CHAPTER **19**

An Update on the Literature for Foot and Ankle Surgery 2018: Are We Practicing Evidence-Based Medicine?

Matrona Giakoumis, DPM
Anthony Jabra, DPM

INTRODUCTION

As publications continue to be written, we must do our best to stay on top of current evidence-based medicine. These high level studies can either provide further support for how we practice or they may be an impetus to evaluate and evolve our current treatment protocols. Three journals were reviewed for all published Level 1 studies from January 2018 to December 2018. A total of 12 studies are summarized below: 3 from *Foot and Ankle International,* 5 from the *Journal of Bone and Joint Surgery (America),* and 4 from the *Journal of Foot and Ankle Surgery.*

PLANTAR FASCIITIS

Although many studies exist on the topic, consensus has yet to be reached regarding the best treatment method for plantar fasciitis. Ugurlar et al (1) randomized 158 patients into 4 different study groups. The participants all had a diagnosis of chronic plantar fasciitis (defined as a duration of ≥12 months) and symptomatic heel spur. The therapeutic effects of extracorporeal shock wave therapy (ESWT), platelet rich plasma injection (PRP), local corticosteroid injection (CS), and prolotherapy over a period of 36 months were examined. Data collected pre- and post-treatment included patients' self-assessments of heel pain, activity, and function level, analgesic use, radiographic findings, ultrasound findings, adverse events, and complications. All treatment methods were performed under ultrasound guidance.

The PRP was procured using the ACP Double Syringe System (Arthrex). For the CS group, 1 ml of betamethasone 40mg/ml and 2 ml of bupivacaine 5 mg/ml were injected into the area of maximum tenderness. For the prolotherapy group, 1 ml of bupivacaine 5mg/ml, 3 ml of 5% dextrose, and 6 ml of 0.9% physiologic sodium chloride solution were injected. All patients in the ESWT group received the same dose (6 Hz, 2,000 pulse, 4.0 bar energy density). The patients in the CS injection, PRP, and prolotherapy group received a total of 3 injections, once each week. The patients in the ESWT group received 3 sessions with an interval of 7 days between each session. At the end of the follow-up period, the mean visual analog scores for all 4 treatment groups were similar to pretreatment and no significant improvement was noted in the Revised Foot Function Index score.

MIDFOOT ARTHRODESIS

Bony healing with arthrodesis procedures continues to be a challenge depending on the fusion level. Previous nonunion rates for midfoot fusions from retrospective studies have been reported to be between 0% and 28% depending on the fixation construct used. According to Ahmad et al (2), a comparison of outcomes of midfoot fusions with screws or with plate-and-screws had not been previously reported. They therefore prospectively randomized and compared a cohort of 50 patients who received one of these constructs. Outcome measures included function and pain, graded with the Foot and Ankle Ability Measures (FAAM) and a visual analog scale (VAS). The procedure was performed on patients with severe midfoot arthritis who had failed nonsurgical treatment on an inpatient basis. Study patients also received autogenous morselized ipsilateral calcaneal bone autograft. Patients randomized in the screw fixation group received 4.0-mm partially threaded self-tapping cannulated cancellous stainless-steel screws while those in the plate-and-screws groups received longitudinal stainless-steel 3.5-mm low-profile compression plates. Postoperatively, patients were nonweightbearing for 6 weeks. At 6 months, healing was assessed in all patients by computed tomography. Healing was defined as greater than 50% of bone crossing the joint. Patients in the screw group were followed for a mean ± SD 44.3 ± 12.1 months and patients in the plate-and-screws group had a mean ± SD follow-up time of 4.1 ± 9.8 months. At final follow up, the plate-and-screws group had mean post-surgical functional and pain scores that were better than the screw population, however, the differences were not statistically significant. The plate-and-screws group also had significantly longer operative times, a higher incidence of wound complications, but also higher percentage of union. Due to the limited population between the 2 study groups, this difference or significance could not be assessed.

