Treatment of Plantar Fasciitis with Xeomin: A Randomized, Placebo-Controlled, Double-Blinded, Prospective Study

Presenting:
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Summary:
The purpose of this study is to prospectively compare the intermediate-term outcomes of Xeomin (Incobotulinum toxin A, Merz Pharmaceuticals, Greensboro, NC) and placebo injection of the plantar fascia in patients with recalcitrant plantar fasciitis over a 2-year period in a single surgeon’s (JA) practice. This study demonstrates that using Xeomin to plantar fasciitis results in a higher rate of improving foot function and pain than placebo injection. In addition, the use of Xeomin eliminates the need for surgical treatment of plantar fasciitis.

Introduction:
The purpose of this study is to prospectively evaluate and compare the intermediate-term clinical outcomes of Xeomin (Incobotulinum toxin A, Merz Pharmaceuticals, Greensboro, NC) and placebo saline injection of the plantar fascia in patients with recalcitrant plantar fasciitis over a 2-year period in a single surgeon’s (JA) practice.

Methods:
Between January 2012 and July 2013, 24 patients presented with plantar fasciitis that had failed at least 3 months of nonsurgical treatment. Patients that received a prior injection of any kind at their plantar fascia were excluded. On the day of injection, 12 patients were randomized to receive a single injection of Xeomin while the remaining 12 were randomized to receive a single injection of saline at their affected plantar fascia. All injections were done under electromyographic (EMG) guidance. Post-injection treatments were identical for both groups of patients. Preoperative and postoperative function and pain was graded using the Foot and Ankle Ability Measures (FAAM) Scoring System and a Visual Analog Scale (VAS) of pain respectively. Data regarding post-injection complications and conversions to surgery were also recorded.

Results:
All 24 patients (100%) with recalcitrant plantar fasciitis that randomly received either a single placebo or Xeomin injection returned for the final evaluation. All 12 patients that received placebo were evaluated with a mean follow-up time of 11.7 months. The mean FAAM score increased from 35.9 of 100 to 40.9 of 100 at the time of most recent follow-up. The mean VAS pain score decreased from 8.4 of 10 to 7.9 of 10 at their latest follow-up. All 12 patients that received Xeomin were evaluated with a mean follow-up time of 12.5 months. The mean FAAM score increased from 36.3 of 100 to 73.8 of 100 at the time of most recent follow-up. This post-injection score is higher than that of the placebo group to a statistically
significant degree (P=0.01). The mean VAS pain score decreased from 7.2 of 10 to 3.6 of 10 at latest follow-up. This post-injection score is lower than that of the placebo group to a statistically significant degree (P=0.01). None of the patients in either study group developed any post-injection complications. At the time of final follow-up, 2 of the 12 patients (17%) that received a placebo injection ultimately had surgical treatment for their plantar fasciitis due to lack of symptom improvement. In contrast, none of the 12 patients that received a Xeomin injection required surgical treatment for their plantar fasciitis.

Conclusion:
This study demonstrates that using Xeomin to recalcitrant plantar fascitis results in a high rate of improving foot function and pain. This study shows that using Xeomin provides results that are better than placebo. In addition, the use of Xeomin eliminates the need for surgical treatment of plantar fasciitis. Studies with a larger patient population and longer follow-up may be needed to further confirm these reported advantages when using Xeomin to manage recalcitrant plantar fasciitis.