



Is low-intensity shockwave therapy for erectile dysfunction a durable treatment option?—long-term outcomes of a randomized sham-controlled trial

Moritz Lange^{1^}, David Charles^{1^}, Aisha Kazeem^{1^}, Marieke Jones^{2^}, Fionna Sun^{1^}, Soutik Ghosal^{2^}, Sarah Krzastek^{3^}, David Rapp^{1^}, Nicolas Ortiz^{1^}, Ryan Smith^{1^}

¹Department of Urology, University of Virginia, Charlottesville, VA, USA; ²Department of Public Health Sciences, University of Virginia, Charlottesville, VA, USA; ³Division of Urology, Department of Surgery, Virginia Commonwealth University, Richmond, VA, USA

Contributions: (I) Conception and design: N Ortiz, S Krzastek, R Smith; (II) Administrative support: D Charles, N Ortiz, R Smith; (III) Provision of study materials or patients: A Kazeem, S Krzastek, F Sun, D Charles, R Smith; (IV) Collection and assembly of data: A Kazeem, F Sun, D Charles, R Smith; (V) Data analysis and interpretation: M Lange, D Charles, M Jones, S Ghosal, R Smith; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Ryan Smith, MD. Department of Urology, University of Virginia, 500 Ray C. Hunt Dr., Charlottesville, VA 22903, USA. Email: RPS2K@uvahealth.org.

Background: Low-intensity shockwave therapy (LiSWT) is an emerging non-invasive and restorative therapy for erectile dysfunction (ED) with demonstrated efficacy and few adverse events. Although LiSWT has been shown to improve erectile function amongst men with ED, few studies have examined its long-term durability. We present the long-term results of a randomized controlled trial (RCT) assessing erectile function after LiSWT.

Methods: A total of 30 patients with baseline ED seen at the University of Virginia were randomized to LiSWT or sham treatment. Patients in the sham group crossed over at 1 month and were unblinded. After initial trial completion, patients enrolled in the long-term outcome study were considered one combined cohort. Patients were treated twice weekly for 3 consecutive weeks with a Storz® Duolith™ device delivering 3,000 shockwaves at 0.1 mJ/mm² to the distal penis, the base of the penis, and the crura. Primary outcomes were changes in Sexual Health Inventory for Men (SHIM) and Erection Hardness Score (EHS) from baseline (3 months pre-treatment) up to 36 months post-treatment. Changes in SHIM and EHS scores were evaluated using linear mixed effects models. Patient satisfaction was assessed with the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) index.

Results: The mean baseline SHIM score was 10.8±0.94. At 12-, 24-, and 36-month assessment following treatment, the mean SHIM scores were 15.6±1.27 (P<0.001), 15.0±1.14 (P<0.001), and 12.2±1.43 (P=0.31). The mean baseline EHS score was 1.87±0.17. At 12-, 24-, and 36-month assessment following treatment, the mean EHSs were 2.70±0.24 (P<0.001), 2.66±0.21 (P<0.001), and 2.29±0.26 (P=0.10). The median [interquartile range (IQR)] EDITS score was 48.9 (22.7, 74.4), indicating moderate satisfaction with LiSWT. There were no adverse events recorded.

Conclusions: Our analysis demonstrates sustained long-term improvement in erectile function after LiSWT for a heterogeneous cohort. While limited by population size, the results suggest durable improvement in erectile function for the first 2 years with a peak treatment effect at 1 year. Treatment effect appears to decline between 2 and 3 years.

Clinical Trial Registration: ClinicalTrials.gov, NCT04434352.

^ ORCID: Moritz Lange, 0000-0003-3423-2478; David Charles, 0000-0001-8855-3627; Aisha Kazeem, 0009-0002-3589-4721; Marieke Jones, 0000-0001-5045-6725; Fionna Sun, 0009-0006-9895-4196; Soutik Ghosal, 0000-0003-0548-3104; Sarah Krzastek, 0000-0002-3791-0660; David Rapp, 0000-0002-8729-5301; Nicolas Ortiz, 0000-0002-4432-4942; Ryan Smith, 0000-0002-3880-9740.