ACHILLES RUPTURE

The number of Achilles tendon ruptures in the US has increased from 0.67 per 10,000 in 2005 to 1.08 per 10,000 in 2011. Conservative versus surgical treatment for acute ruptures is still controversial. Zhou et al (3) were interested in performing a meta-analysis to compare these 2 treatment options, but also to explore the difference in the re-rupture rate if proven early functional rehabilitation protocols were followed. Ten randomized control trials (RCTs) with a total of 934 patients were included after searching PubMed, Embase, Medline, and Cochrane Register of Controlled trials databases including unpublished studies. Inclusion criteria included adults with closed acute Achilles tendon rupture, RCTs comparing surgical and nonsurgical treatment, and at least 1-year follow-up. Patients in the nonsurgical group experienced higher re-rupture rates (11.04%) than patients in the surgical group (4.24%). However, the re-rupture rate between the 2 groups became equal if a functional rehabilitation protocol with early range of motion was implemented. The overall recommendation of the authors was that nonsurgical treatment may be preferable in acute Achilles ruptures if the hospital offers a functional rehabilitation protocol with early range of motion. Otherwise, surgical treatment may need to be considered given its lower rate of re-rupture.

Another meta-analysis by El-Akkawi et al (4) was performed searching PubMed, Embase, and the Cochrane Central Register of Controlled Trials and 5 RCTs with 276 patients were included. The aim of the investigators was to compare the effect of early versus late weightbearing in conservatively treated adult patients with an acute Achilles tendon rupture. No statistically significant difference was found between the 2 groups regarding re-rupture, return to work, and return to sports. However, early weightbearing was defined differently in the included studies, therefore confounders may have been present.

With the increased interest in minimally invasive repair versus open repair for acute Achilles tendon ruptures, Grassi et al (5) performed a meta-analysis comparing complications, subjective outcomes, and functional results of the 2 types of repair. Eligible studies included randomized control trials comparing minimally invasive surgery and open surgical repair for acute Achilles tendon ruptures. Published and unpublished studies in all languages were included, something that was excluded in prior reviews. The reviewers collected data such as patient demographics, surgical details, and rehabilitation. Functional outcomes were assessed using the American Orthopedic Foot and Ankle Society score, ankle range of motion, subjective patient satisfaction, return to preinjury activity, and time to return to work. Complications were defined as re-ruptures, superficial or deep infections, delayed wound-healing, adhesions, keloid formation, sural nerve problems, residual pain/tendinitis, ankle stiffness, and deep venous thrombosis. Eight studies were included in the final analysis: 182 patients underwent minimally invasive surgery and 176 underwent open repair. The mean follow-up ranged from 4 to 30 months and patients were <60 years of age. No significant difference in re-rupture rate, sural nerve injury, or return to preinjury level was revealed. Functional outcomes, ankle range of motion, and time to return to work were also comparable between the 2 techniques. However, patient reported outcome in the minimally invasive surgery group was superior. There was also a reduced risk of postoperative complications, including superficial wound infection, delayed wound-healing, and scar adhesions when minimally invasive surgery was performed. The authors, however, clearly state that the studies were associated with high heterogeneity and a considerable risk of bias.

