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LOWER EXTREMITY REVIEW

May 23 / volume 15 / number 5

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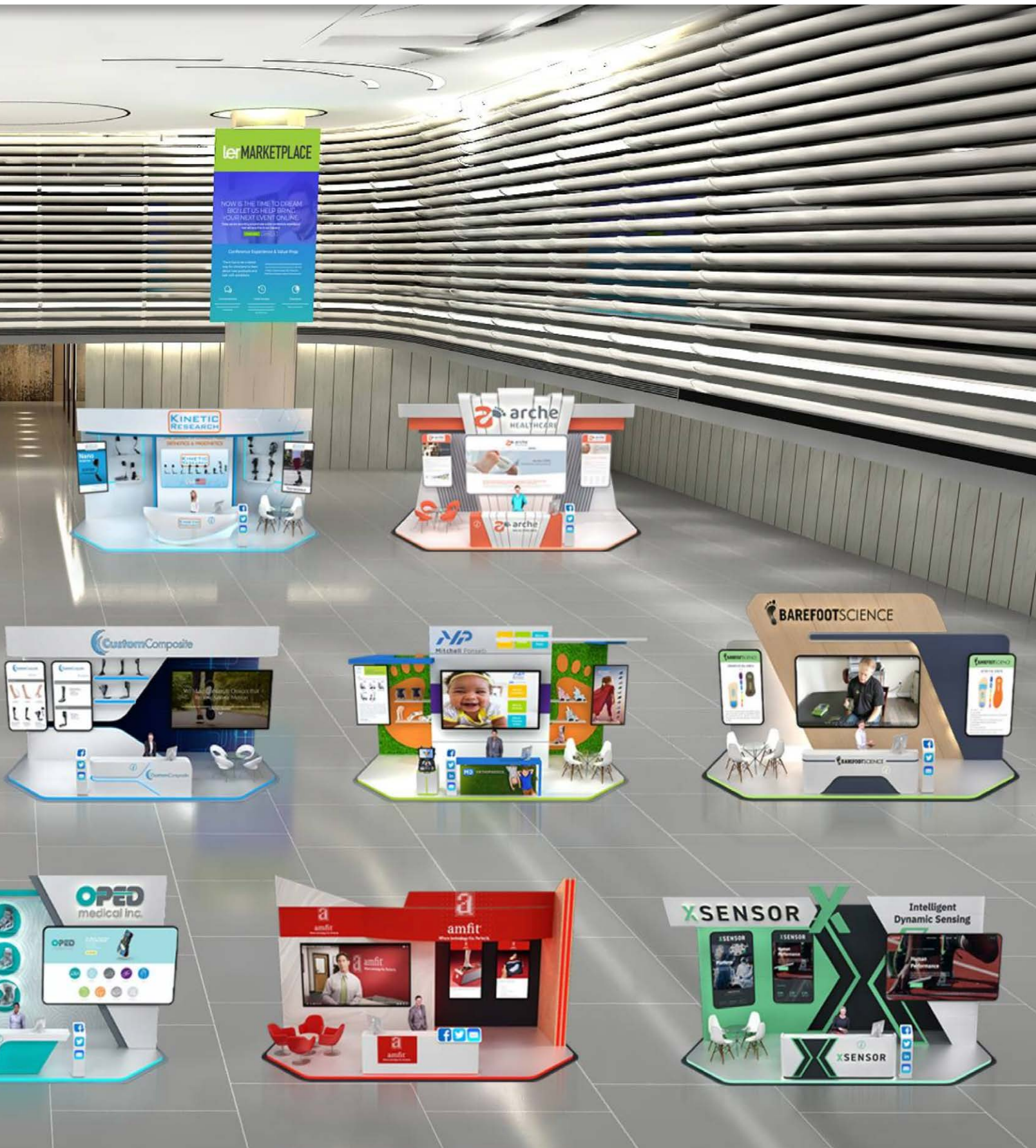
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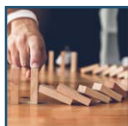


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Every year, more than 1 out of 4 Americans age 65+ falls. Falls are the leading cause of fatal and nonfatal injuries among older adults



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Designed by @YLMsPortScience

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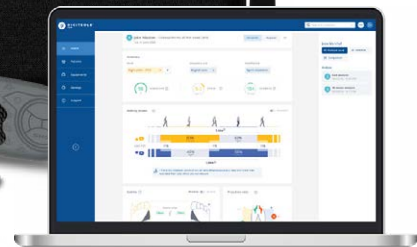


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Lower Extremity Review

Lower Extremity Review informs healthcare practitioners on current developments in the diagnosis, treatment, and prevention of lower extremity injuries. LER encourages a collaborative multidisciplinary clinical approach with an emphasis on functional outcomes and evidence-based medicine. LER is published monthly, except for a combined November/December issue and an additional special issue in December, by Lower Extremity Review, LLC.

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LOWER EXTREMITY REVIEW

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Lower Extremity Review Mission

Showcasing evidence and expertise across multiple medical disciplines to build, preserve, and restore function of the lower extremity from pediatrics to geriatrics.

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- Biomechanics matter
- Injury prevention is possible
- Collaborative care leads to better outcomes
- Movement is essential
- Diabetic foot ulcers can be prevented

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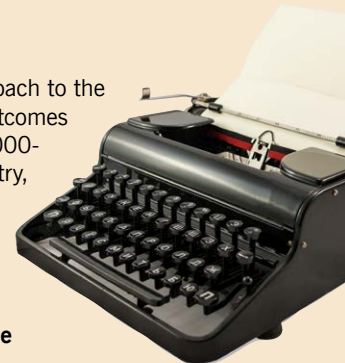
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LER encourages a collaborative multidisciplinary clinical approach to the care of the lower extremity with an emphasis on functional outcomes using evidence-based medicine. We welcome manuscripts (1000-2000 words) that cross the clinical spectrum, including podiatry, orthopedics and sports medicine, physical medicine and rehabilitation, biomechanics, obesity, wound management, physical and occupational therapy, athletic training, orthotics and prosthetics, and pedorthics.

