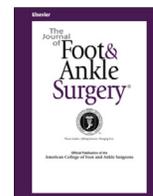




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## Trends in Foot and Ankle Studies Published in High-Impact General Medical Journals: A Systematic Review

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## ABSTRACT

The foot and ankle surgery literature lacks an analysis of studies published in general medical journals. Studies published in general medical journals have high visibility and significant impact on decision making by medical practitioners and health care policy makers. Knowledge of the subject matter and methodologic characteristics of foot and ankle publications being read by general medical practitioners and the lay public is important to the practicing foot and ankle surgeon. A systematic review of foot and ankle studies published from 2000 to 2017 in 5 high-impact general medical journals was undertaken. Data extracted included study topic, study design, study demographics, and methodologic characteristics of randomized controlled trials (RCTs). There were 47 foot and ankle studies published in the selected medical journals examined during the study time period. Most common topics were diabetic foot ulcers (n = 25 [53.2%]), plantar fasciitis (n = 6 [12.8%]), and Achilles tendinopathy (n = 5 [10.6%]). The most common study types were reviews (n = 24 [51.1%]), RCTs (n = 12 [25.4%]), and prospective studies (n = 6 [12.8%]). Of the published RCTs, the most common journal of publication was the *Journal of the American Medical Association* (n = 7 [58.3%]). The median number of citations for RCTs published before 2016 was 242.5. Of the small number of RCTs that compared operative with nonoperative treatment, the majority supported nonoperative management (n = 3 [75%]). Diabetic foot ulcers, plantar fasciitis, and Achilles tendinopathy are the most commonly published foot and ankle topics in general medical journals.

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Value, quality, and standardization of care delivery are crucial to the health care reform under way in the United States (1). Orthopedics and foot and ankle surgery are at the center of many reformations owing to the expected demographic changes in population and the accompanying projected health care use and costs (2,3). High-impact general medical journals, such as the *New England Journal of Medicine* and *The Lancet*, are often the source for dissemination of evidence-based care to medical practitioners, health care policymakers, and the lay public by way of popular media drawing from these well-known journals (4,5). In short, foot and ankle studies published in these journals have far-reaching consequences.

Nwachukwu et al (6) previously characterized orthopedic studies published between 2005 and 2015 for hand surgery, adult reconstruction, pediatrics, spine, sports medicine, and trauma in 5 high-impact medical journals. Of the relatively few orthopedic studies examining

operative versus nonoperative intervention, they found more studies supporting nonsurgical treatment (6). However, foot and ankle studies have not been examined similarly.

The foot and ankle surgery literature lacks a systematic review of studies published in general medical journals. Given the significant impact of research published in these journals, an understanding of the studies being read by general practitioners and the lay public is valuable to the practicing foot and ankle surgeon. The purpose of this study was to assess the overall number of foot and ankle studies published in general medical journals and to examine the study topics and design, as well as the overall conclusions of randomized controlled trials (RCTs).

## Methods

Foot and ankle studies published between 2000 and 2017 in the *New England Journal of Medicine*, *The Lancet*, *Journal of the American Medical Association* (JAMA), *Annals of Internal Medicine*, and *Archives of Internal Medicine—JAMA Internal Medicine* were systematically reviewed in accord with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (Fig. 1). The choice of these medical journals was based on previous methodology as performed by Nwachukwu et al (6), as well as the journals' high-impact factor and general reputation. The screening process was completed on March 20, 2018 (Supplemental Table 1). Reviews, RCTs,