ANKLE FRACTURES/ SYNDESMOTIC INJURIES

Anatomic restoration of the ankle mortise after ankle fractures is important for stable load transmission across the ankle in order to minimize post-traumatic arthritis. Because the syndesmotic ligaments impart a dynamic role, the suture button technique was introduced approximately 10 years ago in order to help facilitate that motion. Anderson et al (6) randomized 97 patients ages 18-70 years with acute traumatic injury to the syndesmosis, with or without concomitant OTA/AO type 44C ankle fractures, and followed them for 2 years. They were interested in comparing clinical and radiographic outcomes of the syndesmotic screw (SS) group (one 4.5 mm quadricortical SS) to the suture button (SB) group. The syndesmosis was reduced with manual pressure or with the use of a reduction clamp. Screw removal usually occurred at 10-12 weeks postoperatively, and patients were allowed to partially bear weight at 2-6 week and fully bear weight at 6 weeks. Patients were evaluated at 6 weeks, 6 months, 1 year, and 2 years. The SS group had more patients with both a medial and posterior malleolar fracture and more osteochondral lesions at enrollment. Due to imbalance at randomization, analyses were also conducted of the subgroups. At 2 years, the SB group had less widening on radiographs. They also had higher American Orthopedic Foot & Ankle Society (AOFAS) ankle-HF scale, Olerud-Molander Ankle (OMA) score, and EuroQol-5D (EQ-5D) index scores as well as lower VAS scores for pain during walking and at rest. It is important, however, to note that the AOFAS scale is not validated, and there are no minimally clinically important differences in scores established for ankle fractures.

Clamp reduction as mentioned is a commonly utilized method for syndesmotic reduction in rotational

ankle fractures. In an effort to prevent or minimize over compression and mal-reduction, manual reduction has also gained popularity. In their prospective study, Park et al (7) enrolled 85 acute rotational fractures, which were randomized into syndesmotic reduction with a reduction clamp or manual manipulation. The aim of their study was to compare the results using radiographic outcome measures. All fractures were Lauge-Hansen supination external rotation, Weber B type, or pronation external rotation, Weber C type. The minimum follow-up was 12 months. Of the 85 patients, 70 completed the study. Radiographic measurements included the tibiofibular clear space and tibiofibular overlap in the anteroposterior view and medial clear space in the mortise view. Radiographic measurements were performed by 2 orthopedic surgeons who were blinded to the reduction method. Pain was assessed using a VAS. Functional outcome was evaluated using the OMA scoring system. Active ankle dorsiflexion and plantarflexion were assessed using a goniometer. Although the tibiofibular clear space and the tibiofibular overlap differed significantly, most of the syndesmoses were within the normal range for both groups at final follow up. Additionally, no significant differences in clinical outcomes, including the VAS score, OMA score, range of motion, time required to return to work, complication rate, or intra-operative time required to achieve reduction were noted.

MISCELLANEOUS

Idiopathic toe-walking is currently an umbrella term that includes all cases of a child walking on their toes and in whom no underlying medical condition explains the toe-walking. Engstrom et al (8) published a follow-up study of the natural history of idiopathic toe-walking in a large, longitudinally followed, population-based cohort of children. More specifically, they were also interested in whether the condition spontaneously diminishes as the child gets older, or if a treating physician should advise intervention, and when. The goal of the study was to improve on the evaluation of current treatment modalities and to provide parents with an informed early prognosis of toe-walking.

A cohort of 1,436 Swedish children were followed for the first 5.5 years of their life. Within this cohort, 1,401 children had no known motor or neurodevelopment conditions, and 35 children had special needs. In the cohort of children without neurodevelopment conditions, 63 of 1,401 (5%) were toe walkers. At age 5.5, 26 (2%) were still toe-walkers, and were subsequently followed at ages 8 and 10. In the neurodevelopment group (18 of 35 children with neuromotor disorders were excluded), 7 of 17 (41%) were still toe-walkers. At the 5.5 year mark, the children identified as toe-walkers had a lower extremity orthopedic assessment as well as a neurological examination. This study focused on the time between 5.5 and 10 years of age. The parents were contacted via telephone at the 8 year and 10 year mark. By 10 years of age, 13% of the healthy children were still toe-walking. A corrective surgical procedure was performed on 4 children (bilateral percutaneous Achilles tendon lengthening) at ages 6 years (2 children), 7 years (1 child), and 8 years (1 child). In the neurodevelopment group, 29% were still toe-walking. The investigators concluded that there are 2 distinct groups of children under the umbrella term idiopathic toe-walking. The first group presents with a contracture in the triceps surae and should undergo prompt surgical intervention. These were originally diagnosed as having a congenital short tendo calcaneus or Achilles. The second and larger group, which should be labeled idiopathic toe-walkers, consists of children who toe-walk without an underlying contracture. About 80% of these children will cease toe-walking without treatment. Idiopathic toe-walking also did not result in decreased ankle dorsiflexion over time. Treatment should be discouraged in this group. However, one should be aware of the potential presence of a later diagnosis of an underlying neurodevelopment comorbidity.