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Introduction

Erectile dysfunction (ED) is an increasingly prevalent disorder with increased age and presence of comorbid conditions (1). As the predominant etiology, vasculogenic ED has the largest research interest (2). While the treatment options beyond lifestyle change and phosphodiesterase 5 inhibitors (PDE5is) are well-established treatments, they are more invasive and less popular as a result (3). A noteworthy problem with the aforementioned treatments, regardless of their degree of invasiveness, is that they are not designed to reverse the underlying pathology. Thus, when low-intensity shockwave therapy (LiSWT) emerged in 2010 (4) as a viable option, it was a significant pivot in the treatment approach for patients with ED. Since its initial application, subsequent studies have shown that LiSWT is a low-risk and well-tolerated technique used to treat ED (5,6). Furthermore, multiple recent randomized controlled trials (RCTs) of men with mild to moderate ED treated

with LiSWT have further supported its use for ED (7-9). Although the exact mechanism of action remains unknown, it has been hypothesized that LiSWT induces focused microtrauma with resultant angiogenic growth factors and neovascularization in the region of interest (10).

While LiSWT has shown sustained results in the short-term (i.e., ≤ 6 months) with improvements in the 5-item International Index of Erectile Function (IIEF-5) score, Sexual Encounter Profile (SEP) score, and Erection Hardness Score (EHS) (7-9), few studies have looked at its long-term durability. Brunckhorst *et al.* performed a systematic review of long-term efficacy of LiSWT and identified a potential plateau in improvement occurring between 6 and 12 months (11). Many of the papers analyzed showed limited subjective improvement beyond 6 months although this analysis was impacted by the limited follow-up duration and heterogeneity of included studies. A study by Chung *et al.* reported significantly longer follow-up (5-year), demonstrating persistent safety and satisfaction with LiSWT, although also demonstrated a plateau after the immediate IIEF-5 improvement (12). We have previously reported our short-term results through 6-month follow-up, demonstrating improved IIEF-5 scores with LiSWT as compared to sham (9). The objective of this study was to extend the follow-up duration of the initial cohort through 36 months. We present this article in accordance with the CONSORT reporting checklist (available at <https://tau.amegroups.com/article/view/10.21037/tau-24-329/rc>).

Highlight box

Key findings

- Low-intensity shockwave therapy (LiSWT) showed statistically significant improvement in erectile function at 1 and 2 years post-treatment compared to baseline.
- Improvements in erectile function seem to decline after 2 years, suggesting that treatment benefits are not indefinite.
- No adverse events occurred.

What is known and what is new?

- A number of studies have shown that LiSWT is a safe and promising short-term treatment option for patients with erectile dysfunction.
- Limited number of studies report long-term data beyond 1 year, thus making it difficult to assess how long these benefits last.

What is the implication, and what should change now?

- LiSWT is an exciting non-surgical treatment option for patients with erectile dysfunction. However, the duration of its efficacy has yet to be fully understood. One future consideration is if patients should be offered additional rounds of therapy to prolong its effects.

Methods

The full original study methodology is detailed in our prior publication (9). In brief, patients with mild to moderate ED as defined by the abridged IIEF-5, also known as the Sexual Health Inventory for Men (SHIM) score, were randomized to LiSWT (n=17) or sham treatment (n=16). The study biostatistician generated the randomization protocol using the blockrand package in R stratified by the clinical group. The clinical research coordinator assigned patients to each group. Only the patient was blinded from the treatment

group. However, patients in the sham group crossed over to treatment at 1 month thus becoming unblinded. For patients taking PDE5is prior to the study, patients were instructed to hold any PDE5is for 2 weeks prior to the start of their LiSWT treatment and to refrain from using any erectile aids until 1 month after completion of their treatment. All patients were treated at the University of Virginia via an experienced urologic surgeon or advanced practice provider twice weekly for 3 consecutive weeks for a total of 6 treatments with a Storz® Duolith™ device (Storz Medical AG, Tägerwil, Switzerland) delivering 3,000 shockwaves at 0.1 mJ/mm² to the distal penis, the base of the penis, and the crura. The sham group was treated with the same device, however an alternative probe tip was used to block any shockwave energy from penetrating the tissue. The combined cohort had a sample size of 30 patients and was treated as a single cohort in this study. The final sample size included in the follow-up study was limited by patient response to the study extension request.