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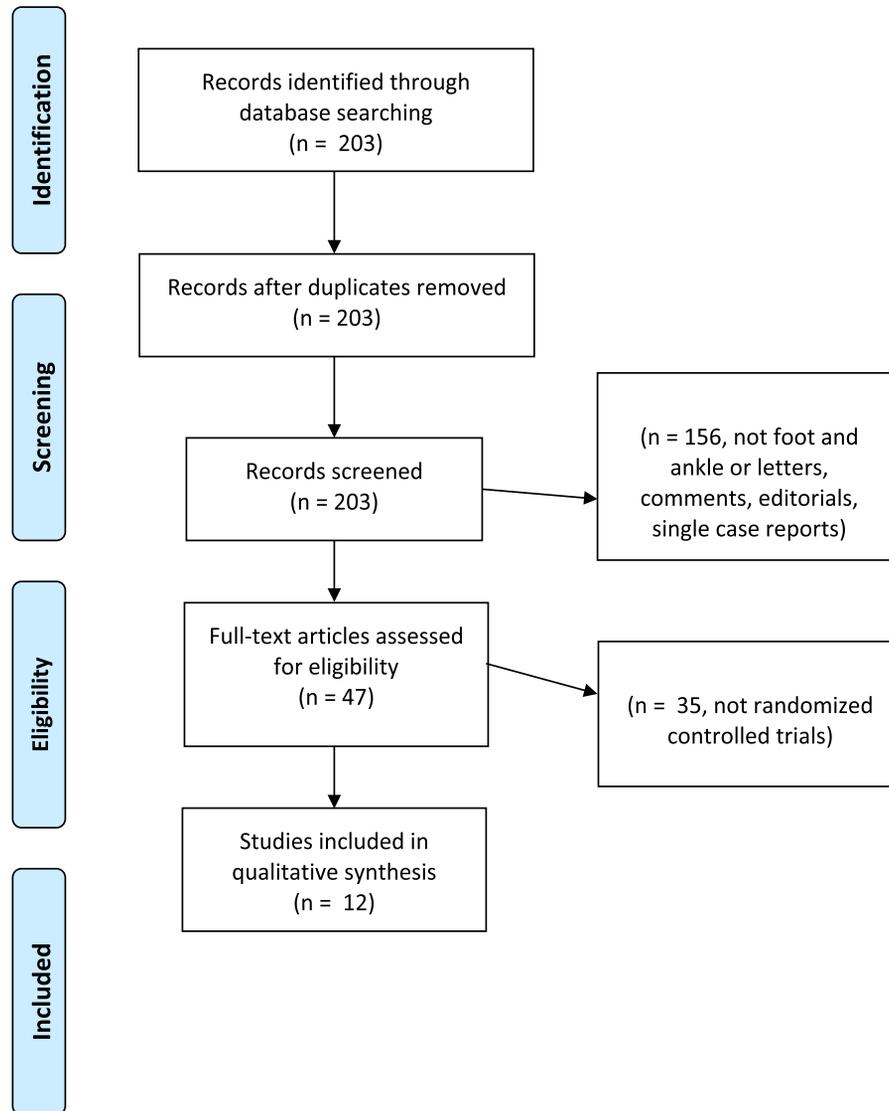


Fig. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram of a systematic review.

retrospective studies, prospective studies, and meta-analyses were included. Single case reports, commentaries, editorials, and letters to authors were excluded. Non-foot and ankle studies were excluded. The search was performed with the PubMed/MEDLINE database based on the results published by Slobogean et al (7), which demonstrated that the highest retrieval rates for orthopedic systematic reviews were achieved by searching MEDLINE (90%) versus EMBASE (81%). The study authors reviewed the studies meeting the inclusion criteria, and any question of inclusion was reconciled based on discussion and consensus.

Descriptive statistics were generated for the body of studies by topic of study and type of study. Next, selected demographic data were extracted from the subset of studies reporting on the outcome of foot and ankle surgical intervention, perioperative management strategies after foot and ankle surgery, perioperative pharmacotherapy, and perioperative radiographic/diagnostic workup. Data collected from RCTs included the following:

1. Journal of publication
2. Date of publication
3. Country of publication
4. Comparison arms
5. Citation rates (obtained using Google Scholar, completed on March 25, 2018)

Studies published from 2016 to 2017 were excluded for the mean citation rate calculation. For RCTs comparing the outcome of operative versus nonoperative management, the following data points were collected:

1. Double blinding
2. Proportion of crossover to the surgical arm from the nonsurgical arm
3. Proportion of patients enrolled from patients screened

## Results

There were 47 foot and ankle studies published in high-impact general medical journals from 2000 to 2017 (8–54). The most common foot and ankle study topics published were diabetic foot ulcers (n = 24 [52.2%]), plantar fasciitis (n = 6 [13%]), Achilles tendinopathy (n = 5 [10.6%]), and osteomyelitis (n = 3 [6.4%]) (Table 1). The most common study type were reviews (n = 24 [51.1%]), RCTs (n = 11 [23.4%]), and nonrandomized prospective studies (n = 6 [12.8%]) (Table 1).

### Foot and Ankle RCTs

Of the foot and ankle RCTs, the most common journal of publication was *JAMA* (n = 7 [58.3%]) (Table 2). The most common countries of publication were the United States (n = 4 [33.3%]) and Australia (n = 3

**Table 1**  
Descriptive statistics of foot and ankle studies published in general medical journals (N = 47)

	No.	%
<b>Study topic</b>		
Diabetic foot ulcers	25	53.2
Plantar fasciitis	6	12.8
Achilles tendinopathy	5	10.6
Infection	3	6.4
Ankle sprain/fracture	4	8.5
Other	4	8.5
<b>Study type</b>		
Review	24	51.1
Randomized controlled trial	12	25.5
Prospective study	6	12.8
Retrospective study	3	6.4
Meta-analysis	2	4.3

[25%]). The median number of times in which foot and ankle RCTs published before 2016 were cited was 242.5 (range [25th percentile] 177.8 to [75th percentile] 294.8). The most cited study was: “Negative Pressure Wound Therapy After Partial Diabetic Foot Amputation: A Multicenter, Randomized Controlled Trial” by Armstrong et al (11).