Equinus due to underlying contracture is a component of idiopathic clubfoot. Alvarez et al (9) performed a double-blind, placebo-controlled, parallel-group study with balanced randomization investigating botulinum toxin type A (BTX-A) versus placebo for idiopathic clubfoot in patients from 2 different sites. Patients with idiopathic clubfoot under the age of 2 months with no previous interventions and whose forefoot could be abducted to 60° in the setting of hindfoot equinus after Ponseti casting (ankle dorsiflexion of 5° ± 5° in knee flexion or 0° ± in knee extension) met the inclusion criteria. The patients were followed for 2 years. Patients in the treatment group (N = 32) received the BTX-A injection (10 U/kg achieved by diluting 100 units of BTX-A in 1 ml of unpreserved saline solution). Patients in the placebo group (N = 30) received injections containing 0.1 ml/kg of unpreserved saline solution. The injections were administered in a stellate pattern into the gastrocnemius-soleus muscle complex. Post injection, above-the-knee casts were applied with the foot in the corrected position. A total of 4 cast changes were done. The patient was then transitioned to a Denis Browne bar and corrective shoes once a minimum of 15° of dorsiflexion with the knee in flexion was achieved. The patients in Site A wore the braces full-time until the child was weightbearing or for a total of 3 months at Site B, after which they were worn only during sleep and at rest. Response to treatment was defined as dorsiflexion ≥15°. The patients were evaluated at 6 weeks, 12 weeks, and 2 years. If at 6 weeks, they had not responded to treatment, they received a rescue BTX-A injection and underwent weekly cast changes until correction (≥15°) or

for 4 weeks. If the clubfoot remained unresponsive, a second rescue intervention was given to patients at Site A, and a percutaneous Achilles tendon lengthening at Site B. No significant difference in response between the BTX-A and placebo groups were noted through the course of the study. 100% of the feet were corrected with a dorsiflexion of ≥15°. At 2 years. The authors concluded that no advantage was seen with the use of BTX-A in terms of response, however, BTX-A use helped avoid tenotomy.

POSTOPERATIVE INFECTIONS

Currently, diagnosing periprosthetic joint infections is a difficult process. Often a combination of clinical presentation and tests are used to make the diagnosis. First line testing typically includes serum erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) level due to previously reported high sensitivity in suspected periprosthetic joint infections. This is usually followed by aspiration of the joint in order to obtain synovial white blood cell count (WBC), synovial polymorphonuclear percentage, and leukocyte esterase activity. A retrospective institutional study was performed of revision total joint arthroplasty between January 2000 and January 2015 by Kheir et al (10). Two different study groups were created: periprosthetic joint infection (N = 549) and aseptic revisions (N = 653). Periprosthetic joint infection was defined as 2 positive cultures of the same pathogen obtained from 2 different periprosthetic tissue or fluid samples or the presence of a sinus tract. Acute infections and acute hematogenous infections were excluded. Aseptic revision was defined as cases undergoing a single-stage revision due to other diagnosis (loosening, wear, instability, malalignment, adverse local tissue reaction, or other unexplained pain). Based on the original cutoff from the ICM definition, the overall sensitivities are 0.85 for serum ESR, 0.88 for serum CRP, 0.83 for synovial WBC count and 0.78 for synovial polymorphonuclear percentage. The investigators concluded that the new cutoff values for diagnosing periprosthetic joint infection should be as follows: serum ESR of 34.5 mm/hour, serum CRP of 1.18 mg/liter, synovial WBC count of 2,659.0 cells/ml, and synovial polymorphonuclear percentage of 64.5%. The results of this present study found that the more traditionally virulent organisms (e.g. *Staphylococcus aureus*) resulted in higher inflammatory markers than less virulent organisms (coagulase-negative *Staphylococcus aureus*) or culture-negative cases. The infecting organisms will influence the false-negative rate, therefore, it is important to consider clinical suspicion when diagnosing periprosthetic joint infection.

