CLINICAL TRIAL HIGHLIGHTS

Table 2. Complications, No. (%)

Complication	Open Strayer or Vulpius, n = 206	Baumann, n = 38	Hoke, n = 52	Endoscopic, n = 344
Superficial infection	13 (6.3)	3 (7.9)	0 (0.0)	0 (0.0)
Sural nerve dysesthesia	7 (3.4)	1 (2.6)	1 (1.9)	10 (2.9)
Weakness of plantar flexion	9 (4.4)	1 (2.6)	5 (9.6)	11 (3.2)
Painful scar	5 (2.4)	1 (1.9)	0 (0.0)	0 (0.0)
Calf muscle atrophy	5 (2.4)	0 (0.0)	0 (0.0)	8 (2.6)

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did not differ in the rate of sural nerve dysesthesia, painful scar, and calf muscle atrophy (Table 2).

This study is limited by the fact that it was retrospective, by the inherent difficulty in comparing outcomes from different sources of contracture, and because the surgical techniques were selected by surgeon preference.

In this study, all techniques led to significant improvement of functional outcomes. The Hoke technique was associated with significantly shorter operative time but less equinus correction and a higher incidence of plantar flexion weakness. Patients treated with EGR had lower rates of wound complications and painful scar. There was a low incidence of sural nerve symptoms and weakness of plantar flexion with all 4 approaches.

Incobotulinum Toxin A Effective in Treating Plantar Fasciitis

Written by Emma Hitt Nichols, PhD

Treatment of plantar fasciitis with incobotulinum toxin A resulted in improved functional and pain outcomes and increased patient satisfaction as compared with placebo. Jamal Ahmad, MD, Rothman Institute, Philadelphia, Pennsylvania, USA, presented data from the Treatment of Plantar Fasciitis With Xeomin study [NCT01678001].

Up to 2 million patients per year require treatment for plantar fasciitis, with risk factors including prolonged weight-bearing activity, inappropriate shoe wear, greater body weight, and medical comorbidities. Botulinum toxin has been studied for the treatment of plantar fasciitis in several short-term prospective studies, demonstrating symptom improvement in up to 90% of patients at 3- and 6-month follow-up [Diaz-Llopis IV et al. *Clin Rehabil.* 2013; Placzek R et al. *Clin J Pain.* 2006]. The purpose of this study was to evaluate long-term outcomes of patients with plantar fasciitis treated with incobotulinum toxin A. In this prospective double-blind study, 28 patients with plantar fasciitis who had unsuccessful nonsurgical treatment were randomly assigned to receive a 1-cc injection of 100 U of botulinum toxin or placebo. A board certified neurologist placed the injection at the flexor digitorum brevis muscle, which is continuous with the plantar fascia. Postinjection, patients completed physical therapy, including plantar fascial and Achilles stretching. Clinical end points included Foot and Ankle Ability Measure, visual analog scale, and patient satisfaction.

At 1-year follow-up, patients who received botulinum toxin had a significantly higher mean Foot and Ankle Ability Measure score of 73.8, compared with 40.9 in placebo-treated patients (P=.01). In addition, the mean visual analog scale score, a measure of pain, was significantly lower in the botulinum toxin arm, with a score of 3.6 out of 10, compared with 7.9 in the placebo arm (P=.01). Approximately 86% of patients in the botulinum toxin arm and 36% of patients in the placebo arm reported symptom improvement, with about 29% in the botulinum toxin arm indicating that they had achieved complete relief. In the botulinum toxin group, about 14% of patients experienced no change in symptoms, although none received surgery. In the placebo arm, about 64% of patients experienced no change in symptoms, with 2 patients undergoing surgery at 6 months.

Table1. Effect of Botulinum Toxin on Patient Satisfaction, No. (%)

	Incobotulinum Toxin A	Placebo
Excellent	4 (28.6)	0 (0)
Good	7 (50)	1 (7.1)
Fair	1 (7.1)	4 (28.6)
Poor	2 (14.3)	9 (64.3)

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Patient satisfaction was greater in the botulinum toxin arm, with about 29% and 50% reporting that they had excellent and good satisfaction, respectively, compared with 0% and 7% in the placebo arm (Table 1). There were no reports of injection-related complications in either study arm.