Of the 4 RCTs that compared operative with nonoperative treatment, 3 (75%) demonstrated nonsuperiority of operative management to nonoperative management in the primary outcome of interest. The most cited RCT comparing operative to nonoperative management was “Platelet-Rich Plasma Injections for Chronic Achilles Tendinopathy: A Randomized Controlled Trial” by de Vos et al (15), published in *JAMA* in 2010. Overall, 50% of RCTs used double blinding. The mean proportion

enrollment from patients screened was 0.69; the mean crossover from a conservative to a surgical arm during the study was 3%. The 3 studies that demonstrated nonsuperiority of operative to nonoperative management had a mean proportion enrollment from patients screened of 0.60, whereas the single study showed that the superiority of operative management over nonoperative management had a mean proportion enrollment from patients screened of 0.99.

## Discussion

This is the first study in the foot and ankle literature to assess study topics, study types, and methodologic characteristics of foot and ankle-related publications in high-impact general medical journals such as *New England Journal of Medicine*, *The Lancet*, *JAMA*, *Annals of Medicine*, and *Archives of Internal Medicine*.

Given its overall burden of disease, studies of diabetic foot ulcers (n = 25 [53.2%]) met our a priori expectation of being the most common study topic published in general medical journals. However, the second and third most common study topics of plantar fasciitis (n = 6 [12.8%]) and Achilles tendinopathy (n = 5 [10.6%]), although common pathologies, could not have been as easily predicted based on the burden of disease, nor could the overall trends have been expected based on any similar representation in journals focusing on foot and ankle pathology (53). For comparison, in a nonsystematic query of the 806 studies in *The Journal of Foot & Ankle Surgery* from January 2015 to December 2017 (query through PubMed/MEDLINE was completed on March 24, 2018), diabetes and related terms appeared in the title or abstract of 70 (8.6%) studies.

Level I and II studies, such as RCTs and nonrandomized prospective studies, provide higher levels of clinical evidence and are more likely to

**Table 2**  
Foot and ankle randomized controlled trials published in general medical journals

Study Title	Author (Year)	Journal	Country	Comparisons
Surgery vs Orthosis vs Watchful Waiting for Hallux Valgus: A Randomized Controlled Trial	Torkki et al (2001) (9)	<i>JAMA</i>	Finland	Surgery (distal chevron osteotomy) vs orthosis vs watchful waiting
Ultrasound-Guided Extracorporeal Shock Wave Therapy for Plantar Fasciitis: A Randomized Controlled Trial	Buchbinder et al (2002) (10)	<i>JAMA</i>	Australia	Ultrasound-guided extracorporeal shock wave therapy vs placebo
Effect of Therapeutic Footwear on Foot Reulceration in Patients With Diabetes: A Randomized Controlled Trial	Reiber et al (2002) (45)	<i>JAMA</i>	United States	Extra depth and width therapeutic shoes with inserts vs usual footwear
Effect of Magnetic vs Sham-Magnetic Insoles on Plantar Heel Pain: A Randomized Controlled Trial	Winemiller et al (2003) (42)	<i>JAMA</i>	United States	Cushioned insoles with active bipolar magnets vs sham magnets
Negative Pressure Wound Therapy After Partial Diabetic Foot Amputation: A Multicentre, Randomised Controlled Trial	Armstrong et al (2005) (11)	<i>Lancet</i>	United States	Negative-pressure wound therapy with vacuum-assisted closure vs standard moist wound care
Ertapenem Versus Piperacillin/Tazobactam for Diabetic Foot Infections (SIDESTEP): Prospective, Randomised, Controlled, Double-Blinded, Multicentre Trial	Lipsky et al (2005) (47)	<i>Lancet</i>	United States	Ertapenem vs piperacillin/tazobactam
Effectiveness of Foot Orthoses to Treat Plantar Fasciitis: A Randomized Trial	Landorf et al (2006) (12)	<i>Arch Int Med</i>	Australia	Sham orthosis (soft, thin foam) vs prefabricated orthosis (firm foam) vs customized orthosis (semirigid plastic)
Mechanical Supports for Acute, Severe Ankle Sprain: A Pragmatic, Multicentre, Randomised Controlled Trial	Lamb et al (2009) (14)	<i>Lancet</i>	United Kingdom	Below the knee cast vs tubular compression bandage vs Aircast vs Bledsoe
Rehabilitation After Immobilization for Ankle Fracture: The EXACT Randomized Clinical Trial	Moseley et al (2015) (16)	<i>JAMA</i>	Australia	Supervised exercise program and advice about self-management vs advice alone
Platelet-Rich Plasma Injection for Chronic Achilles Tendinopathy: A Randomized Controlled Trial	de Vos et al (2010) (15)	<i>JAMA</i>	The Netherlands	Platelet-rich plasma injection vs saline injection
Close Contact Casting Vs Surgery For Initial Treatment Of Unstable Ankle Fractures in Older Adults: A Randomized Clinical Trial	Willett et al (2016) (17)	<i>JAMA</i>	United Kingdom	Surgery vs casting
Effect of Antibiotic Prophylaxis on Surgical Site Infections Following Removal of Orthopedic Implants Used for Treatment of Foot, Ankle, and Lower Leg Fractures: A Randomized Clinical Trial	Backes et al (2017) (54)	<i>N Engl J Med</i>	The Netherlands	Single-dose intraoperative cefazolin vs 0.9% saline