POSTOPERATIVE PAIN MANAGEMENT

The use of postoperative analgesia via peripheral blocks has become increasingly studied in light of the opioid crisis. In their prospective, randomized and blinded study, Stefani et al (11) were interested in evaluating the analgesia time and pain intensity after an ankle block. Sixty-one patients (64 feet) were randomized into the study group and control group. The study group only received spinal anesthesia. The control group also received spinal anesthesia and a peripheral nerve block (20ml of 0.75% Ropivacaine). About 90% of the procedures were performed to the ankle and forefoot (47% and 42%, respectively). Data collected included pain intensity using the VAS. The study group reported a significantly lower mean pain intensity and longer postoperative analgesia time than the control group ($P < 0.001$). The first night's sleep for the study group was also significantly more comfortable ($P = 0.005$). Past the benefits seen on the day of surgery, pain intensity scores did not significantly differ on the first and second postoperative days.

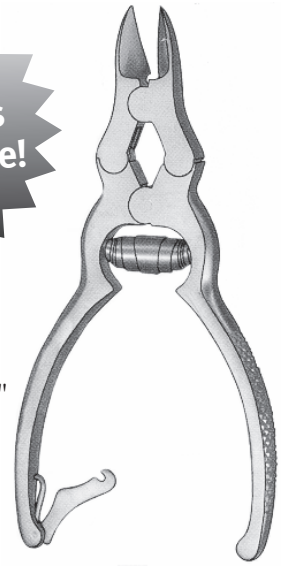
In another prospective, double-blind, placebo-controlled single-center trail by Braito et al (12), 50 patients undergoing an osteotomy of the distal metatarsal for idiopathic hallux valgus in an inpatient study were randomized into a study group and control group. The study group received continuous wound infiltration of Ropivacaine 2 mg/ml at a rate of 2 ml/hour for 24 hours postoperatively and the control group received a placebo. Forty-two patients were analyzed, however, only 39 completed follow up. All patients received a preoperative block of 15 ml of equal parts Lidocaine plain 20 mg/ml and Bupivacaine 5 mg/ml. The primary outcome measures were average and peak pain for the first 48 hours, and the secondary outcome measures included opioid consumption, clinical outcome, postoperative complications and patient satisfaction. The study group did not result in any statistically significant differences in any outcome measures between the two groups.

