

Letter to the Editor

Re: Fojecki G, Tiessen S, Osther PJ. Effect of Linear, Low-intensity Extracorporeal Shock Wave Therapy for Erectile Dysfunction. Eur Urol Suppl 2018;17:e1701

Erectile Dysfunction Treatment Using Linear Low-intensity Extracorporeal Shockwaves

We read with great interest the study by Fojecki and colleagues [1] regarding focused, linear, low-intensity extracorporeal

shockwave therapy (LLi-ESWT) for erectile dysfunction (ED). We found their claim that LLi-ESWT has no short- or long-term effects on ED surprising, because we have treated hundreds of patients in the past few years using the same shockwave device and have obtained very satisfactory treatment outcomes. Because of the difference in clinical outcomes, we carried out an analysis and calculated the energy used by Fojecki et al.

The settings used by Fojecki et al. deliver approximately 6 mJ for every pulse. The energy setting we use is 15.45 mJ

Table 1 – Patient characteristics before treatment and satisfaction after treatment^a

	Active treatment (n = 30)	Sham treatment (n = 30)	p value ^b
Before treatment			
Sexual Encounter Profile Q 2, n (%)	11 (36.7)	17 (56.7)	0.195
Sexual Encounter Profile Q 3, n (%)	0 (0.0)	0 (0.0)	1.000
Hypertension, n (%)	24 (80.0)	17 (56.7)	0.095
Dyslipidemia, n (%)	22 (73.3)	21 (70.0)	1.000
Diabetes, n (%)	13 (43.3)	8 (26.7)	0.279
Coronary artery disease, n (%)	6 (20.0)	3 (10.0)	0.472
Obesity (BMI ≥ 30 kg/m ²), n (%)	13 (43.3)	12 (40.0)	1.000
Late-onset hypogonadism, n (%)	4 (13.3)	3 (10.0)	1.000
Smoking, n (%)	4 (13.3)	5 (16.7)	1.000
Previous treatment, n (%)	20 (66.7)	20 (66.7)	1.000
Phosphodiesterase type 5 inhibitors	16 (53.3)	19 (63.3)	0.601
Alprostadil	4 (13.3)	1 (3.3)	0.353
Age at the time of examination (yr)	54.7 ± 9.2; 54.0 (40.0–70.0)	53.9 ± 9.3; 53.0 (40.0–70.0)	0.767
Erectile dysfunction duration (mo)	58.7 ± 49.2; 45.0 (6.0–204.0)	62.6 ± 57.6; 42.0 (6.0–204.0)	0.929
BMI (kg/m ²)	29.6 ± 4.2; 29.0 (23.0–39.0)	29.6 ± 4.8; 29.0 (22.0–43.0)	0.885
Testosterone (ng/ml)	18.1 ± 5.8; 16.5 (10.8–36.6)	18.8 ± 5.7; 18.1 (12.1–38.3)	0.487
IIEF score	13.1 ± 3.6; 13.0 (6.0–20.0)	12.8 ± 3.9; 14.0 (5.0–19.0)	0.864
Erectile hardness score	2.1 ± 0.5; 2.0 (1.0–3.0)	2.1 ± 0.5; 2.0 (1.0–3.0)	0.619
After 4 wk of treatment			
Very satisfied with the treatment, n (%)	6 (20.0)	13 (43.3)	0.095
Partly satisfied with the treatment, n (%)	7 (23.3)	6 (20.0)	1.000
Dissatisfied with the treatment, n (%)	17 (56.7)	11 (36.7)	0.195
Partner high satisfaction, n (%)	7 (23.3)	12 (40.0)	0.267
Partner intermediate satisfaction, n (%)	6 (20.0)	7 (23.3)	1.000
Partner low satisfaction, n (%)	17 (56.7)	11 (36.7)	0.195
After 12 wk of treatment			
Very satisfied with the treatment, n (%)	5 (16.7)	19 (63.3)	<0.001
Partly satisfied with the treatment, n (%)	4 (13.3)	6 (20.0)	0.863
Dissatisfied with the treatment, n (%)	21 (70.0)	5 (16.7)	<0.001
Partner high satisfaction, n (%)	5 (16.7)	19 (63.3)	<0.001
Partner intermediate satisfaction, n (%)	4 (13.3)	6 (20.0)	0.863
Partner low satisfaction, n (%)	21 (70.0)	5 (16.7)	<0.001

