

# Low Intensity Linear Extracorporeal Shockwaves Improves Erectile Function for Patients who are Unsatisfied from Phosphodiesterase Type 5 (PDE5) Inhibitors

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# **Background**

The current standard of care for ED consists of lifestyle changes such as management of diet and diabetes, along with pharmacotherapies. The current gold standard treatment is the use of phosphodiesterase 5 inhibitors (ref. 1).

All three PDE5 inhibitors have shown a comparable efficacy profile with success rates of 70–75% in broad-spectrum ED populations. However, the efficacy profile declines in special subpopulations, such as diabetic patients (ref. 2).

This study is intended to evaluate the effect of low-intensity linear shockwaves on patients who suffer from Vasculogenic erectile dysfunction, being treated regularly by PDE5 inhibitors and are not fully satisfied from the pharmacotherapy outcomes.

#### **Patients and Methods**

20 men participated in this study; all patients were PDE5 inhibitors users who were diagnosed as Vasculogenic ED patients with different levels of severities. Patients arrived for a screening session in which their physical condition and their medical history were examined. The severity of symptoms was evaluated by International Index of Erectile Function (IIEF, erectile function domain), the Sexual Encounter Profile (SEP) and the Erection Hardness Score (EHS). All of these questionnaires were filled out by the patients at screening session and referred to sexual attempts in which PDE5 inhibitors were used. Included patients were those who have been suffering from Vasculogenic ED for at least 6 months and their IIEF-EF score was between 11 and 25 while using PDE5 inhibitors. Patients who suffer from a hormonal, psychological or neurological disease, had a radical prostatectomy or suffer from a clinically significant chronic hematological disease were excluded from this study.

Patients arrived to the clinic four times on a weekly basis for a shockwave therapy. The treatment was conducted by an electromagnetic device, producing low intensity linear shockwaves ('Renova', Direx Group/Initia Ltd Israel). Shocks were applied to the Crura and at the Corpora, each at both sides, for a total number of 5000 shocks per treatment session.

Patients continued to use PDE5 inhibitors regularly during the treatment and follow-up.

At 1 month post the end of treatment, patients arrived once again to the clinic and answered the following questionnaires for erectile function evaluation and treatment evaluation: IIEF-EF, SEP, EHS and Global Assessment Questions (GAQ).

### **Results**

Out of the 20 patients that were recruited for this study, 19 patients have finished treatment. 1 patient had dropped out of the study after 1 treatment session because of personal issues.

The mean age of patients was  $41.6\pm12.3$  years (24-70), 31% of them were smokers. These patients have been suffering from erectile dysfunction for a mean duration of 6.4 years.

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26.3% of the subjects suffered from Diabetes and 21.1% had high Cholesterol levels. The outcomes of the evaluation questionnaires that were used before and after treatment are presented in the following table.

	IIEF-EF	SEP-	SEP-	EHS	GAQ-	GAQ-
		question 2	question 3		question 1	question 2
Baseline	16.6±2.3	63.2%	0.0%	2.68		
		answered	answered			
		"Yes"	"Yes"			
1 month	25.2±1.5	100.0%	100.0%	4.00	100.0%	100.0%
follow-up		answered	answered		answered	answered
		"Yes"	"Yes"		"Yes"	"Yes"

# **Conclusions**

This study deals with men who regularly use oral medications in order to improve their erectile function. These men report on a positive response to PDE5 inhibitors, yet, their erectile function does not enable them to perform sexually satisfactorily. The examined treatment is hereby proved to have great influence on Vasculogenic ED patients. In addition, almost 50% of the subjects have succeeded in performing sexually without any medications in the month following shockwave treatment.

#### References

- George F. Lasker, Jason H.Maley, and Philip J. Kadowitz, A Review of the Pathophysiology and Novel Treatments for Erectile Dysfunction, Hindawi Publishing Corporation Advances in Pharmacological Sciences Volume 2010, Article ID 730861, 10 pages doi:10.1155/2010/730861
- 2. Hartmut Porst, PhosphodiesteraseType-5 Inhibitors: A Critical Comparative Analysis, EAU Update Series 2 (2004) 56–63.