REFERENCES

1. Ugurlar M, Sönmez MM, Ugurlar ÖY, Adıyeke L, Yıldırım H, Eren OT. Effectiveness of four different treatment modalities in the treatment of chronic plantar fasciitis during a 36-month follow-up period: a randomized controlled trial. J Foot Ankle Surg 2018;57:913-8.
2. Ahmad J, Lynch MK, Maltenfort M. Comparison of screws to plate-and-screw constructs for midfoot arthrodesis. Foot Ankle Int 2018;39:922-9.
3. Zhou K, Song L, Zhang P, Wang C, Wang W. Surgical versus non-surgical methods for acute Achilles tendon rupture: a meta-analysis of randomized controlled trials. J Foot Ankle Surg 2018;57:1191-9.
4. El-Akkawi AI, Joanroy R, Barfod KW, Kallemose T, Kristensen SS, Viberg B. Effect of early versus late weightbearing in conservatively treated acute Achilles tendon rupture: a meta-analysis. J Foot Ankle Surg 2018;57:346-52.
5. Grassi A, Amendola A, Samuelsson K, Svantesson E, Romagnoli M, Bondi A, et al. Minimally invasive versus open repair for acute Achilles tendon rupture. Meta-analysis showing reduced complications, with similar outcomes, after minimally invasive surgery. J Bone Joint Surg Am 2018;100:1969-81.
6. Anderson MR, Frihagen F, Hellund JC, Madsen JE, Figved W. Randomized trial comparing suture button with single syndesmotic screw for syndesmosis injury. J Bone Joint Surg Am 2018;100:2-12.
7. Park YH, Ahn JH, Choi GW, Kim HJ. Comparison of clamp reduction and manual reduction of syndesmosis in rotational ankle fractures: a prospective randomized trial. J Foot Ankle Surg 2018;77:19-22.
8. Engstrom P, Tedroff K. Idiopathic toe-walking: Prevalence and natural history from birth to ten years of age. J Bone Joint Surg Am 2018;100:640-7.
9. Alvarez CM, Wright JG, Chhina H, Howren A, Law P. Botulinum toxin type A versus placebo for idiopathic clubfoot. A two-center, double-blind, randomized controlled trial. J Bone Joint Surg Am 2018;100:1589-96.
10. Kheir MM, Tan TI, Shohat N, Foltz C, Parvizi J. Routine diagnostic tests for periprosthetic joint infection demonstrate a high false-negative rate and are influenced by the infecting organism. J Bone Joint Surg Am 2018;100;2057-65.
11. Stefani KC, Ferreira GF, Filho MVP. Postoperative analgesia using peripheral anesthetic block of the foot and ankle. Foot Ankle Int 2018;39:196-200.
12. Braito M, Dammerer D, Schlager A, Wansch J, Linhart C, Biedermann R. Continuous wound infiltration after hallux valgus surgery. Foot Ankle Int 2018;39:180-8.

Delta Surgical Instruments

Mycotic Nail Nippers Now Available!



Mycotic Nail Nippers

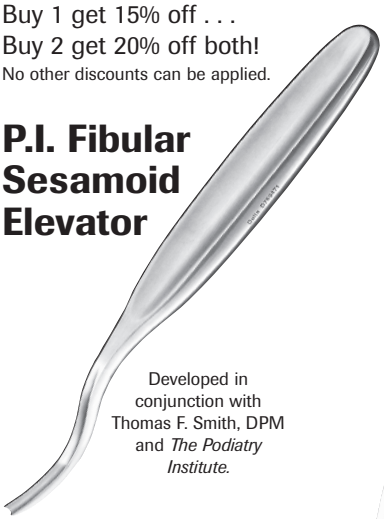
Available in 6" & 4-1/2" concave or straight cutting blades.

First Time Ever!

Take advantage of our first ever sale on these Delta Exclusive Instruments
Buy 1 get 15% off . . .
Buy 2 get 20% off both!
No other discounts can be applied.

Save up to 20% Off Delta Exclusives!

P.I. Fibular Sesamoid Elevator



Developed in conjunction with Thomas F. Smith, DPM and *The Podiatry Institute.*

Modified Inge Retractor w/K-Wire Guides

Just Starting Out?

Ask about our Instrument Sets

- Podiatry Institute Nail Pack™
- PNA Nail Pack
- Starter Nail Pack

Quality Instruments

- *German manufactured from the finest surgical stainless steel*
- *Outstanding craftsmanship – feel the difference*
- *Podiatry focused product line*

Fair Pricing

- *Highest quality available at competitive prices*
- *Life-time warranty*

Customer Service

- *Attentive, knowledgable staff to help you before and after the sale*
- *Sharpening/Repair Service*

To place an order call Toll Free 866-390-2226 Visit us at: *www.deltasurgicalinstruments.com*

THE PODIATRY INSTITUTE

Exclusive licensed instrument provider for and proud Silver Sponsor of *The Podiatry Institute.*
Delta pays royalties to *The Podiatry Institute* on sales of their exclusive instruments. These royalties support ongoing research and development.