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## Efficacy of Low-intensity shock wave therapy for the treatment of ED in diabetic patients : A Pooled analysis

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### Introduction

Low-intensity shock wave therapy (LI-ESWT) using the Omnispec model ED1000 has been shown to be effective as a non-invasive treatment for men suffering from vasculogenic Erectile Dysfunction (ED). It has provided benefit for both PDE5i responders and non-responders regardless of severity level. Diabetes induced ED is more severe and more difficult to treat due to combined vasculopathy and peripheral neuropathy that both negatively affect the erectile mechanism. Our aim was to assess the efficacy of LI-ESWT specifically on diabetic ED patients.

### Aim

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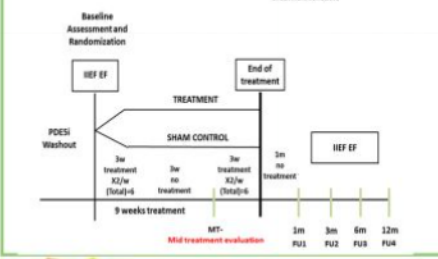
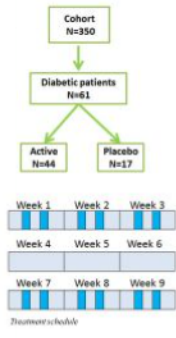
### Method

Analysis of pooled data from 4 double-blind, sham-controlled trials conducted in Israel, USA, Greece and India was performed.

The analysis provided a cohort of 350 PDE5i responders with vasculogenic ED that underwent LI-ESWT therapy. We sub-analyzed the 61 diabetic patients that were part of this cohort. Of these, 44 had received LI-ESWT treatment and 17 underwent sham.

The treatment protocol was identical in all 4 studies; LI-ESWT was applied to five sites on the corpora X2 weekly for 3 weeks and repeated after a 3 week rest period for a total of 12 treatment sessions.

IIEF-EF domain scores were documented at baseline, at mid-treatment (MT-end of rest period); 1-month (FU1), 3-months (FU2), 6-months (FU3) and 12 months (FU4) post last treatment.

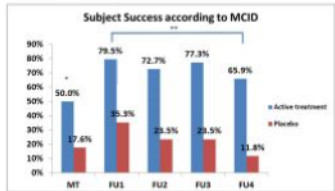


### Results

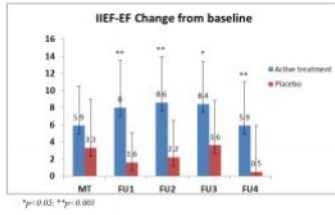
The average baseline IIEF-EF scores were: 11.4±4 and 11.5±3.8 for the treated and sham group respectively. The mean change in IIEF-EF domain scores of the treated group from baseline to MT, FU1, FU2, FU3 and FU4 were 5.9(±4.6), 8(±5.5), 8.6(±5.3), 8.4(±5.0) and 5.9(±5.1); (p<0.001) respectively. The difference between the treated and sham groups was significant (p<0.05) at all follow-up visits.

Minimally clinical important difference (MCID; 2.5,7, points change for mild, moderate and severe ED, respectively) in IIEF-EF score was achieved in 50%, 79.5%, 72.7%, 77.3% and 65.9% of the subjects in the treated group in MT, FU1, FU2, FU3 and FU4 respectively. The sham group achieved MCID in 17.6%, 35.3%, 23.5%, 23.5% and 11.8% of the subjects in MT, FU1, FU2, FU3 and FU4, respectively. The difference between the groups was significant (p<0.05) at MT and all follow-up visits.

	Placebo		Active			
	N	Mean	STD	N	Mean	STD
Age	17	53.6	11.4	44	53.0	8.9
ED Duration (yrs)	15	5.9	4.7	28	4.6	3.3



\*p<0.05; \*\*p<0.001  
MCID- Minimal clinically important differences according to Rosen RC, Allen AR, Ni X, Anagnostou AD. Minimal clinically important differences in the erectile function domain of the International Index of Erectile Function scale. European urology. Nov 2012;60(5):1010-1016



\*p<0.05; \*\*p<0.001

### Conclusion

LI-ESWT was demonstrated to be effective for the treatment of ED in patients suffering from DM. LI-ESWT was well tolerated; adverse events were mild, self-limited and resolved spontaneously. Success is noted already following 6 treatment sessions according to MCID, however even patients who failed to demonstrate improvement following 6 treatment sessions may improve following 12 treatment sessions. These results support the use of LI-ESWT with the Omnispec model ED1000 applying the original treatment protocol for Diabetes induced ED.

### Acknowledgements

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