Abbreviations: *Arch Int Med*, *Archives of Internal Medicine*; *JAMA*, *Journal of the American Medical Association*; *Lancet*, *The Lancet*; *N Engl J Med*, *New England Journal of Medicine*.

be published in high-impact journals. This finding is evidenced by the fact that these high-level studies were among the most common foot and ankle studies published in the medical journals examined in this investigation. Similarly, it is reasonable to assume that higher-quality studies are required of foot and ankle submissions (or from other non-medical specialties) to achieve publication in prestigious medical journals. A previous analysis by Nwachukwu et al (6) of hand surgery, adult reconstruction, pediatrics, spine, sports medicine, and trauma demonstrated an overall preference for nonoperative management for RCTs published in these 5 high-impact general medical journals. Some of the differences in results, however, included the rate of crossovers from nonsurgical to surgical arms. This study found that the mean rate of crossover from nonsurgical to surgical arms in foot and ankle RCTs was relatively small (3%) compared with the 33% found by Nwachukwu et al (6) in other orthopedic specialties. This difference may be partially explained by the sample size of this study and partially by the mean rate of double blinding in foot and ankle RCTs (50%) versus the rate of double blinding in the study conducted by Nwachukwu et al (6) of other orthopedic specialties (26.7%). The low rate of crossover from nonsurgical to surgical arms validates the use of intent-to-treat analysis, because each treatment arm is appropriately analyzed by the representative treatment received.

The low crossover rate demonstrated in this investigation and the high methodologic rigor for all foot and ankle RCTs support the high quality of evidence provided by these studies. Although tempered by the small number of foot and ankle RCTs published in the selected medical journals, it is interesting to note that the single foot and ankle RCT showing significant benefit of operative management over nonoperative management had a proportion enrollment from patients screened of 0.99 versus a mean proportion enrollment from patients screened of 0.60 for studies supporting nonoperative management. Inclusion and exclusion of potential surgical candidates thus remain important methodologic characteristics for future RCTs to be evaluated on and for future study designers to account for to achieve the greatest validity and generalizability (55).

It is noteworthy to compare the results of this systematic review with other systematic reviews of positive versus nonpositive study findings. For example, in *The Journal of Bone and Joint Surgery*, Okike et al (56) analyzed 1181 manuscripts submitted to the journal and found that 72% of the manuscripts submitted showed a positive study outcome for the intervention of interest. Turner et al (57) reviewed 74 studies registered with the US Food and Drug Administration of new antidepressant medications in 12,564 patients and found that the published literature demonstrated that 94% of these trials had a positive result, whereas the US Food and Drug Administration analyses showed that 51% of the registered studies had a positive result.

There are several limitations to this study. We could not compare the acceptance rates of foot and ankle studies submitted based on positive or nonpositive results owing to the unavailability of submission data from the selected medical journals. Furthermore, we could not assess the volume of foot and ankle submissions or acceptance rates in general for similar reasons. Additionally, the authors recognize that this analysis is a cross-section of select medical journals examined over a specific study period and reflects only a portion of the current medical literature. Despite these limitations, this work may be useful for practicing foot and ankle surgeons to understand the subject matter and methodologic characteristics of foot and ankle publications being read by general practitioners. An understanding of the findings from these studies may be particularly important given the extremely high citation rates of foot and ankle studies published in high-impact medical journals. Furthermore, as more and more external agencies influence and regulate the delivery of foot and ankle care, an understanding of the evidence presented to the lay public and those who guide health care policy may be important.

In conclusion, diabetic foot ulcers, plantar fasciitis, and Achilles tendinopathy are the most commonly published foot and ankle topics in general medical journals, and the most common study types are reviews, RCTs, and nonrandomized prospective studies. The average citations for RCTs in these journals are high. Of the small number of foot and ankle RCTs comparing operative with nonoperative management, more studies support nonoperative management for the primary outcome of interest.

## Supplementary Material

Supplementary material associated with this article can be found in the online version at doi:10.1053/j.jfas.2018.09.005.

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