

AN UPDATE ON THE LITERATURE FOR FOOT AND ANKLE SURGERY: Are We Practicing Evidence-Based Medicine?

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This update chapter summarizes recent Level I and Level II scientific articles related to foot and ankle surgery that were published between January 2013 and November 2013. The sources for these articles include *Foot and Ankle International*, *The Journal of Bone & Joint Surgery* (American volume), and the *Journal of Foot & Ankle Surgery*. A total of 13 Level I and 23 Level II studies were published during that time. At the end of the article, you will also find a short summary from the Cochrane Libraries that are also relevant to our field.

FOREFOOT

Plantar Plate

In the last several years, the plantar plate has received much attention. In their Level II, prospective study, Mazzuca et al (1) were interested in comparing the effectiveness of fluoroscopic arthrography to magnetic resonance (MR) arthrography for the diagnosis of plantar plate and joint capsule pathology. Forty patients (30 second metatarsophalangeal joints [MTPJ], 2 third MTPJs, and 1 fourth MTPJ) underwent both imaging studies, which were subsequently compared to one another and correlated to intraoperative findings when available. It was noted that MR arthrography was more accurate in identifying tears, but when a steep lateral oblique image was added to the fluoroscopic protocol, it was as reliable and more cost-effective than the MR arthrography.

In another Level II, prospective study involving the plantar plate, Nery et al (2) enrolled 35 patients, involving 62 lesser MTP joints. The patients were divided into two groups. The radiologists who read Group B's MRIs were also given a drawing of the Anatomic Grading System of plantar plate tears. The authors concluded that the senior radiologists had much better levels of accuracy when provided this grading system and proposed that the Anatomic Grading System be included in radiology curricula and in foot and ankle fellowship training.

Morton's Neuroma

Various treatment modalities exist for Morton's neuroma, ranging from conservative to surgical options. Åkermark et al (3) looked at outcome and adverse events of resected neuromas using a dorsal versus a plantar incision in their Level I, prospective randomized trial. They found no significant differences between the two approaches concerning pain or restrictions with daily activities, and scar tenderness. Consistent with previous reports, there was a difference in the type of complications depending on which incision was used.

Gurdezi et al (4) report their five-year follow-up on 45 ultrasound guided alcohol sclerosing injections for Morton's neuroma in their Level II, prospective case series. By 5 years, 16 of the 45 patients had undergone surgery and 13 had a return of symptoms. Only 29% remained symptom free in this only long-term follow-up for alcohol injections.

In a similar Level I study by Thomson et al (5), the cocktail of choice for injection was methylprednisolone [40 mg] with 1 mL 2% lignocaine in the study group and 2% lignocaine in the control group. The primary outcome measure was global assessment of foot health, which was significantly better at three months in the study group.

HINDFOOT

Heel Pain

Plantar fasciitis is one of the most common presenting chief complaints to the foot and ankle specialists. Rodriguez et al (6) compared the use of botulinum toxin A to intralesional steroids for the treatment of plantar fasciitis in a Level I randomized, double-blinded therapeutic study. Thirty-six patients were involved and both groups performed stretching exercises over the six month study period, however, the group that received intramuscularly applied botulinum toxin A (BTX-A) in the gastroc-soleus complex exhibited more rapid and sustained improvement.

In another Level I, prospective randomized study by Zelen et al (7), the use of injectable micronized dehydrated amniotic/chorionic membrane (mDHACM) allograft for plantar fasciitis was studied as an alternative to surgery. The inclusion criteria was the presence of heel pain present for at least eight weeks and use of three of the five following nonoperative treatments: RICE, corticosteroid injection, stretching, NSAIDs, and orthotics. Forty-five patients were then randomized into three groups. All of the participants received 2 cc 0.5% plain Marcaine and then either 1.25 cc saline (controls), 0.5 cc mDHACM, or 1.25 cc mDHACM. At final follow-up, 8 weeks post injection, there was a significant improvement of symptoms in the two groups receiving mDHACM compared to the control group, but no significant difference was seen between the two groups themselves.

Achilles Pathology

In a Level I systematic meta-analysis, Al-Abbad et al (8) reviewed prospective articles that looked at the effectiveness of extracorporeal shock wave therapy (ESWT) on chronic non-insertional and insertional Achilles tendinopathies. Generally, satisfactory evidence existed for the use of low-energy ESWT with a minimum follow-up of three months before considering surgery. Notably, superior results were seen if ESWT was combined with eccentric loading.