All patients enrolled in the initial trial were periodically seen in routine follow-up for ED or via telephone at roughly 12-, 24-, and 36-month after LiSWT. Primary outcomes were changes in SHIM score and EHS from baseline (3 months pre-treatment) to latest post-treatment follow-up (follow-up time is dated based on the time of completion of the LiSWT treatment course). The SHIM has a maximum score of 25, with ranges indicating severity as follows: 17 to 21 for mild ED, 12 to 16 for mild-moderate ED, and 8 to 11 for moderate ED. EHS has a maximum score of 4, with a score of 3 indicating successful penetration. The secondary outcome assessed overall patient satisfaction with the treatment at 12 months post-treatment using the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) score, with 0 being lowest satisfaction and 100 being the highest satisfaction. All patients were asked to verify that there were no changes to their treatment; including PDE5i use, intracavernosal injections, or additional LiSWT at another institution throughout the study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was approved by the institutional review board of the University of Virginia (IRB No. 190082) and registered in ClinicalTrials.gov (No. NCT04434352). Clinical research coordinators enrolled patients, and all participants provided written consent. Enrollment for the original study began in April 2020 and ended in June 2022. Any adverse events related to treatment were also collected.

Statistical analysis

Linear mixed effects models with a random effect of patient were built to explain our outcomes (SHIM score, EHS). The number of days past treatment, fit with restricted cubic splines using degree of freedom (df) =3, was the independent variable. This type of model accounts for correlations among data from the same individual and allows a non-linear relationship between time and the outcome. We then investigated the effects of age, diabetes status, coronary artery disease (CAD), hypertension (HTN), hyperlipidemia (HLD), low testosterone, prior response to treatment, and smoking as covariates in multiple regression models. Marginal means estimated from the models were calculated at 3-month prior to the end of treatment, the final day of treatment (day 0), and 12-, 24-, and 36-month past the end of treatment. All analyses and plots were created in R (vers. 4.3.3 “Angel Food Cake”) using packages lme4 (13), lmerTest (14), and emmeans (15). Comparisons between time points were analyzed using Satterthwaite’s *t*-tests. Unless otherwise specified, all mean values in the report are estimated marginal means.

Results

The median [interquartile range (IQR)] time of baseline measurements was 2.73 (1.86, 4.69) months pre-treatment. The median (IQR) follow-up period post-treatment was 30.0 (25.5, 33.0) months. The sample size was 30, 6, and 21 patients at 12, 24, and 36 months, respectively. Demographics and baseline clinical characteristics can be found in *Table 1*. The median (IQR) age was 69 [63, 72] years old. Six patients (20%) had a history of diabetes, 5 (17%) had low testosterone levels at baseline and 7 (23%) had a known history of smoking.

Multiple regression models testing for the effect of age, diabetes status, CAD, HTN, HLD, low testosterone, prior response to treatment, and smoking as covariates found no significant effect of any covariate in either outcome model, so the models presented only include time as an independent variable.

The estimated marginal mean [95% confidence interval (CI)] baseline SHIM score was 10.8 (8.95, 12.7). At 12-, 24-, and 36-month, the SHIM scores were 15.6 (13.07, 18.1), 15.0 (12.79, 17.3), and 12.2 (9.38, 15.0), respectively (*Figure 1*, *Table 2*). When compared to baseline, SHIM scores were improved (*P*<0.05) at all time points except at 36-month (*P*=0.31). The estimated marginal mean (95%

Table 1 Baseline demographics

Characteristics	Values (n=30)
Age (years), median [IQR]	69 [63, 72]
History, n [%]	
Diabetes	6 [20]
CAD	3 [10]
HTN	14 [47]
HLD	13 [43]
Low testosterone	5 [17]
Smoking	7 [23]
PDE5i response prior to treatment, n [%]	8 [27]

IQR, interquartile range; CAD, coronary artery disease; HTN, hypertension; HLD, hyperlipidemia; PDE5i, phosphodiesterase 5 inhibitor.

CI) baseline EHS was 1.87 (1.53, 2.21). At 12-, 24-, and 36-month, the EHSs were 2.70 (2.23, 3.17), 2.66 (2.24, 3.07), and 2.29 (1.77, 2.82), respectively. Similarly, the EHSs were significantly improved over baseline ($P<0.05$) at all time points except at 36-month ($P=0.10$). Graphical representation of this data can be seen in *Figure 2*.

The median (IQR) EDITS score after treatment with LiSWT was 48.9 (22.7, 74.4). There were no adverse events reported.

