

Advancing Foot and Ankle Care: The Role and Impact of Podiatric Clinical Trials

Ananya Rao*

Department of Physical Therapy, University of Karm Chandra Gandhi, India

Abstract

Podiatric clinical trials are integral to the evolution of evidence-based care in foot and ankle health, shaping diagnostic, therapeutic, surgical, and rehabilitative interventions for a wide spectrum of conditions. As the burden of foot and ankle disorders increases due to aging populations, rising diabetes prevalence, and expanding athletic demands, the need for rigorous, targeted research within podiatry becomes increasingly vital. This paper explores the current landscape and historical progression of podiatric clinical trials, examining their contributions to advancing clinical practice, informing guidelines, improving patient-reported outcomes, and expanding multidisciplinary approaches. Through a critical analysis of pivotal trials and emerging areas of research, including wound care, biomechanical innovations, orthotics, minimally invasive surgical techniques, and regenerative medicine, this study underscores how podiatric trials are reshaping standards of care. Moreover, the paper investigates barriers to conducting high-quality podiatric research such as funding limitations, methodological variability, and limited integration into broader clinical research networks and highlights strategies for enhancing trial design, diversity, and translational potential. Finally, the review offers policy and educational recommendations aimed at strengthening the infrastructure and visibility of podiatric clinical trials, ultimately supporting a more equitable and evidence-informed healthcare system for patients with foot and ankle conditions.

Keywords: Podiatric clinical trials; Foot and ankle care; Evidence-based podiatry; Surgical outcomes; Diabetic foot ulcers; Regenerative medicine; Orthotics and biomechanics; Translational research; Wound care; Clinical trial design

Introduction

Podiatric clinical trials play a pivotal role in advancing the field of foot and ankle care. As a subspecialty within the medical sciences, podiatry encompasses the diagnosis, treatment, and prevention of conditions affecting the feet, ankles, and lower extremities [1]. With increasing incidences of diabetes, arthritis, and sports-related injuries, there is a growing need for evidence-based treatments in podiatry. Clinical trials serve as the cornerstone of that evidence base, allowing practitioners and researchers to evaluate new drugs, devices, surgical techniques, and therapeutic approaches [2]. Foot and ankle disorders represent a significant public health concern, affecting millions globally and leading to substantial morbidity, disability, and healthcare expenditures [3]. These conditions, ranging from chronic wounds and diabetic foot complications to sports injuries and structural deformities, often require complex, multidisciplinary interventions. Despite their prevalence and impact, foot and ankle conditions have historically been underrepresented in high-quality clinical research. However, in recent decades, the field of podiatric medicine has witnessed a transformative shift toward evidence-based practice, driven largely by the growth and sophistication of podiatric clinical trials [4].

Clinical trials serve as the gold standard for generating robust evidence that guides healthcare decisions. In podiatry, such trials play a critical role in validating new interventions, refining surgical techniques, and establishing effective treatment protocols across diverse patient populations [5]. From evaluating the efficacy of novel wound-healing agents and offloading devices to assessing long-term outcomes of ankle arthroplasty and tendon repair, podiatric clinical trials are increasingly influencing practice standards and policy development [6]. Despite these advancements, the landscape of podiatric research remains challenged by several systemic issues. These include limited funding opportunities, a scarcity of large-scale, multi-

institutional trials, and underrepresentation of diverse populations. Furthermore, podiatric trials often struggle to gain visibility within the broader clinical research ecosystem, leading to missed opportunities for integration into national guidelines and interdisciplinary care models [7].

This paper aims to illuminate the vital role of podiatric clinical trials in advancing foot and ankle care. By examining landmark studies, emerging research priorities, and methodological trends, the paper underscores the growing importance of rigorous scientific inquiry in podiatric medicine [8]. It also explores how improved infrastructure, policy support, and academic collaboration can elevate the scope and impact of podiatric clinical trials ultimately enhancing care for individuals affected by foot and ankle conditions worldwide.