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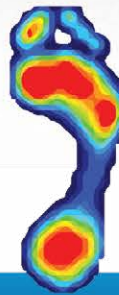


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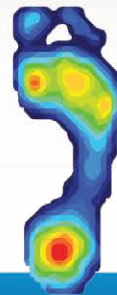
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The Time Is NOW to Prevent Falls

BY JASON KRAUS, BS

Let's start with some basic facts:

- Every year, more than 1 out of 4 Americans age 65+ falls
- Falls are the leading cause of fatal and nonfatal injuries among older adults
- The cost of treating injuries caused by falls is projected to increase to over \$101 billion by 2030
- Falls result in more than 3 million injuries treated in emergency departments annually, including over 800,000 hospitalizations
- In 2015, the total cost of non-fatal fall injuries was \$50 billion
- Each year about \$754 million is spent on medical costs related to fatal falls
- For older adults in the U.S., fall death rates went up by 30% from 2007 to 2016, and researchers predict there will be 7 deadly falls every hour by 2030
- People with mild hearing loss are nearly 3x as likely to fall, with each 10 decibels of hearing loss increasing falls risk
- The majority (60%) of falls happen in the home, 30% in a public setting, and 10% in a health care center

These statistics from the National Council on Aging¹ paint a pretty grim picture, but it's from a 10,000-foot view. Let me bring it closer to home with my personal story.

My Father passed away in 2005. But a couple years before that he fell. Not once, not twice, but probably 6 or 8 times. Some were minor, others led to major problems, broken



femur, broken wrist, broken leg. He ended up confined to a wheelchair and his family—my mother, brothers, and sisters and me—were all at wits' end as to how to take care of him those last 18 months.

Fast forward to 2011 when I was president of OHI (Orthotic Holdings, Inc). I led the company in the acquisition of Arizona AFO. The Moore Balance Brace came as part of that acquisition—it's a custom-designed balance ankle-foot-orthotic designed to reduce the risk of falls in elderly patients.

I spent the next 9 years with the brace's designer, Dr. Jonathan Moore, working together to educate practitioners around the globe on how and why the utilization of these types of modalities could really make a difference in people's lives. But I was left with nagging questions: Could something have been done for my dad? Could he have remained ambulatory that

last year-and-a-half of his life? Could his quality of life and the quality of my family's life been different had I known in 2005 what I learned in 2011? My Dad had been treated by many practitioners—podiatrist, physiologist, primary care doctor, occupational therapist and a whole host of others—and not one time do I recall anyone recommending him for a comprehensive assessment.

I never thought about that until I was reviewing the recent JAMA article: *Lower-Limb Factors Associated with Balance and Falls in Older Adults: A systematic review and clinical synthesis.*² Not unsurprisingly, Dr. Moore was one of the authors.

The article, which was a review of 81 peer-reviewed published studies, was written by what amounts to a think tank of fall prevention experts and I encourage you to read it for yourself. Basically, the article painted a high correlation between foot and ankle problems

This Guest Perspective was excerpted and modified from a longer talk given by Mr. Kraus at the lerEXPO event: Introducing Balance AFOs into Your Clinical Practice, sponsored by Orthotica Labs. The program also included talks by Michael King, DPM, and Jonathan Moore, DPM, both of whom were authors on the article mentioned here as reference 2. The 2-hour program comes with 2 CEUs. Find it at lerEXPO.com/past-events.



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and the incidence of falls in older adults. In fact, it identified 8 pathways of lower limb-related influences on fall risk in this population, 6 of which support a direct link to fall risk.

What jumped out at me, and it may seem obvious, but there was no recommendation to check for foot problems in annual checkups. Sure, it's in today's diabetes care protocol, but not for everybody else...yet we all age. And it wasn't always in the diabetes care protocol. I started out in podiatry in the late 1970s and utilization of prevention modalities in the treatment of the at-risk diabetic population was really quite low and the complications, especially amputations began to climb. But then the training in podiatry schools and residencies evolved to include prevention protocols, and ultimately third-party reimbursements caught up to where we are today: patients with diabetes represent between 15% and 20% of revenue in a podiatric practice environment.

And I would argue, with the data that we see, that falls management and treating patients with balance deficits could approach those revenue numbers in the years to come. How can

I say that? We're halfway through a generational change in how healthcare is delivered and paid for in this country. We're moving from a fee-for-service model to a fee-for-value model that is an outcomes-based payment system. The benefit of this transition is that finally, *finally*, the ability to prevent serious and life-altering injury is becoming worthy of third-party reimbursement.

And then there is the large and growing patient population that will need falls risk mitigation: Every day, 10,000 people in the United States turn 65—they've been doing so for nearly a decade and will continue to do so for at least the next decade. And those who survive to 75 and 80 years of age face an exponential increase in risk from when they were at 65. So you've got a very large addressable market that's literally walking through your clinic doors everyday.

And finally, today's business environment is witnessing the acquisition of podiatric practices by private equity backed consolidators and healthcare systems. If you bring these ancillary services into your practice now, your valuation at your exit will be more significant.

While falls and preventing them could be complex, the protocol builds on 3 pillars:

- Perform an assessment
- Identify modifiable risk factors
- Implement appropriate interventions and protective devices

If you do those 3 things, you'll inevitably be able to help your patients in ways I wasn't able to help my dad or my family all those years ago.

Jason Kraus, BS, has been in the medical device industry for more than 40 years and is co-founder of Orthotica Labs, which was established in 2022.

References

1. National Council on Aging. Get the Facts on Falls Prevention. March 13, 2023. Available at <https://ncoa.org/article/get-the-facts-on-falls-prevention>. Accessed April 15, 2023.
2. Neville C, Nguyen H, Ross K, et al. Lower-limb factors associated with balance and falls in older adults: a systematic review and clinical synthesis. *J Am Podiatr Med Assoc.* 2020;110(5):Article_4. doi: 10.7547/19-143.

Table 1. Lower Limb Factors Leading to Increased Fall Risk²

Risk Factor	Evidence-based link to increased fall risk
1. Age-related changes in lower limb range of motion	✓
2. Age-related changes in lower limb strength	✓
3. Age-related changes in lower limb deformity	✓
4. Age-related use of footwear	✓
5. Age-related use of orthoses	✓
6. Age-related lower limb pain	✓
7. Age-related changes in plantar skin and soft tissues	
8. Age-related changes in sensory input	