Continuing debate still exists on whether an Achilles rupture is best treated surgically or non-surgically. Dorian M van der Eng et al (9) performed a Level I meta-analysis of 576 adult patients. They looked at the rerupture rate after early weightbearing (within 4 weeks) and after 4 weeks in both surgically and non-surgically treated groups. Although there were higher rerupture rates in the non-surgical group for both outcome measures, none of these were statistically different.

Raikin et al (10) were interested in retrospectively analyzing 406 Achilles tendon ruptures in the general US population. The authors of this Level II study argued that the present studies primarily involved US military or European populations and did not correlate to the American population. They found that in the United States, basketball was the most commonly involved sport, whereas in Europe, it is soccer. They also found that for the non-sporting mechanism of injury, increasing age and increasing body mass index were associated with delayed diagnosis.

Gross et al (11) performed a Level II systematic review of the literature for clinical studies that looked at the efficacy of injectable therapies for non-insertional, chronically degenerated Achilles tendons. Although function improves and pain decreases in patients who receive injection therapy, there is a paucity of high quality

evidence regarding the injectables (ranging from platelet-rich plasma, autologous blood injection, sclerosing agents, protease inhibitors, hemodilysate, corticosteroids, and prolotherapy). Also, a great variability in study outcome measures and follow-up makes comparisons between the different injectables and studies difficult. Therefore, prospective, randomized studies are necessary to guide treatment regarding injection therapies.

ANKLE

Lateral Ankle Instability

A total of 50 patients with chronic lateral ankle instability were included in the Level I prospective study by Cho et al (12). They compared the functional and clinical outcomes in patients who received either a single or double suture anchor with the modified Brostrom procedure. The patients were followed for over 2 years and both the single and double suture anchor techniques produced similar outcomes except with respect to mechanical stability, which the double anchor was superior.

Rearfoot Arthritis

Historically, arthrodesis procedures have proven to be reliable salvage procedures. In their article, DeVries et al (13) created and presented a statistical model to predict the risk of amputation in patients following a tibiototalcalcaneal (TTC) with an intramedullary (IM) nail. In this Level II, prognostic study, a chart and radiographic review of 179 limbs treated with TTC fusion and an IM nail was performed. Of the 179 limbs, 21 went on to major amputation, resulting in an overall salvage rate of 88.2%. The greatest risk factor for amputation was diabetes, followed by revisional surgery, presence of preoperative ulcer and finally age. The equation they derived to calculate the probability of amputation is $ex / (1 + ex)$ where x is a factor of age, diabetes, revision and ulceration. The authors recognize this is a complicated formula and provide a link to a usable spreadsheet formula page in the paper.

Twenty-eight patients with post-traumatic and primary ankle osteoarthritis and 14 normal volunteers serving as the control group were involved in the Level II, prospective study by Flavin et al (14). All the patients in the arthroplasty group received the Scandinavian total ankle replacement ankle prosthesis (STAR). Neither the arthrodesis nor the arthroplasty group functioned better than the control group but compared to their own preoperative function, they both had significant improvements in different parameters of gait. Parameters included velocity, cadence, step length, sagittal range of motion, sagittal max moment, coronal range of motion, coronal max moment, sagittal max power, center of

pressure heel strike, center of pressure toe-off, center of pressure heel rise. Neither study group was superior to the other and it was shown that the major parameters of gait for an arthritic deformed ankle undergoing arthrodesis were comparable to an arthritic non-deformed ankle undergoing total ankle arthroplasty at one year post intervention.

PEDIATRIC

Collapsing Pes Valgus

In the pediatric population, a common concern for parents is their child's flat feet, especially when they are painful. Cha et al (15) designed a Level II, prospective therapeutic study where they followed 50 flexible flatfeet with a symptomatic type 2 accessory navicular. The feet were divided into two groups; one group received a simple excision of the accessory bone (group 1) and the other the Kidner procedure (group 2). At the end of a minimum 3 year follow-up, both groups reported similar satisfactory results, 86% (group 1) and 82% (group 2), and both procedures restored the medial longitudinal arch similarly.

The following study was established to provide information on the adolescent pes planus population, which has not been focused on in the past. This level II epidemiological study of 825,964 seventeen-year-old adolescents by Tenenbaum et al (16), found a greater prevalence of flexible pes planus (FPP) in males compared to females. Shorter body height and increased body mass index were also associated with all grades of FPP severity.

Equinus

Another common presenting complaint is that of idiopathic toe-walking. Many treatments exist for this condition, and in their Level I therapeutic scientific article, Pähr et al (17) randomized 47 children into two groups. One group of children underwent four weeks of below-the-knee cast treatment as the sole intervention and the other group received botulinum toxin A into their calves one to two weeks before cast application. At the end of the twelve-month study period post cast removal, no differences were found in any of the outcome parameters between the two groups.