Discussion

Our long-term follow-up data showed that there was a statistically significant improvement in SHIM score and EHS when compared to baseline up to 24 months post-treatment. Maximum values in both outcomes occurred

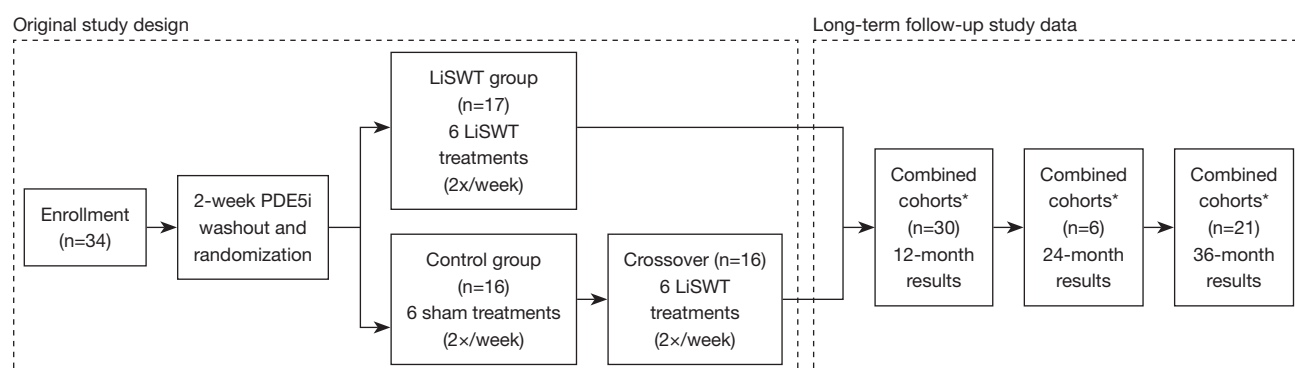


Figure 1 Study protocol outlining the methodology used in the initial study and for the combined long-term follow up study data as is highlighted by the dotted box. One patient in the sham arm was lost to follow up prior to the primary outcome was able to be assessed, leaving 16 patients in the original control group. *, all participants in the combined cohort received LiSWT treatments with follow-up dated after the completion of their treatment course. LiSWT, low-intensity shockwave therapy; PDE5i, phosphodiesterase 5 inhibitor.

Table 2 Long-term data showing the effect of LiSWT treatment on the primary outcomes (SHIM score and EHS) at 1, 2, and 3 years after treatment completion

Primary outcomes	Baseline	1 year [†]	2 years [‡]	3 years [§]
SHIM score				
Mean (95% CI)	10.8 (8.95, 12.7)	15.6 (13.07, 18.1)	15.0 (12.79, 17.3)	12.2 (9.38, 15.0)
P value		<0.001*	<0.001*	0.31
EHS				
Mean (95% CI)	1.87 (1.53, 2.21)	2.70 (2.23, 3.17)	2.66 (2.24, 3.07)	2.29 (1.77, 2.82)
P value		<0.001*	0.004*	0.10

[†], between baseline and 1 year: n=30, 99 data points; [‡], between 1 and 2 years: n=6, 6 data points; [§], between 2 and 3 years: n=21, 21 data points; *, $P<0.05$. All values are estimated means. P values are a comparison with baseline. LiSWT, low-intensity shockwave therapy; SHIM, Sexual Health Inventory for Men; EHS, Erection Hardness Score; CI, confidence interval.

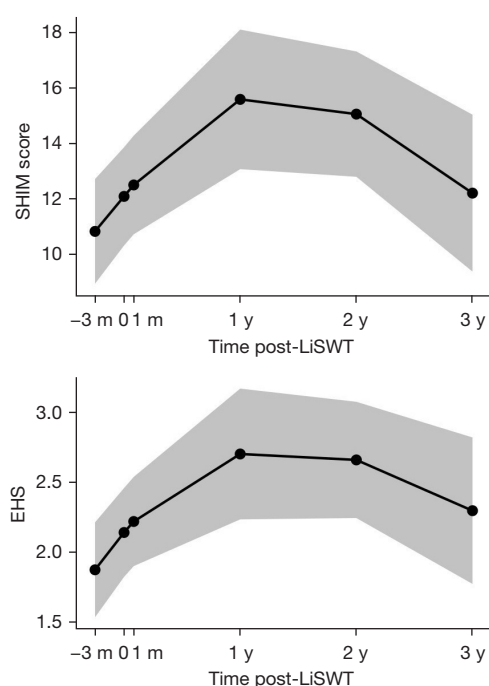


Figure 2 Estimated marginal mean and 95% CI of SHIM score (top) and EHS (bottom) for participants after LiSWT treatment. SHIM, Sexual Health Inventory for Men; EHS, Erection Hardness Score; LiSWT, low-intensity shockwave therapy; CI, confidence interval; m, months; y, years.

at the 12-month follow-up, suggesting that the largest improvements in erectile function when treated with LiSWT are observed within the first year of treatment. Between 12 and 24 months, these improvements were sustained, consistent with a previously described plateau effect (12). However, only 6 patients completed the survey at 24 months, thus limiting these conclusions. According to Rosen *et al.*, a minimal clinically important difference for the IIEF-5 is an increase of at least four points (16). This would suggest that the observed improvement in this study likely has clinical significance.