In conclusion, Dr Ahmad stated that, in his opinion, the data from this study indicate that treatment of plantar fasciitis with botulinum toxin resulted in greater functional scores and patient satisfaction, as well as lower pain scores, when compared with placebo. However, the study was limited by a small sample size, potential differences in physical therapy regimens, and potential use of patient-directed treatments.

c-hAM Comparable to Corticosteroids in Plantar Fasciitis

Written by Emma Hitt Nichols, PhD

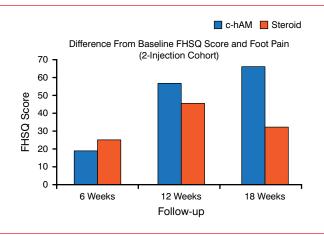
In the treatment of plantar fasciitis, micronized amniotic membrane (c-hAM) injection demonstrated similar efficacy to corticosteroid injection without adverse events. Robert D. Santrock, MD, West Virginia University, Morgantown, West Virginia, USA, presented data from a randomized, controlled, double-blinded, single-center, prospective study comparing plantar fasciitis injection of c-hAM to steroid injection [Hanselman AE et al. *Foot Ankle Int.* 2014].

Fetal tissues, including the amnion, are currently used in ophthalmology, orthopedics, and other surgical specialties. Use of fetal tissues in surgery is appealing because the tissue is able to regenerate without inflammation or scarring. The study hypothesis was that c-hAM is a safe treatment option for plantar fasciitis and is noninferior to corticosteroids.

In this study, 23 patients diagnosed with plantar fasciitis and symptomatic for >3 months but <1 year were randomly assigned to receive an initial injection of either 1 mL (40 mg) of corticosteroid plus 4 mL 0.5% bupivacaine, or 1 mL c-hAM plus 4 mL 0.5% bupivacaine. At 6-week follow-up, all patients were given the option to receive a repeat injection of either study drug if needed. Patients were followed for 12 weeks after the most recent injection. Activities were not restricted, but all patients were advised to perform foot and ankle-stretching exercises 5 times a day.

Exclusion criteria included previous plantar fasciitis injection or treatment within 3 months, previous foot surgery or injury, lower extremity neuropathy, lack of ambulation, or unwillingness to receive human tissue. The primary end point was the Foot Health Status Questionnaire

Figure 1. Effect of 2 Injections of c-hAM on FHSQ Score



c-hAM, micronized amniotic membrane; FHSQ, Foot Health Status Questionnaire. Reproduced with permission from R Santrock, MD.

(FHSQ). Secondary end points included the visual analog scale (VAS) and patient-reported improvement.

There was no significant difference between the 2 arms in terms of foot pain, foot function, and VAS. However, in the 1-injection cohort, patients who received the corticosteroid demonstrated greater FHSQ foot pain scores at 6 and 12 weeks compared with patients who received c-hAM. Interestingly, in the 2-injection cohort, patients who received c-hAM demonstrated a trend toward a greater FHSQ foot pain score compared with the corticosteroid arm (Figure 1). A similar trend was observed in FHSQ foot function, in which 2 injections of c-hAM demonstrated increased effectiveness compared with 1 injection. After 2 injections, the c-hAM arm trended toward a greater improvement in VAS and patient-reported improvements at 18 weeks compared with the corticosteroid arm. There were no adverse events in this study.

According to Dr Santrock, the data from this study suggest that c-hAM has comparable efficacy to corticosteroids in the treatment of plantar fasciitis, and there may be a double-dose effect associated with c-hAM. He indicated that that a larger, longer-term, multicenter trial is needed to further evaluate c-hAM for plantar fasciitis.

Differences in Component Revision and Reoperation for Ankle Arthroscopy Implants

Written by Emma Hitt Nichols, PhD

A study of 4 implants used for total ankle arthroscopy (TAA) found that the Agility and Mobility implants required higher rates of metal component revisions

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