TRAUMA

Metatarsal Fractures

A Level II, prospective study, by Shahid et al (18) compared pain, functional outcome, and time taken off after treatment in 39 patients with a fifth metatarsal avulsion fracture who were treated with either a walking boot or a short-leg cast.

Patients who received a walking boot had an improved combined level of pain and function three weeks earlier than the short-leg cast group.

Calcaneal Fractures

Eighty-two patients with intra-articular calcaneal fractures and ≥ 2 mm of displacement were randomized into a surgical and non-surgical treatment group. At the end of the study period (ranging 8-12 years), 76 patients were available for follow-up in this Level II study. Årgren et al (19) concluded that even though surgical treatment was associated with more complications, there was a significant risk reduction of 41% for post-traumatic arthritis in the surgical study group.

Berberian et al (20) from the Department of Orthopaedic Surgery at UMDMJ performed computed tomographic scans on 100 displaced intra-articular calcaneal fractures. They hypothesized that the sustentacular fragment does not always maintain its relationship to the talus, and is not actually "constant." Displacement of the fragment was defined as more than 10 degrees of angulation and more than 3 mm of translation. The fragment was displaced in 42 of the 100 fractures. According to the authors, this Level II diagnostic study disproves that the sustentacular fragment is the "constant fragment" in displaced intra-articular calcaneal fractures.

High-energy open calcaneal fractures are associated with a high incidence of infection and future amputation. In their Level II prognostic study, CPT (P) Dickens et al (21) reviewed 102 consecutive combat-related open calcaneal fractures. They found that at a mean follow-up of 4 years, 43 limbs (42%) underwent amputation. Interestingly, these individuals showed improved pain and activity levels compared with those whose limb salvage was successful. Amputation was predicted by injury mechanism, wound location and size, and open fracture type and severity.

Ankle Fractures

According to early epidemiologic studies, over 5 million ankle injuries occur in the United States yearly. Ankle fractures are increasingly common injuries that require accurate evaluation and proper management. A Level I, prospective randomized cohort study by Mayich et al (22) showed that patients who received information enhancement explaining the postoperative course were more satisfied with treatment at 3 months post surgery. This is the time patients usually have the most questions and concerns for their health care team. These individuals also showed significant improvements in work/activity ability at six weeks, but this improvement was no longer present at 3

months. The information enhancement was provided as pamphlets and due to the limitations of the current health care system, this may be a way to enhance patient satisfaction and properly educate them.

A Level II randomized inter- and intraobserver agreement study by Tennant et al (23) involved 93 orthopedic surgeon volunteers. They were shown a series of ankle fractures and asked questions pertaining to severity of injury, need for higher level imaging, need for acute inpatient versus outpatient management, and plan of treatment. They found that strong reliability for radiographic assessment of ankle injuries occurred between a handheld mobile device and 23-inch computer monitor and that over 3/4ths of the volunteers felt “completely” or “very” comfortable with the handheld mobile device. Of note, memory bias did occur given that the volunteers were shown the radiographs on one device and then immediately following on the other.

Hong et al (24) aimed to evaluate the functional outcome and ability to return to preinjury activities of 26 surgically treated bimalleolar compared to 21 surgically treated trimalleolar ankle fractures. This Level II, retrospective series showed no difference in functional outcome between the two types of fracture patterns. About half of the total patients had residual pain, swelling, and stiffness. Less than half of the patients who were involved in sporting activities prior to surgery were able to return to pre-injury level and one-fifth of the patients were unable to do sports at all, even though the majority recovered well and were satisfied with their outcome.

Appropriate syndesmotic reduction in ankle fractures is important to the final outcome from surgical repair. Two trauma services, one in New York, and the other in Israel participated in this Level II study that compared the accuracy of syndesmotic reduction obtained with three-dimensional imaging versus standard fluoroscopic techniques. The authors, Davidovitch et al (25) found that regardless of the imaging tool used, high rates of malreductions were noted regarding the anterior fibular distance and anterior translation distance. The only significant difference among the two centers was seen when the posterior fibular distance data was analyzed, in which case the intraoperative computed tomography group performed better. Data supports previous investigations regarding high rates of syndesmotic malreductions.

Lower-Limb Fractures

Ceroni et al (26) from Geneva enrolled 50 adolescents who underwent cast immobilization for a leg or ankle fracture in their Level I prospective study. Subsequent to immobilization, bone mineral loss was highly significant,

both proximal and distal to the fracture site. However, by eighteen months, full bone recovery had occurred.