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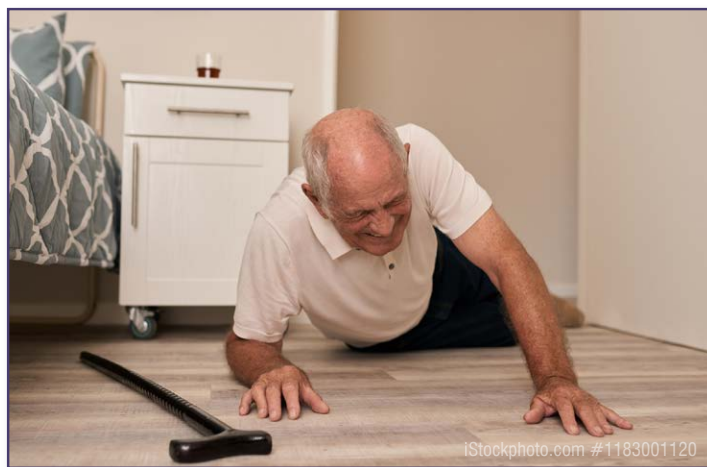
As more of the world population continues to live into old age, falls are becoming a global health challenge and their prevention paramount. Malaysian researchers developed a clustering algorithm to sort 1400 patients (age 55+) into low, intermediate A, intermediate B, and high risk groups which corresponded with fall occurrence of 13%, 19%, 21%, and 31%, respectively. Participants clustered in the high falls risk group possessed 50% higher odds of falls compared to the overall dataset. Participants included in the high falls risk group had slower gait, poorer balance, weaker muscle strength, presence of cardiovascular disorder, poorer cognitive performance, and advancing age. The authors concluded that this clustering algorithm represents a potential clinical decision support tool to identify high risk fallers for falls prevention initiatives, thus improving case finding and reducing burdens on the currently limited resource of clinicians trained in managing older adults. ^(ler)

Source: Goh C-H, Wong KK, Tan MP, Ng S-C, Chuah YD, Kwan B-H. Development of an effective clustering algorithm for older fallers. *PLoS ONE*. 2022;17(11):e0277966. <https://doi.org/10.1371/journal.pone.0277966>.



tributing to the short-term changes in gait biomechanics and physical function such as reduced inflammation. ^(ler)

Source: Lisee C, Bjornsen E, Berkoff D, et al. Changes in biomechanics, strength, physical function, and daily steps after extended-release corticosteroid injections in knee osteoarthritis: a responder analysis. *Clin Rheumatol*. 2023. doi: 10.1007/s10067-023-06568-x.



IMPACT OF CORTICOSTEROID INJECTIONS IN KNEE OA

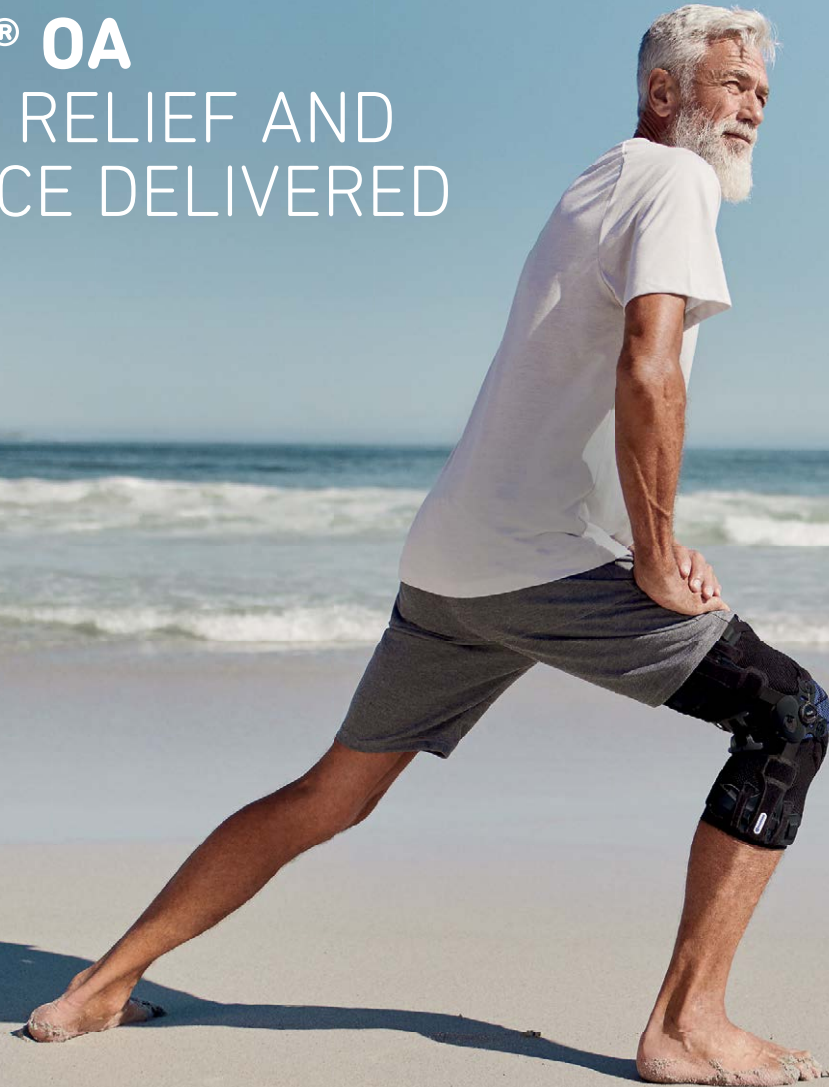
Extended-release corticosteroid injections demonstrated short-term improvements in gait biomechanics, quadricep strength, and physical function for up to 8 weeks. However, non-responders demonstrated gait biomechanics associated with osteoarthritis progression prior to the corticosteroid injection, suggesting that non-responders demonstrate more deleterious gait biomechanics prior to corticosteroid injection. The authors called for future research to determine the mechanisms con-

TRICEPS SURAE MUSCLE STIFFNESS CONTRIBUTES TO PASSIVE ANKLE JOINT STIFFNESS

Researchers from Waseda University and Shibaura Institute of Technology, both in Saitama, Japan, sought to investigate the association between the triceps surae muscle and passive ankle joint stiffness. The results revealed that the muscle shear modulus of the entire triceps surae influences the passive ankle joint stiffness, especially when the triceps surae/ankle joint is lengthened/dorsiflexed and the ankle joint stiffness is normalized to body size. Additionally, even Soleus, which is the most compliant muscle between the triceps surae, affects the passive ankle joint stiffness. Moreover, the results also indicate that the association between the muscle shear modulus and ankle joint stiffness is independent of age, although the association is clearer in young than in older adults due to age-related decrease in the contribution of muscle stiffness to joint stiffness. These findings suggest that modulation of the triceps surae stiffness may change the ankle joint stiffness, leading to the improvement of functional ability, such as postural balance and walking, and decrease in injury and fall risks. ^(ler)

Source: Hirata K, Akagi R. Contribution of muscle stiffness of the triceps surae to passive ankle joint stiffness in young and older adults. *Front Physiol*. 2022;13:972755. doi: 10.3389/fphys.2022.972755

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DOES ASYMPTOMATIC HYPERURICEMIA = KNEE OA?

