## CLINICAL TRIAL HIGHLIGHTS

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 patientreported 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.

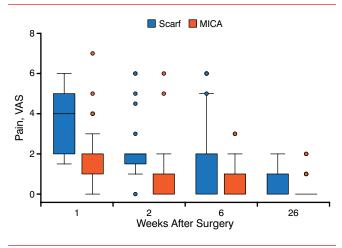
Although the scarf method for hallux valgus correction is popular in Sydney, there have been no published, randomized trials comparing the technique with the MICA osteotomy method. The scarf method can correct an intermetatarsal angle (IMA) of up to 6°, but structural failure at the proximal aspect can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



Figure 1. Effect of Minimally Invasive Chevron/Akin Osteotomy on Pain



MICA, minimally invasive chevron/akin osteotomy; VAS, Visual Analog Scale. Reproduced with permission from P Lam, MD.

(Figure 1). The operation time was longer with the scarf approach (mean of 33.7 minutes) compared with the MICA approach (mean of 29.7 minutes). In addition, the mean length of the combined scar was 108 mm in the scarf group compared with 24.2 mm in the MICA group.

In the scarf group, complications included 2 cases of mild second metatarsalgia and 1 case of increased depth of forefoot. In the MICA group, there were 6 cases of screw removal. Overall ratings of the scarf or MICA methods indicated that patients were satisfied (7 vs 4, respectively) or extremely satisfied (18 vs 21, respectively); no patients reported being unsatisfied or extremely unsatisfied with either method.

According to Dr Lam, the use of MICA was associated with less pain, greater improvement in HVA, shorter operation time, and shorter scar length. Overall, the same number of patients was satisfied with either method.

## Fresh Osteochondral Allograft for Ankle Arthroplasty

Written by Emma Hitt Nichols, PhD

A bipolar fresh osteochondral allograft is a treatment option with good clinical outcomes for patients with severe osteoarthritis. According to Sandro Giannini, MD, University of Bologna Istituti Ortopedici Rizzoli, Bologna, Italy, prostheses are widely used to treat severe osteoarthritis; however, fresh osteochondral allografts may be a beneficial treatment alternative. Via the use of an allograft, 1 cm of subchondral bone gives rise to viable cartilage and can result in complete osteointegration. The purpose of this study was to evaluate clinical outcomes among patients with severe osteoarthritis who were treated with fresh osteochondral allografts.

Fresh osteochondral allografts are currently best used in patients < 50 years old. Contraindications include serious joint deformity, significant osteoporosis, osteonecrosis, vascular pathologies, infection, and severe ligament instability. In a case series of 64 patients with a mean follow-up time of 32.8 months, 32 patients received an allograft via lateral approach and 32 received an allograft via anterior approach [Giannini S et al. *Foot Ankle Int.* 2013; Giannini S et al. *Foot Ankle Int.* 2010]. Following the procedure, patients wore a cast for 15 days. After cast removal, active and passive mobilization began, and a below-knee prosthesis was used to prevent ambulation of the ankle. Patients could bear total weight after 6 months.

The mean age of patients who received an allograft (lateral or anterior approach) was about 35. The preoperative American Orthopaedic Foot & Ankle Society (AOFAS) score was 33.1 in the lateral approach group and 26.6 in the anterior approach group. The 6-year AOFAS score significantly increased to 60.4 in the lateral approach group (P < .0005) and to 72.3 in the anterior approach group (P < .0005). Patient satisfaction was reported at 76%, with no significant difference between the 2 groups. In addition, a bioptic cartilage harvest demonstrated that >95% of chondrocytes were viable. Genetic typing demonstrated the exclusive presence of the recipient DNA in 10 of the 15 allografts, with an additional 2 samples having a mixed DNA profile [Neri S et al. OARSI 2011; (abstr 505)].

In both groups, there were 6 failures (12 total in the case series). At follow-up, there was evidence of increased arthritis that did not necessarily correspond with the clinical result. Interestingly, data from a cohort of patients receiving immunosuppressant therapy within the case series suggest that immunosuppression resulted in a better clinical score, a lower rate of radiographic arthritis at 2 years, and better histologic results of the transplanted cartilage.

According to Prof Giannini, the use of fresh osteochondral allograft is a potential treatment option for severe osteoarthritis and may be especially useful in younger patients. However, he indicated that several questions remain concerning the mechanisms of allograft recolonization, the role of the degenerated joint environment on allograft success, and the effect of the immunologic response on the allografts. These questions are currently being evaluated in animal models.

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