A different type of analysis regarding incidence of adult fractures was presented by Court-Brown et al (27) in their Level I prognostic study that analyzed the relationship between social deprivation and adult fractures. Social deprivation was considered present and derived from patients' postal codes. A significantly increased incidence of fractures was associated with the most deprived 10% of the population.

COMPLEX REGIONAL PAIN SYNDROME (CRPS)

A Level II systematic review and meta-analysis by Shibuya et al (28) identified 4 studies, one specific to foot and ankle surgery that evaluated the effectiveness of vitamin C in the prevention of CRPS after extremity surgery and trauma. At the conclusion of the article, the authors state that at least 500 mg of Vitamin C should be taken immediately after surgery or trauma to help reduce the occurrence of CRPS. It is recommended that this daily administration be continued for 45 to 50 days. This is the current recommendation for Type I CRPS for wrist fractures.

MISCELLANEOUS

Adult Acquired Flatfoot Deformity

In their Level II, prospective comparative study, Mani et al (29) validated the Foot and Ankle Outcome Score (FAOS) for adult acquired flatfoot with acceptable construct and content validity, reliability, and responsiveness. Therefore, they present the FAOS as a valid alternative subjective survey to the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Score, which has recently come under scrutiny.

Bone Graft Substitutes

Autogenous bone grafting in foot and ankle surgery is still considered the gold standard, however, it is often associated with perioperative morbidity. A Level I multi-center study by DiGiovanni et al (30) studied the radiographic, clinical, functional, and quality-of-life end points for purified recombinant human platelet-derived growth factor-BB (rhPDGF-BB) homodimer in 394 joints and autogenous bone grafting in 203 joints. The authors found that for patients requiring hindfoot or ankle arthrodesis, the rhPDGF-BB/ β -TCP group had comparable fusion rates to autogenous bone grafting, but with fewer side effects and with less pain.

Glazebrook et al (31) studied another product, B2A-coated ceramic granules (Amplex) in their Level II prospective study. The small clinical trial (24 patients) was designed to compare the safety and effectiveness of the B2A-granule to autogenous bone grafting. B2A, a synthetic peptide is designed to augment osteodifferentiation by augmenting endogenous BMP-2. Fusion was achieved in 100% of the B2A-granule group and 92% of the autograft group. These results support a larger clinical trial.

In their Level I study, Damron et al (32) prospectively analyzed the incorporation of the bone graft ultraporous β -tricalcium phosphate (TCP) in bone cavities after surgical curettage to TCP combined with bone marrow aspirate in 55 patients. At the end of two years, no significant difference was found.

Charcot

Charcot neuropathic osteoarthropathy can be associated with devastating outcomes. Hastings et al (33) from Washington University were interested in observing the magnitude and timing of foot alignment changes in 15 subjects with Charcot and 19 subjects with diabetes mellitus and peripheral neuropathy, but without Charcot. Their data showed progressive changes occurring over two years. The medial column usually worsened before the lateral and there was a change in hindfoot-forefoot angles. These findings support the need for aggressive intervention, ranging from bracing to surgery in order to prevent complications.

Osteomyelitis

When imaging modalities are employed for the diagnosis of diabetic foot osteomyelitis, magnetic resonance imaging (MRI) has proven to be most accurate. Fujii et al (34) retrospectively analyzed preoperative MRI findings with histopathologic results of surgically excised bone in a Level II study of 104 bones. Overall, the MRI was not as sensitive at detecting osteomyelitis in diabetics with ischemic ulcers as it was in those with the neuropathic ulcers.

Postoperative Pain Management

With mortality from prescription opiate overdose reaching epidemic proportions nationally, prudent use of these substances in postoperative pain management is crucial. Holman et al (35) queried the Utah Controlled Substance Database and found that patients who had filled more than one opiate prescription in the three months prior to injury were more than six times as likely to continue use of these medications twelve weeks after sustaining the injury. They are also 3.5 times more likely to obtain another prescription from a provider other than their surgeon.

Regional Anesthesia

Regional nerve blockade at the level of the popliteal fossa is particularly common in foot and ankle surgery. Seroz et al (36) prospectively studied 48 patients in their Level II comparative study. The patients were divided into 3 groups based on their HbA1c level. The onset of sensory and motor blockade and motor and sensory regression time was noted to be significantly higher in group 3 (HbA1c 9%-10%). These results should be considered when peripheral nerve blocks are performed in diabetic patients with poor glycemic control.