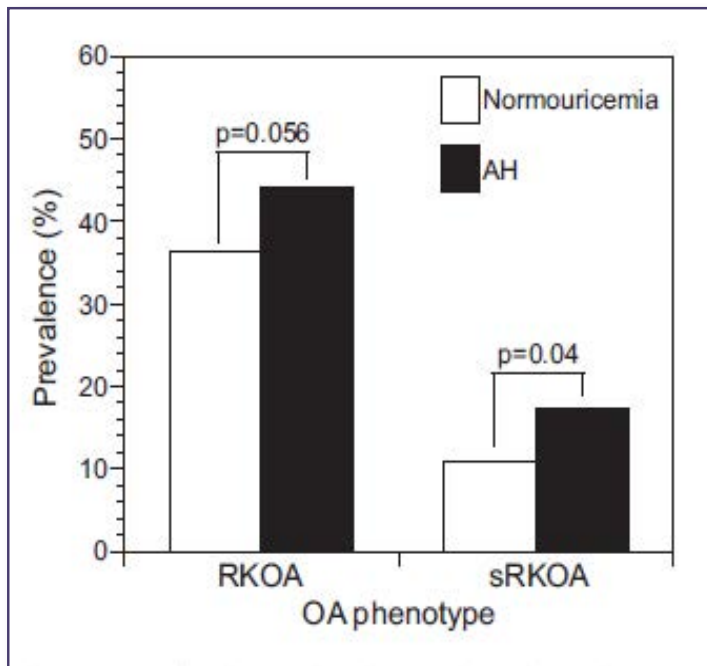



Figure. Prevalence ratios of Radiographic knee OA (RKO) and symptomatic RKO (sRKO) among adults age 60 or older with asymptomatic hyperuricemia (AH) vs normouricemia.

Several studies suggest that urate may contribute to osteoarthritis (OA) risk. So researchers from the Albert Einstein College of Medicine tested the associations between hyperuricemia and knee OA, and examined the role of obesity, using a cross-sectional, nationally representative dataset.

The National Health and Nutrition Examination Survey (NHANES) III used a multistage, stratified probability cluster design to select USA civilians from 1988 to 1994. Using NHANES III, the research team studied adults >60 years, with or without hyperuricemia (serum urate > 6.8 mg/dL), excluding individuals with gout (i.e., limiting to asymptomatic hyperuricemia [AH]). Radiographic knee OA (RKO) was defined as Kellgren-Lawrence grade ≥ 2 in any knee, and symptomatic radiographic knee osteoarthritis (sRKO) was defined as RKO plus knee pain (most days for 6 weeks) in the same knee.

AH prevalence was 17.9% (confidence interval (CI) 15.3–20.5). RKO prevalence was 37.7% overall (CI 35.0–40.3) and was 44.0% for AH vs 36.3% for normouricemic adults ($P = 0.056$) (Figure.). sRKO was more prevalent in AH vs normouricemic adults (17.4% vs 10.9%, $P = 0.046$). In multivariate models adjusting for obesity, model-based associations between AH and knee OA were attenuated (for RKO, prevalence ratio [PR] = 1.14, 95% CI 0.95, 1.36; for sRKO, PR = 1.40, 95% CI 0.98, 2.01). In stratified multivariate analyses, AH was associated with sRKO in adults without obesity (PR = 1.66, 95% CI 1.02, 2.71) but not adults with obesity (PR = 1.21, 95% CI 0.66, 2.23).

Conclusions: Among adults aged 60 or older, AH is associated with knee

OA risk that is more apparent in adults without obesity. 

Source: Wang S, Pillinger MH, Krasnokutsky S, Barbour KE. The association between asymptomatic hyperuricemia and knee osteoarthritis: data from the third National Health and Nutrition Examination Survey. *Osteoarthritis Cartilage*. 2019;27(9):1301-1308. doi: 10.1016/j.joca.2019.05.013.

COUNTY POLICY LIMITING FIREWORKS ACCESS REDUCES INJURY

Researchers from Hawaii sought to examine trends in fireworks-related injuries (FRI) before and after enactment of an ordinance to limit access in the City and County of Honolulu (the island of Oahu).

Methods: Surveillance of FRI treated in all emergency departments in the state, for 18 New Year's periods (31 December through 1 January) from 2004 to 2021. Prelaw (2004 to 2011) and postlaw (2012 to 2021) number of FRIs were compared, by patient age and county.

Results: The average annual number of FRI for all ages decreased significantly in Oahu, from 74 during the prelaw period to 27 during the postlaw period ($P < 0.01$), but not in the remaining neighbor islands ($P = 0.07$). Decreases were particularly evident for Oahu pediatric patients (under 18 years), among whom FRI declined from 42 to 10 per year ($P < 0.01$). FRI were approximately halved for older Oahu patients and neighbor island pediatric patients.

The researchers concluded that legislation requiring permits for a specified number and type of fireworks, and limiting access to persons 18 years and older was associated with significant decreases in FRI in the City and County of Honolulu.

[Editor's note: For more about fireworks related injuries, be sure to read "Fireworks-Related Lower Extremity Injuries Treated at United States Emergency Departments" on page 43.]

Source: Galanis DJ, Koo SS, Puapong DP, et al. Decrease in injuries from fireworks in Hawaii: associations with a county policy to limit access. *Injury Prevention*. 2022;28:325-329. doi: 10.1136/injuryprev-2021-044402.



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PHYSICAL EXERCISE PROGRAM IMPROVES PHYSICAL CAPACITY IN OLDER ADULTS




Physiotherapy researchers from Colombia found that a community-level supervised program of physical activity had significant positive outcomes on the physical capacities of older adults including strength, flexibility, balance, and aerobic capacity.

Their quasi-experimental study involved >5,000 adults with a mean age of 70.7 years (range, 60-97 years). The 3x/wk program included strength training with free weights, static stretching, joint mobility

exercises, aerobic activities lasting 15-60 minutes, and dynamic and static balance exercises. Pre-and post-program intervention measures were recorded using the senior fitness test.

The researchers found all areas showed significant differences before and after the program in terms of the participants' physical capabilities ($P < 0.05$); muscular strength and flexibility had a more significant mean difference and a large effect (>0.80), except for aerobic capacity, which had a small effect.

In their conclusion, the team wrote that a supervised physical exercise program at the community level has positive effects on the physical capacities of coordination, balance, flexibility, strength, and aerobic capacity, which are essential components for a better functional capacity at this stage of life, with improvements that encompassed the improved self-perception of their health status, a reduction of overweight and obesity. The reinforcement of these programs is recommended, consequently, promoting pre-sport games and sports championships among the elderly population, as a public health strategy. The team also noted the majority of the population that attends this type of intervention is female (92% in this study), so programs should look for strategies that allow greater adherence and participation of older adults of both sexes. 