When compared to baseline, our results suggest that LiSWT has a sustained improvement for 2 years after treatment completion. After which, the results from our 36-month follow-up indicate that there may be a time-sensitive decline in sustained improvement. Comparing our long-term data to other published results, the decline in long-term efficacy seems to be variable among study groups. For example, Chung *et al.* reported an initial small continuous decrease in erectile function before reaching a sustained plateau around 4 years after completion of a

single course of LiSWT treatment (12). Whereas, Kitrey *et al.* reported that while LiSWT is effective in the short term, treatment efficacy was maintained after 2 years in only half of their patients. Further subgroup analysis of their results revealed that milder forms of ED were more likely to have a sustained response beyond 2 years, maintaining treatment efficacy in 76% of patients (17). Despite both studies suggesting that sustained improvement likely extends up to or even beyond 2 years, there exists a significant variance regarding the onset and duration of the plateau period. Some studies have even cited concerns that a decline in efficacy can occur within the first 12 months after initial treatment (11). The systematic review published by Brunckhorst *et al.* reported that of the five studies that reported 12-month outcomes, two showed a plateauing effect by 12 months, while three showed a deterioration at the 12-month follow-up (11). In general, our authors postulate if this deterioration over time is due to treatment regression or if this is secondary to disease progression as increasing age is a known cause of worsening ED (18).

One of the biggest challenges in comparing studies using LiSWT to treat ED is that treatment protocols are heterogeneous. Variations in devices, energy levels, number of shockwaves delivered and treatment frequency make direct comparisons difficult. A systematic review by Yao *et al.* examining various treatment protocols published between 2011 and 2021 found that LiSWT protocols were most effective in treating ED when they had an energy density of 0.09 mJ/mm² and pulse number of 1,500 to 2,000 (6).

However, while this represents progress in determining the optimal treatment settings, the effectiveness of multiple rounds of LiSWT treatments remains uncertain, particularly in individuals who have a robust response with an early decline in function. Some studies have reported promising results, showing improved function with repeat treatments (19,20). For instance, Geyik *et al.* reported results on two rounds of LiSWT being used to treat ED (20). In their study, 41 patients were administered two rounds of LiSWT separated by 6 months. The primary outcome of their study looked at changes in the mean International Index of Erectile Function-Erectile Function Domain (IIEF-EF). At 6-month following the first course, there was a statistically significant increase of 6.44 points in the IIEF-EF score. At 6-month following the second course, there was also a statistically significant increase of 3.66 points. These findings suggest a potential additive effect of multiple treatment rounds, supporting the idea that additional courses may be beneficial if initial improvements deteriorate

over time.

Limitations of our study include a small sample size, performance at a single institution, and lack of objective measurements of penile hemodynamics. Although, there is good evidence to suggest that subjective erectile function evaluations correlate well with objective penile hemodynamics (21,22). Another limitation is that participants were unblinded after crossover, thus making it difficult to discern between placebo effect and treatment response in follow-up. ED treatments carry a known high degree of placebo response which cannot be ruled out. Despite these limitations, our data contributes to the literature of long-term data supporting the use of LiSWT as an effective and safe non-invasive treatment options for patients experiencing ED. Study participants reported no adverse events.

Conclusions

Our long-term data demonstrates sustained improvement in erectile function for up to 2 years after treatment with LiSWT, after which we observed a decline in erectile function by 3 years. Further research is needed to standardize treatment protocols, as well as to explore the potential opportunity for multiple treatment courses in patients who do not have a sustained improvement in erectile function.

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Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at <https://tau.amegroups.com/article/view/10.21037/tau-24-329/rc>

Trial Protocol: Available at <https://tau.amegroups.com/article/view/10.21037/tau-24-329/tp>

Data Sharing Statement: Available at <https://tau.amegroups.com/article/view/10.21037/tau-24-329/dss>

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Conflicts of Interest: All authors have completed the ICMJE

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of University of Virginia (IRB No 190082) and registered in ClinicalTrials.gov (No. NCT04434352) and informed consent was obtained from all individual participants.

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