THE COCHRANE COLLABORATION

Dumville et al (37) were interested in evaluating the effects of negative pressure wound therapy in the healing of foot ulcers in individuals with diabetes. They found 5 studies with a total of 605 participants that met their inclusion criteria. These studies suggested that negative pressure increased the healing of foot wounds in individuals with diabetes mellitus who sustained an amputation or had their wounds debrided compared to individuals who received moist wound dressings. The authors do caution that there may be some risk of bias in the studies; therefore, further trials are required to reduce this uncertainty.

Another product that has been used on wounds since the time of Hippocrates is honey. Jull et al (38) reviewed the literature to see if there was strong evidence to support the use of honey on acute and chronic wounds. Twenty-five trials for a total of 2,987 participants met the inclusion criteria. These dressings in conjunction with compression for venous leg ulcers did not increase healing rates and although honey may be superior to some conventional dressing materials, the applicability of this evidence is uncertain. Thus, the authors caution against the routine use of honey dressings since there is not enough evidence to guide clinical practice in wounds other than venous stasis ulcers.

Continuing on this analysis and review pertaining to wounds, Cruciani et al (39) analyzed the literature on granulocyte-colony stimulating (G-CSF) factor for the treatment of diabetic foot infections. Five trials comprising of 167 people were identified. These studies showed that G-CSF reduced the likelihood of lower extremity surgical interventions, such as amputation, and length of hospital stay. The authors suggest that G-CSF might be added to the usual treatment protocol, particularly in diabetics with limb-threatening infections.

Another common staple in diabetic foot ulcer management are hydrogel dressings. Dumville et al (40)

reviewed 5 studies with 446 participants and found that hydrogel dressings were more effective than basic wound contact dressings. However, there was not enough research comparing it to advanced dressing types to make any solid conclusions in terms of healing low-grade ulcers.

Dumville et al (41) also reviewed the literature on yet another product that is used on diabetics with foot ulcers, alginate dressings. A total of 375 participants in 6 studies with short follow-up times and small samples were included in this review. No statistically significant difference was found between alginate dressings and basic wound contact dressings, foam dressings or anti-microbial hydrocolloid dressings. Since there is a paucity of research evidence, the authors recommend basing your decision on factors such as dressing cost and wound properties.

Similar recommendations as were made for alginate dressings were made by Dumville et al (42) regarding foam dressings based on 6 trials and 157 participants.

Lewis and Lipp (43) reviewed studies that looked at healing of foot ulcers in diabetic individuals who were placed in non-removable pressure-relieving interventions (foot casts) compared to other external pressure-relieving methods. Fourteen trials comprising 709 participants met the inclusion criteria and the final analysis showed that non-removable, pressure-relieving casts were superior at healing plantar diabetic foot ulcers than removable casts, or dressings alone. In the case of forefoot ulcerations, an Achilles tendon lengthening combined with a non-removable cast was more effective than a non-removable cast alone.

Discussions regarding treatment for chronic osteomyelitis are numerous and Conterno and Turchi (44) provided an update to the Cochrane review first published in 2009. They found limited and low quality evidence to support that if the bacteria was susceptible, the route antibiotic administration did not affect disease remission rate.

Wechalekar et al (45) searched the literature for trials that evaluated the safety and efficacy of intra-articular glucocorticoids in the treatment of acute gout. Although none were found that met the inclusion criteria, the authors suggest that the evidence that exists for intra-articular glucocorticoids in individuals with osteoarthritis and rheumatoid arthritis can be generalized for people with acute gout; particularly, if there are any contraindications for nonsteroidal antiinflammatory drugs or colchicine.

Needle-related medical procedures can often cause significant pain and distress in children and adolescents. Uman et al (46) updated the original Cochrane review on this topic that was published in 2006. Studies included

3,394 participants, 2 to 19 years of age. Consistent with the original review, studies continue to provide strong evidence for the efficacy of distraction and hypnosis.

Calcaneal fractures make up less than 2% of all fractures and displaced intra-articular fractures are typically treated surgically. Bruce and Sutherland (47) reviewed the literature to find the optimal management of displaced intra-articular calcaneal fractures. They found 4 trials consisting of 602 participants, all with methodological flaws and concluded that there is insufficient high quality evidence to say whether conservative or surgical management is superior.

Lastly, CRPS can be a devastating and debilitating condition. O'Connell et al (48) looked at the interventions available for treating pain and disability in these individuals. They found that high quality evidence was lacking and therefore, it would be difficult to formulate an evidence-based approach to this condition.

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