Source: Buriticá-Marín ED, Daza-Arana JE, Jaramillo-Losada J, Riascos-Zuñiga AR, Ordoñez-Mora LT. Effects of a Physical Exercise Program on the Physical Capacities of Older Adults: A Quasi-Experimental Study. *Clin Interv Aging*. 2023;18:273-282. doi: 10.2147/CIA.S388052.

Continued on page 19

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ENDOCANNABINOID SYSTEM & SKELETAL MUSCLE

In a first-of-its-kind study, researchers from the Institute of Neuroscience, Université Catholique de Louvain, Louvain-la-Neuve, Belgium, investigated the regulation of the endocannabinoid system using several exercise paradigms in human skeletal muscle. They also compared endocannabinoid regulation in healthy and prediabetic people in response to an acute endurance exercise. Blood and muscle samples were taken before and after resistance and endurance exercise in normoxia and hypoxia to measure plasma endocannabinoid levels as well as muscle protein expression of CB1, CB2, and downstream signaling. They found that:

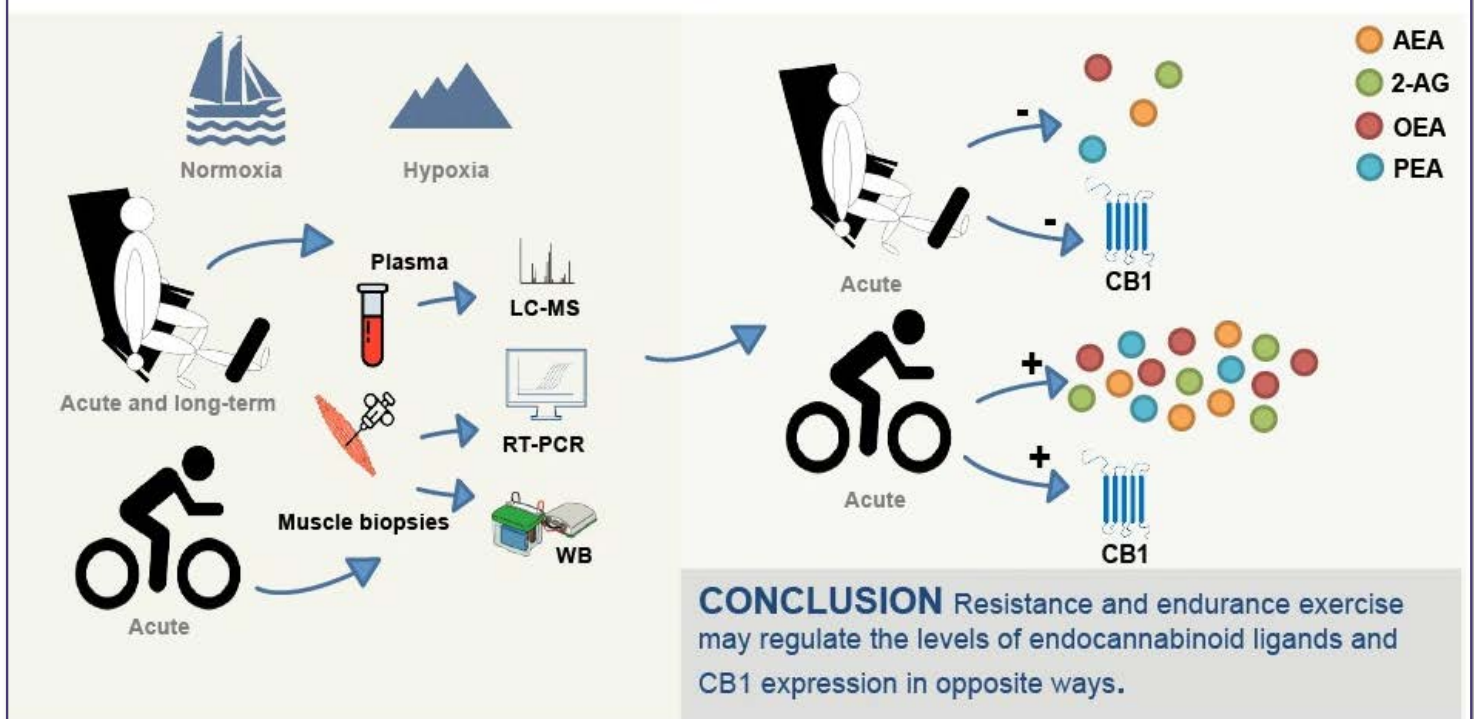
- 1) an acute resistance exercise session decreased plasma 2-AG and N-palmitoylethanolamine (PEA) levels in normoxia;
- 2) 4-wk resistance training decreased plasma AEA, PEA, and N-oleoylethanolamine (OEA) levels in both normoxia and hypoxia;
- 3) an acute moderate-intensity endurance exercise increased plasma OEA levels in the healthy and prediabetic groups in normoxia and hypoxia, whereas plasma 2-AG levels increased in the healthy group and AEA in the prediabetic group only in normoxia.

Overall, the expression of the cannabinoid receptors was only marginally regulated by acute exercise, hypoxia, and prediabetes, and downstream signaling did not follow the changes detected in the endocannabinoid ligands. According to the research team, these results suggest that resistance and endurance exercise regulate the levels of the endocannabinoid ligands and CB1 expression in opposite ways.

These findings, which were published in the *Journal of Applied Physiology* were noteworthy as the first to analyze both endocannabinoids ligands and receptors in response to endurance and resistance exercise. Additionally, no prior study had compared both exercise paradigms regarding endocannabinoid tone, which is of interest as endocannabinoids regulate energy metabolism, and these are different between endurance and resistance exercise. Furthermore, the team investigated whether the endocannabinoid tone was differently regulated in response to acute endurance exercise in prediabetic people – linking exercise, endocannabinoids and (pre)diabetic people had never been done before. 

Source: van Doorslaer de Ten Ryen S, Dalle S, Terrasi R, Koppo K, Muccioli GG, Deldicque L. Regulation of the endocannabinoid system by endurance and resistance exercise in hypoxia in human skeletal muscle. *J Appl Physiol* (1985). 2023;134(3):569-580. doi: 10.1152/japphysiol.00645.2022.

Regulation of the endocannabinoid system by resistance and endurance exercise



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AN OSTEOARTHRITIS ACTION ALLIANCE CONSENSUS STATEMENT

PREVENTING OSTEOARTHRITIS AFTER AN ANTERIOR CRUCIATE LIGAMENT INJURY

After an anterior cruciate ligament (ACL) injury, people need secondary prevention strategies to identify osteoarthritis at its earliest stages so that interventions can be implemented to halt or slow the progression toward its long-term burden. The Osteoarthritis Action Alliance formed an interdisciplinary Secondary Prevention Task Group to develop a consensus on recommendations to provide clinicians with secondary prevention strategies that are intended to reduce the risk of osteoarthritis after a

person has an ACL injury. The group achieved consensus on 15 out of 16 recommendations that address patient education, exercise and rehabilitation, psychological skills training, graded-exposure therapy, cognitive-behavioral counseling (lacked consensus), outcomes to monitor, secondary injury prevention, system-level social support, leveraging technology, and coordinated care models. We hope this statement raises awareness among clinicians and researchers on the importance of taking steps to mitigate the risk of osteoarthritis after an ACL injury. 