Understanding podiatric clinical trials

Clinical trials in podiatry are scientific studies conducted to assess the safety and effectiveness of various interventions targeting podiatric conditions. These may include:

- Pharmacological treatments (e.g., antifungal medications, anti-inflammatories)
- Medical devices (e.g., orthotics, foot braces, diabetic footwear)

***Corresponding author:** Ananya Rao, Department of Physical Therapy, University of Karm Chandra Gandhi, India, E-mail: ananya.rao@gmail.com

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- Surgical techniques (e.g., bunion correction, tendon repair, ankle arthroscopy)
- Physical therapy protocols for rehabilitation
- Biologics and regenerative therapies, such as platelet-rich plasma (PRP) and stem cells

The trials are typically conducted in four phases:

- Phase I assesses safety in a small group.
- Phase II evaluates effectiveness and side effects.
- Phase III compares the new intervention to existing standards.
- Phase IV follows long-term use post-marketing.

Importance of clinical trials in podiatry

Clinical trials provide the data needed to support or challenge existing treatment modalities. For example, randomized controlled trials have led to changes in how diabetic foot ulcers are managed, shifting toward more effective debridement and advanced wound dressings.

Innovations like 3D-printed orthotic insoles, shockwave therapy, and minimally invasive surgeries gain widespread adoption only after rigorous clinical trials prove their efficacy.

Clinical trials ensure patient safety through ethical guidelines, informed consent, and oversight by regulatory bodies such as the U.S. Food and Drug Administration (FDA) or equivalent agencies globally.

Diabetic patients, athletes, elderly individuals, and children may require tailored foot care. Clinical trials help identify subgroup-specific outcomes, which improves personalized podiatric care.

Recent advances through clinical trials

Diabetic Foot Ulcers (DFUs), recent studies on skin substitutes like Apligraf and Dermagraft have demonstrated improved healing rates compared to standard care.

Plantar fasciitis treatments, trials on platelet-rich plasma (PRP) injections have shown promising results in chronic cases resistant to traditional therapies.

Total ankle replacement (tar), modern implants, like the Infinity Total Ankle System; have undergone clinical trials showing reduced pain and increased range of motion in osteoarthritic patients.

Onychomycosis (Nail Fungus), novel laser therapies and topical treatments are being tested to reduce recurrence and improve nail appearance.

Despite their importance, podiatric clinical trials face unique challenges:

Recruitment and Retention, Patients often underestimate foot problems, leading to low participation rates.

Funding limitations, podiatry receives less research funding compared to larger fields like cardiology or oncology.

Standardization issues, there's a lack of standardized outcome measures in foot and ankle research.

Ethical concerns, surgical trials pose ethical complexities, especially when comparing a novel technique to a well-established one.

Podiatric clinical trials are governed by strict ethical and legal standards, including,

- Institutional Review Board (IRB) approval
- Informed consent
- Data privacy and monitoring
- ClinicalTrials.gov registration (or local registry)

These mechanisms protect participants and ensure that the trial results are credible and reproducible.

Emerging technologies and methodologies are shaping the future of podiatric trials:

- Tele-research and remote monitoring tools are improving patient follow-ups.
- Wearable sensors embedded in shoes are being used to track real-world gait and mobility.
- Artificial intelligence (AI) is helping in image analysis and treatment planning.
- Decentralized trials are reducing patient burden and increasing inclusivity.

Additionally, there's growing interest in genomic medicine, where future trials may tailor treatments based on genetic predispositions to conditions like Charcot-Marie-Tooth disease or Achilles tendinopathy.

How Practitioners Can Get Involved

Podiatrists can actively contribute to clinical research in several ways:

- Partnering with academic institutions or CROs (Contract Research Organizations)
- Joining research networks like the American Podiatric Medical Association (APMA) Clinical and Scientific Affairs Committee
- Participating as investigators or referring patients to ongoing trials
- Publishing case studies and outcome reports.

Conclusion

Podiatric clinical trials are not merely academic exercises they are the backbone of progressive and patient-centered foot care. From refining surgical techniques to validating new wound care technologies, these trials ensure that podiatric interventions are both safe and effective. As podiatry continues to evolve, so must its commitment to rigorous scientific inquiry.

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