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

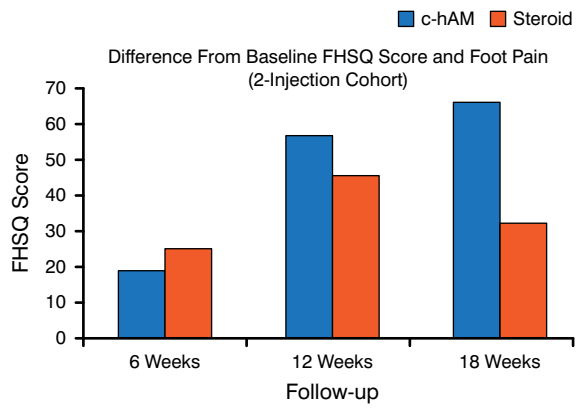
In the treatment of plantar fasciitis, micronized amniotic membrane (c-hAM) injection demonstrated similar efficacy to corticosteroid injection without adverse events. Robert D. Santrock, MD, West Virginia University, Morgantown, West Virginia, USA, presented data from a randomized, controlled, double-blinded, 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 (FHSQ). Secondary end points included the visual analog scale (VAS) and patient-reported improvement.

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.

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

when compared with the Hintegra and STAR implants. In addition, the Mobility implant demonstrated less improvement in the total Ankle Osteoarthritis Scale (AOS) score and the mean AOS pain difference. Tina Lefrancois, MD, Dalhousie University, Nova Scotia, Canada, presented the study results.

End-stage ankle arthritis is frequently treated by TAA; with modern prostheses, clinical outcomes and patient-reported satisfaction are good. The purpose of this study was to determine any differences in clinical outcomes based on the 4 TAA implants (STAR, Hintegra, Agility, and Mobility).

In this multicenter study, prospectively collected data from the Canadian Orthopaedic Foot and Ankle Society ankle reconstruction database were analyzed to identify patients who underwent TAA from November 2001 to August 2010. Patients were excluded if they were < 40 years old or had nerve or muscle disease, severe osteoporosis, severe mental illness, a severe deformity, or an active infection within the previous 12 months. The baseline characteristics were similar among all 4 groups. Patients had a mean age of 63 and a mean body mass index of 28. About 10% of patients had diabetes, and about 10% were smokers, although only 5% in the Mobility arm were smokers. Approximately 22% of patients had inflammatory arthritis (28% in the Agility arm), and nearly half of the patients were men.

The primary end point of the study was SF-36 scores and the AOS scores. The secondary end point was the need for reoperation. The mean follow-up time varied according to the implant used: 6.3 years for STAR, 3.5 for Hintegra, 6.1 for Agility, and 4.2 for Mobility.

Among patients who received the STAR, Hintegra, or Agility implant, the mean difference in total AOS score from baseline was similar; patients who received the Mobility implant demonstrated a lower mean difference in AOS score. In addition, the difference in AOS pain scores from baseline was smaller in the Mobility group (21.2) when compared with the STAR, Hintegra, and Agility groups (29.1, 29, and 29.8, respectively).

About 25% of patients who received the Hintegra, Agility, or Mobility implant and 36% of patients who received the STAR implant required reoperation. Reoperation in the STAR group was a result of isolated polyethylene exchange due to polyethylene failure, which was not observed in any other implant group. Revision of metal components due to aseptic failure was 15% and 20% in the Mobility and Agility implant groups, compared with 7% and 8% in the Hintegra and STAR implant groups, respectively. The amputation rate after TAA was 0% for the Hintegra group, 1% for the STAR and Mobility groups, and 3% for the Agility group. After adjusting for the requirement of metal component revision and polyethylene exchange, use of the Mobility implant resulted in poorer outcomes as compared with the STAR, Hintegra, and Agility implants ($P = .01$ for all).

According to Prof Lefrancois, the study results indicate that there are subtle differences among the TAA implants, and knowledge of these differences is important when determining which implant is the best option for a given patient.

Less Pain With MICA Osteotomy in Hallux Valgus

Written by Emma Hitt Nichols, PhD

Minimally invasive chevron/akin (MICA) osteotomies resulted in less pain, shorter operation time, shorter scar length, and greater patient satisfaction rates compared with scarf/akin osteotomies for the treatment of hallux valgus. Peter Lam, MD, Orthopaedic Foot and Ankle Specialist, Sydney, Australia, presented data from a prospective study comparing scarf/akin osteotomies with MICA osteotomies for the treatment of hallux valgus.

Although the scarf method for hallux valgus correction is popular in Sydney, there have been no published, randomized trials comparing the technique with the MICA osteotomy method. The scarf method can correct an intermetatarsal angle (IMA) of up to 6°, but structural failure at the proximal aspect can occur. Troughing may also be seen in up to 35% of cases.

In this prospective, single-center study, 51 patients were randomly assigned to undergo scarf or MICA osteotomy. The end points of the study included the Visual Analog Scale (VAS) for pain, radiographic review, and the American Orthopaedic Foot & Ankle Society (AOFAS) Hallux Metatarsophalangeal-Interphalangeal Scale.

There was no significant difference between the scarf and MICA groups in the AOFAS forefoot score; the postoperative score was 83 in the scarf group (95% CI, 83 to 87) and 89 in the MICA group (95% CI, 87 to 91). The IMA was also not significantly different between the 2 groups at 6 weeks or 6 months after the procedure ($P = .25$). However, the hallux valgus angle (HVA) was significantly better in the MICA arm at both 6 weeks and 6 months after the procedure ($P = .033$). Pain score, as measured by the VAS, was significantly lower in the MICA arm compared with the scarf arm at 1 day ($P < .001$), 2 weeks ($P < .001$), and 6 weeks ($P = .004$); however, there was no significant difference in pain scores at 26 weeks