Source: Driban JB, Vincent HK, Trojian TH, et al. Preventing Osteoarthritis After an Anterior Cruciate Ligament Injury: An Osteoarthritis Action Alliance Consensus Statement. *J Athlet Train.* 2023;58(3):193–197. doi: 10.4085/1062-6050-0255.22. Used with permission; all rights reserved.

Table. Consensus on Recommendations for Secondary Prevention of Osteoarthritis After an Anterior Cruciate Ligament (ACL) Injury

Recommendation ^a	Support in Final Round, %
Recommendations with consensus (total = 15)	
Provide accessible resources that health care providers can distribute to a patient.	95
Provide educational opportunities to health care professionals regarding how to best educate patients about osteoarthritis prevention.	100
A toolkit should be developed to enable the caregiver to identify a patient's willingness for rehabilitation and the patient's preferred mode of obtaining self-management resources.	91
After an ACL injury or reconstruction, individuals should undergo a supervised, comprehensive, and progressive rehabilitation program to address impairments and neuromuscular deficits, specifically those related to quality of movement, knee range of motion, quadriceps muscle strength/performance, and functional performance, before return to activity.	100
Before full reintegration into a sport, individuals should gradually resume sport-specific training to restore metabolic conditioning, build tolerance to chronic training loads, and adopt desired movement strategies.	100
After an ACL injury, individuals should be encouraged to meet the <i>Physical Activity Guidelines for Americans</i> , 2nd edition. ²⁵	100
Psychological skills training should be considered as part of the short-term and long-term care plans after ACL injury and reconstruction to prevent reinjury, improve overall health and wellness, and encourage engagement in and adherence to physical activity.	86
Graded exposure therapy can be added to therapy programs after ACL injury and reconstruction to overcome fear and prevent reinjury.	91
Patients should be monitored regularly after an ACL injury using a comprehensive approach, including patient-reported outcomes, performance-based outcomes, and measures of disease progression.	100
A multifaceted return-to-sport test battery should be used to inform a shared decision among all stakeholders (eg, patient, parents, health care team, and coach) when determining readiness to return to play.	95
A multifaceted preventive training program should be implemented that includes strategies to improve agility, balance, flexibility, strength, and movement quality in order to reduce the risk of secondary injury.	95
Organizations should optimize socially supportive environments for athletes, service members, employees, providers, families, and caregivers. This can be achieved by recognizing and providing support for psychosocial stressors during the rehabilitation process, including injury-related stigma, uncertainty regarding return to activity, and threats to personal identity.	100
Technology should be used to enable individuals with a knee injury to monitor their physical and psychological well-being over time, access evidence-based educational materials developed specifically for their needs, and engage in health promotion.	100
Practitioners ought to consider both the ethics and effectiveness of how and which technology is adopted for monitoring health outcomes and osteoarthritis prevention after joint injury.	82
An interdisciplinary, coordinated, patient-centered care strategy is recommended to comprehensively address the needs of patients with a history of knee injury.	100
Proposed recommendations lacking consensus ^a	
Cognitive-behavioral counseling should be considered to promote patient engagement with therapies and exercise, prevent reinjury, and improve overall health and wellness after ACL injury or reconstruction.	77

^a Consensus was defined as >80% of voters supporting a recommendation.

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Young Children's Footwear: Importance of Different Features

BY CYLIE M. WILLIAMS, HELEN A. BANWELL, KADE L. PATERSON, KATHERINE GOBBI, SAM BURTON, MATTHEW HILL, EMMA HARBER, AND STEWART C. MORRISON

Purchasing footwear for children can be a concern for parents and caregivers, so clear and credible footwear information is important to help them with these decisions. This is particularly pertinent to the first 6 years, where a child's development and foot growth and change is the greatest.

Footwear research with children under the age of 6, or young children, has focused primarily on design components such as sole flexibility. This is because there is rapid foot change thought to be associated with growth and tissue plasticity in the first 6 years and a theoretical shift to wanting feet to develop in a 'natural' way. Yet no evidence supports or refutes this hypothesis, nor whether influencing foot movement is positive or negative. Notably, recommendations for desirable footwear characteristics are not static across childhood as foot demands change. This means recommendations should be tailored and specific. A small but building pool of evidence of the impact of footwear on children's function means understanding the different beliefs of stakeholders about footwear key features and flexibility is critical for translation into recommendations and to support parents and caregivers in purchasing footwear for their children.

Therefore, the primary aim of this study was to describe how different stakeholders (parents, health professionals and footwear industry representatives) viewed the importance of flexibility of key footwear components. The secondary aim was to understand what other footwear features stakeholders viewed as important for young children.

