treatment course.

3) Treatment protocol

We currently offer a non-FDA approved treatment for ED with an MTS electrohydraulic device (MTS). Treatment is not covered by insurance. The out-of-pocket cost is $2,400 for a series of 6 treatments, which is substantially less than the average cost of treatment by other providers [39]. Our treatment protocol was chosen after discussion with the device company and review of prior literature. We ultimately developed a protocol based on a series published by Goldstein et al [40], in which significant improvements in objective erectile parameters were seen in patients treated with weekly sessions of 3,000–5,000 shocks compared to patients treated with 5,000 shocks treated every 3 weeks.

When patients sign up for treatment, we recommend they undergo LiSWT for 6 consecutive weeks. Most patients follow this treatment schedule, however patient preference and scheduling logistics occasionally lead to treatments over a longer duration. Each session consists of 3,000 shocks. The initial treatment is at an energy of 0.12 mJ/mm^2 with a frequency of 3.5 Hz. Five areas are treated during each session. We start with 500 shocks to the right penile base, with an additional 500 shocks the mid/distal right corpora. This is repeated on the left side. Treatment is concluded with 1,000 shocks to proximal corpora in the perinium. In subsequent sessions, the energy is increased by 0.01 J per session, to a maximum energy of 0.16 J (or lower pending patient tolerability). Patients are closely followed after completion of treatment to assess their response.

CONCLUSIONS

There is an evolving debate regarding the efficacy of LiSWT for ED. The results of studies are variable, but one thing that is consistent across the literature is the minimal harm and lack of side effects of LiSWT [41]. As long as patients are appropriately selected and counseled regarding cost, benefits, and long-term efficacy, we believe that LiSWT is a reasonable and ethical treatment option with anecdotally high patient satisfaction.

The field could undoubtedly benefit from further randomized, sham-controlled trials, with a focus on specific patient subsets and long-term follow-up. Future practice patterns will be guided by emerging evidence, as well as updated guidance from the AUA and EAU. It is possible that other restorative therapies may emerge in the future, but at this time we do not think there is enough evidence to support the increased cost to patients [3]. LiSWT is a low-risk therapy with mounting positive evidence, and is in our opinion the most promising, accessible, and cost effective "restor-

ative" treatment commercially available to patients.

Conflict of Interest

The authors have nothing to disclose.

Funding

None.

Acknowledgements

None.

Author Contribution

Conceptualization: SH, NEB. Data curation: SH, EJP, NEB. Formal analysis: SH, EJP, NEB. Funding acquisition: None. Investigation: SH, EJP. Methodology: SH, EJP, NEB. Project administration: SH. Resources: SH, EJP. Supervision: NEB. Validation: EJP. Visualization: EJP. Writing – original draft: SH, EJP. Writing – review & editing: SH, EJP, NEB.

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