BMI = body mass index; IIEF = International Index of Erectile Function; IIEF-5 = The IIEF-5 score is the sum of the ordinal responses to the 5 items; 22–25 = No erectile dysfunction; 17–21 = Mild erectile dysfunction; 12–16 = Mild to moderate erectile dysfunction; 8–11 = Moderate erectile dysfunction; 5–7 = Severe erectile dysfunction.

^a Results for continuous variables are presented as mean ± standard deviation; median (range).

^b Fisher's exact test for categorical variables and a Mann-Whitney U test for continuous variables.

for every pulse. Four sessions of 6000 pulses thus results in total energy of approximately 370 000 mJ delivered over the total treatment, compared to ~36 000 mJ (6000 pulses \times 6 mJ) in the protocol used by Fojecki et al.

In addition, Fojecki et al. use a 0-mm gel pad [2], which means that the shockwave focus is at a depth of 0 mm, so the highest energy level occurs at the skin surface and not within the target tissue. The decision to use a 0-mm gel pad also reduces the total energy delivered to approximately 20 000 mJ, which is only 4.3% of the energy we use. In our setting we use a gel pad of 10 or 15 mm so the shockwave focus and the highest energy are 10–15 mm under the skin, directly into the cavernous tissues and not on the skin surface, taking the shape of the shockwave field into consideration.

Finally, unlike our setting, Fojecki et al. did not use a linear shockwave tissue coverage (LSTC)-ED technique, which ensures complete tissue coverage by moving the applicator over the entire erectile tissue.

We conclude that that the extremely low intensity settings, the shockwave depth of penetration, and the treatment delivery technique used by Fojecki et al. resulted in a treatment dose insufficient for a clinical effect and that their treatment protocol provides no therapeutic effect because of inappropriate parameters.

We would agree with their conclusion elsewhere that “LLi-ESWT using 600 shockwaves per treatment session for 10 weeks, with an energy flux density of 0.09 mJ/mm² did not improve erectile function. Future studies should evaluate whether a larger number of pulses and changing the shockwave penetration depth might increase efficacy” [2].

We performed a similar study with more suitable settings and an LSTC-ED technique that delivers a sufficient amount of energy to the cavernous tissues. We included 60 patients in the study (Table 1) and found a significant difference in erection quality between the active and sham groups at 4 and

12 wk after treatment as measured using the International Index of Erectile Function (IIEF-5; $p = 0.049$ and $p < 0.001$, respectively), and an increase in erectile hardness score (EHS) after 4 and 12 wk ($p = 0.030$ and $p < 0.001$, respectively). Thus, after 12 wk, the differences in IIEF-5 score and EHS between the groups were highly significant.

Our study therefore confirms that LLi-ESWT with a sufficient amount of energy delivered to the cavernous tissues and applied using a technique that guarantees complete cavernous tissue coverage can improve ED.

Conflicts of interest: The authors have nothing to disclose.

References

- [1] Fojecki G, Tiessen S, Osther PJ. Effect of linear, low-intensity extracorporeal shock wave therapy for erectile dysfunction. *Eur Urol Suppl* 2018;17:e1701. [http://dx.doi.org/10.1016/S1569-9056\(18\)32030-X](http://dx.doi.org/10.1016/S1569-9056(18)32030-X).
- [2] Fojecki GL, Tiessen S, Osther PJ. Effect of low-energy linear shockwave therapy on erectile dysfunction—a double-blinded, sham-controlled, randomized clinical trial. *J Sex Med* 2017;14:106–12.

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