

ORTHOSPEC™ VS. PLACEBO FOR THE TREATMENT OF CHRONIC PROXIMAL PLANTAR FASCIITIS

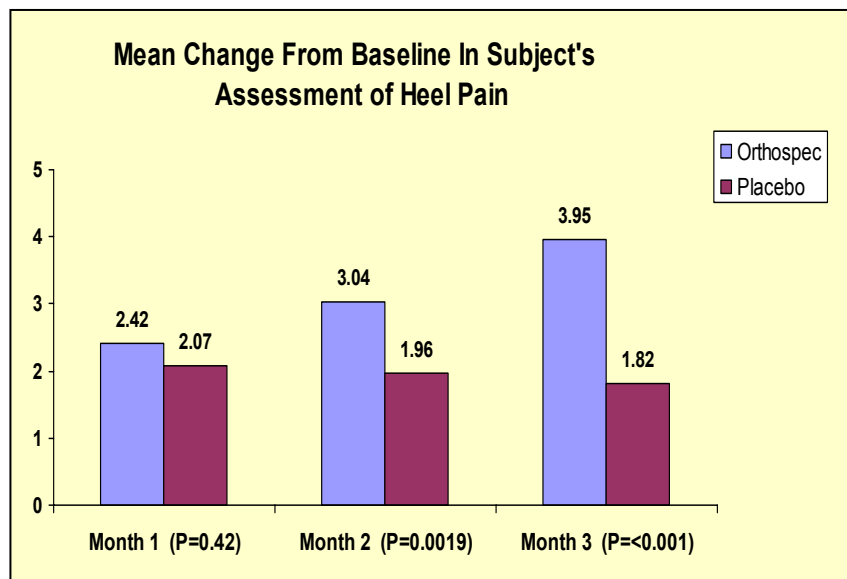
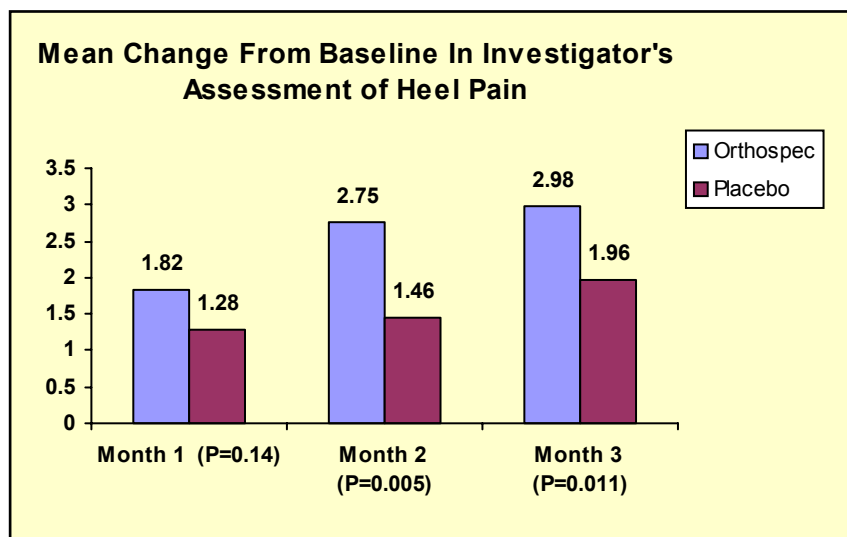
OBJECTIVE: To demonstrate efficacy and safety of the Orthospec™ ESWT device for the treatment of chronic heel pain caused by plantar fasciitis

METHODS: Randomized, placebo-controlled, multi-center, double-blind, IRB approved, FDA clinical trial.

RESULTS: 172 participants were randomized to either the Orthospec™ treatment or Placebo. The purpose was to assess the improvement of patients' heel pain measured by the Visual Analog Scale (pain score). Orthospec™ showed significantly greater reduction in the investigator's and subject's assessment of heel pain, and the reduction in the use of analgesics. There were no serious adverse events encountered in this clinical trial. Three participants in the Orthospec™ group reported one adverse event each; two cases of local bruising and one case of mild swelling.

Efficacy Results

Mean change from baseline in the investigator's and subject's assessment of heel pain:

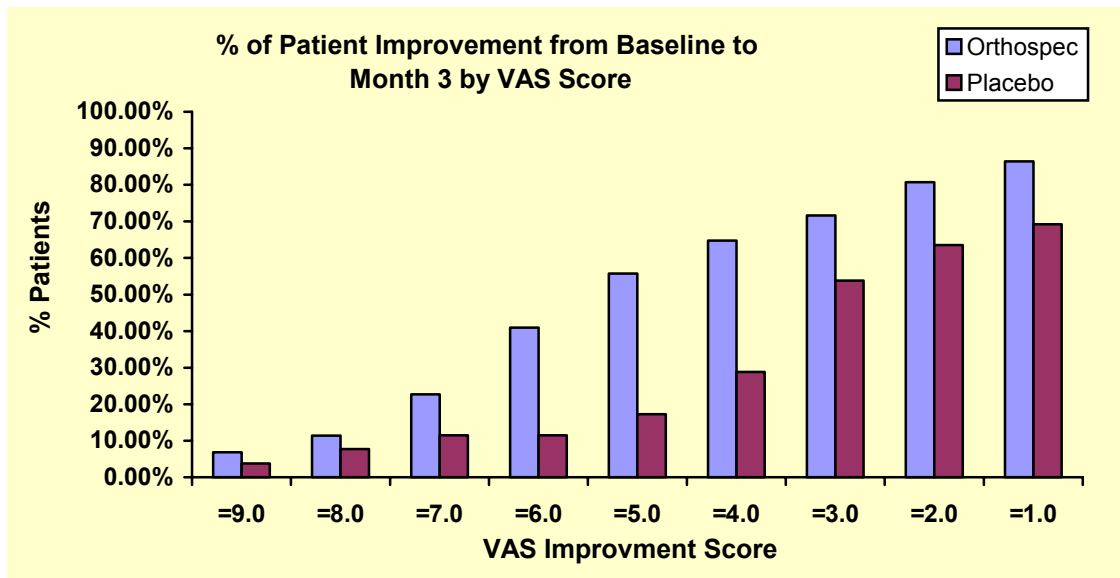


MM **ORTHOSPEC™ VS. PLACEBO FOR THE TREATMENT OF
CHRONIC PROXIMAL PLANTAR FASCIITIS**

Overall results from baseline to 3 months post-treatment in all outcome measures in Orthospec™ subjects with energy level > 4.5:

Summary of Effectiveness Results at Three Months¹ Orthospec Patients With Energy Level > 4.5			
Measure	Orthospec™ N=88	Placebo N=52	P-Value
Investigator's Assessment of Heel Pain			
Mean change from baseline	-2.98	-1.69	0.011
Response rate	50.0%	21.2%	<0.001
Patient's Assessment of Heel Pain			
Mean change from baseline	-3.95	-1.82	<0.001
Response rate	62.1%	28.9%	<0.001
Change in the use of Pain Medication			
Increased	1.0%	11.8%	<0.001
No change	65.0%	74.5%	
Decreased	34.0%	13.7%	

Percent of patient improvement by VAS score in Orthospec™ patients with energy level >4.5 from baseline to Month 3.



Safety Results

Summary of All Adverse Events	Orthospec™ (N = 115) n (%)	Placebo (N = 57) n (%)	P-Value
Any Adverse Event	3 (2.6%)	0 (0%)	0.55
Bruising	2 (1.7%)	0 (0%)	1.0
Mild local swelling	1 (0.9%)	0 (0%)	1.0