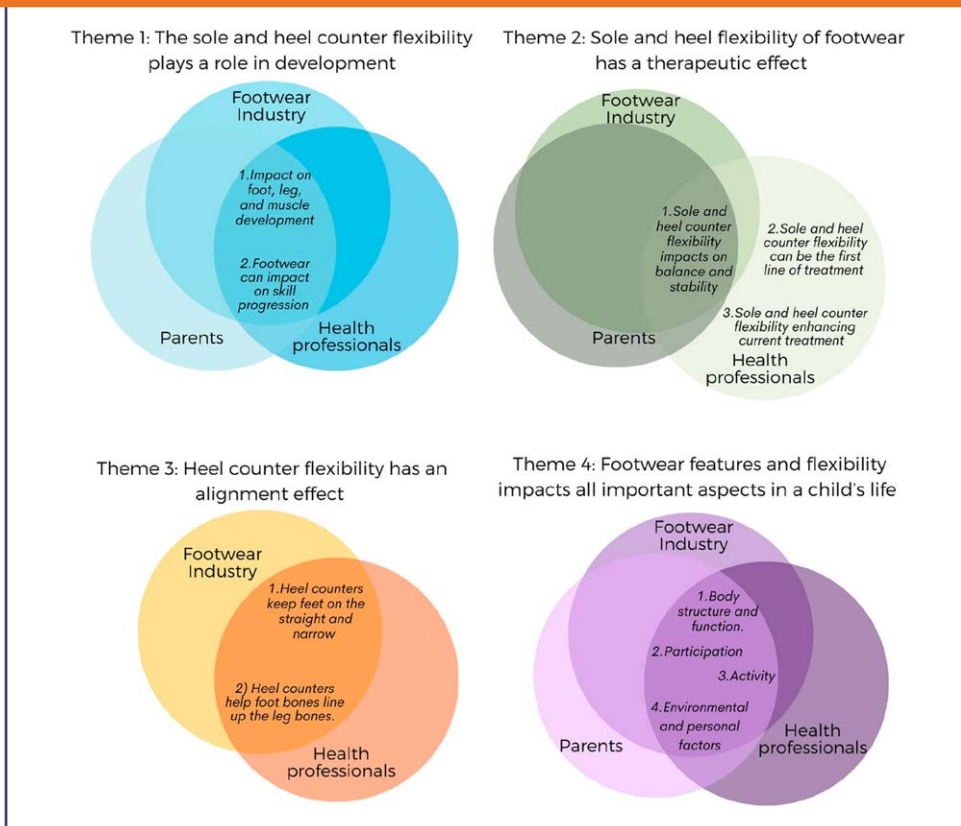


Figure. Four major themes and subordinate themes identified by stakeholder groups

Methods

This qualitative study was nested within an international modified Delphi online survey. There were 159 participants who consented to complete the first round. Participants responded to open-ended questions about footwear component flexibility and asked if and why flexibility in these areas were important. Participants also described any other important footwear features. Inductive thematic analysis was used to generate themes.

Results

There were 121 responses from 3 stakeholder groups including health professionals (n = 90), parents of young children (n = 26), and footwear industry representatives (n = 5). Overarching

themes described by participants included developmental impacts of footwear, therapeutic impact, and how footwear may play a role in function.

Discussion

This study explored the perceptions of flexibility of footwear components and other features determined important by parents, health professionals, and footwear industry representatives. In doing so, the study authors identified differences relevant to stakeholder experience, while determining 4 main themes related to the impact footwear flexibility has on development, desired therapeutic effects, foot and/or leg alignment, and the child's life (including function and participation, activity, and personal choice effects). These are

This article has been excerpted from "Parents, Health Professionals and Footwear Stakeholders' Beliefs on the Importance of Different Features of Young Children's Footwear: A Qualitative Study," from the same authors, which was published in *Journal of Foot & Ankle Research*. 2022;15:73. <https://doi.org/10.1186/s13047-022-00580-1s>. Editing has occurred, including the renumbering or removal of tables and figures, and references have been removed for brevity. Use is per CC Attribution 4.0 International License.

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illustrated in a map of themes, subordinate themes, and the stakeholder groups these themes aligned to (Figure).

Theme 1: Sole and heel counter flexibility plays a role in development

Participants described their beliefs of footwear sole and heel counter flexibility as being strongly linked with various aspects of the child's development. There were 2 subordinate themes: 1) Impact on foot, leg, and muscle development and 2) Footwear can impact on skill progression.

Theme 2: Sole and heel flexibility of footwear has a therapeutic effect

There were 3 subordinate themes arising from participants relating to the perceived therapeutic effect of footwear features including 1) Sole and heel counter flexibility impacts on balance and stability, 2) Sole and heel counter flexibility can be the first line of treatment, and 3) Sole and heel counter flexibility enhancing current treatment.

Theme 3: Heel counter flexibility has an alignment effect

Health professionals and footwear industry stakeholders—but not parents—described beliefs relating to the heel counter flexibility (or firmness) having an alignment effect. There were 2 subordinate themes, primarily relating to the flexibility of the heel counter in having a proximal, local, or distal impact: 1) Heel counters keep feet straight and 2) Heel counters help foot bones line up the leg bones.


Theme 4: Footwear features and flexibility impacts all important aspects in a child's life

All participants provided other comments on footwear features relating broadly to footwear's impact on children's lives. These comments instinctively aligned with the domains of the International Classification of Functioning, Disability and Health. These being a) Body structure and functions, b) Participation, c) Activity, and d) Environmental and personal factors.

As the first exploration of perceptions around footwear flexibility, participant groups frequently identified common outcomes associated with increased and decreased sole and heel

counter stiffness. All stakeholders also expressed the belief that sole firmness needs to meet the developmental requirements of the child, which was noted to change over time and circumstance. It has, however, also highlighted some inconsistencies in perceptions of what footwear flexibility can, or does, impact upon.

Conclusion


There were key differences in how stakeholders viewed footwear and any perceived benefits of footwear components, much of which was not backed with empirical evidence. It was also identified that health professionals are using footwear within treatment recommendations. This work highlights the importance of understanding circumstances in which footwear may have a therapeutic impact or be the first line of treatment for children with complex foot needs. This information is key to developing contemporary footwear recommendations for parents and caregivers. 

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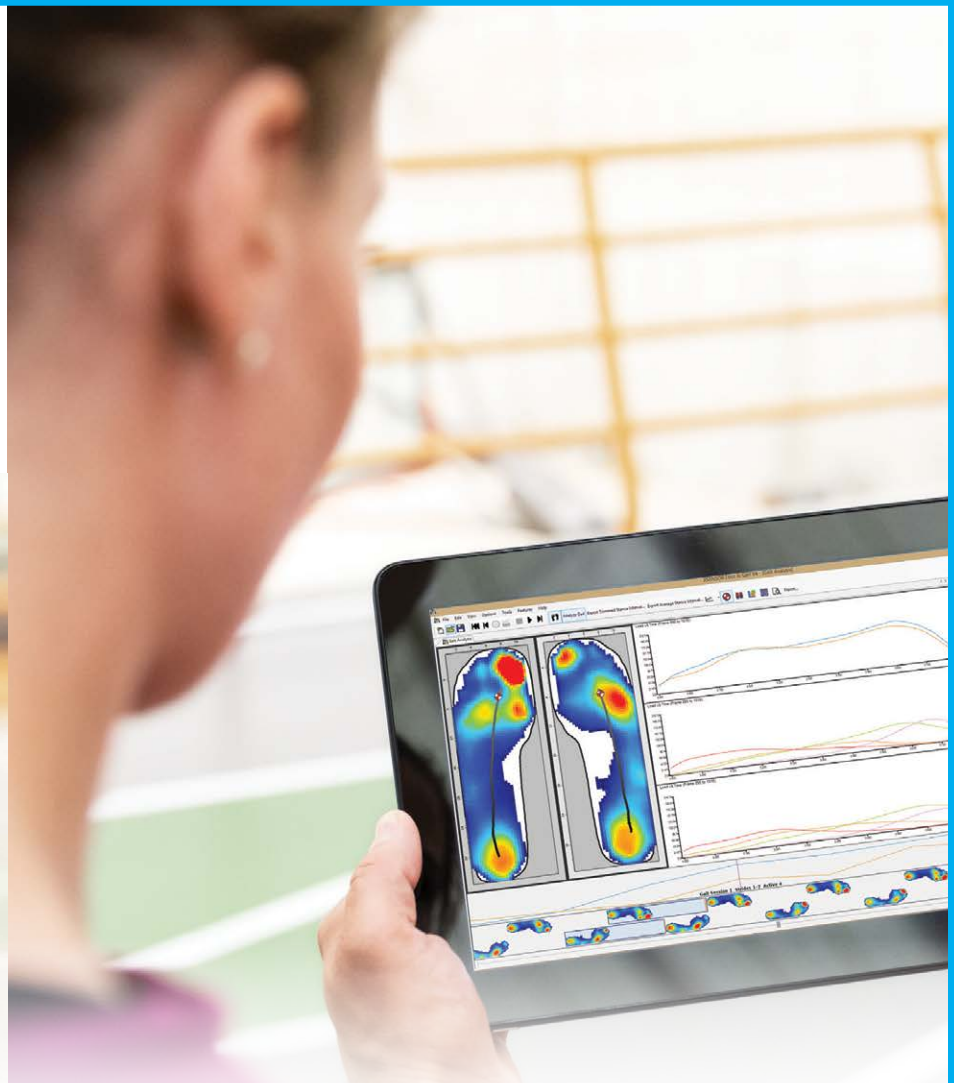
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Rehabilitation Needed for People Wearing DFU Offloading Devices

BY KATHERINE H. JONES, MICHAEL R. BACKHOUSE, AND JULIE BRUCE

Offloading devices improve healing of diabetes-related foot ulcers (DFUs) but they can limit mobilization. Rehabilitation during or after removal of these devices may promote physical activity in a population at risk of poor health outcomes for which inactivity is a reversible risk factor.



Diabetes-related foot ulcers (DFUs) are associated with poor health outcomes, including increased risk of infection, lower limb amputation, and mortality. Recurrence is common, with 40% of people re-ulcerating within a year of healing. The annual healthcare cost of managing DFUs is staggering.

Few studies have examined the broader health-related consequences of prolonged immobilization associated with offloading devices. Furthermore, there is limited guidance for healthcare practitioners on how best to reintroduce physical activity and rehabilitate patients, to support and encourage mobility after removal of offloading devices. This review systematically evaluated the clinical effectiveness of rehabilitation interventions designed to promote or support physical activity in people using offloading devices for DFUs.

Methods

This systematic review examined the effectiveness of rehabilitation interventions to promote physical activity during and/or after wearing an offloading device to treat diabetes-related foot ulcers. Searches using MESH terms and free-text combinations: foot ulcer, diabetic foot, casts, surgical, orthotic devices were applied to MEDLINE, Embase, The Cochrane Library and clinical trial registers for randomized and observational studies published to September 2022. Methodological quality assessment of included studies was undertaken using the Cochrane Risk of Bias (RoB 2.0) and Risk of Bias in Non-randomized studies of Interventions (ROBINS-I) tools. After review, 8 studies were included.

Results

Of the 8 included studies (n = 441 participants), 4 were randomized controlled trials (RCTs) and 4 were prospective cohorts. Total contact casts and removable cast walkers were the most popular devices for ulcer management, used in 5 studies each. Two studies investigated healing sandals and the remaining devices, used in 1 study each, included a half-shoe, shear-reducing walker, cast shoe, prefabricated forefoot-offloading shoe with some other devices not described.

None of the 8 studies delivered any form of structured or unstructured rehabilitation nor prescribed a physical activity intervention at any time during the period that offloading devices were worn, nor after device removal to promote activity or support participants with returning to full mobilization.

This article has been excerpted from "Rehabilitation for People Wearing Offloading Devices for Diabetes-related Foot Ulcers: A Systematic Review and Meta-analyses," J Foot Ankle Res 16, 16 (2023). <https://doi.org/10.1186/s13047-023-00614-2>. Editing has occurred, including the renumbering or removal of tables, and references have been removed for brevity. Use is per CC BY 4.0 International License.

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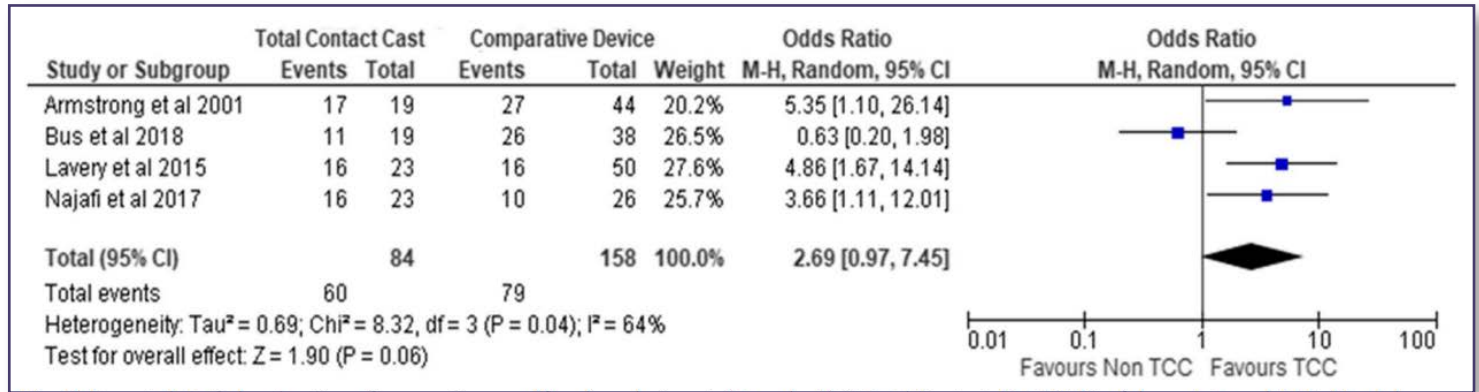


Figure. Forest plot of ulcer healing after wearing an offloading device at 12 weeks. TCC, Total Contact Cast; CI, Confidence Interval; M-H, Mantel Haenszel

All studies reported 1 or more physical activity outcomes, measured objectively using waist or ankle-worn pedometers or wearable sensors attached to clothes or embedded within offloading devices. Activity outcomes were reported as steps over time (hours, days, or weeks), daily stride count (distance of both right and left step), gait speed, percentage of time spent in different postures (sitting, lying, standing, walking) or in postural transition,

e.g., sit-to-stand and stand-to-sit. Activity monitors were used for different purposes, to capture periods of (in)activity, to determine adherence to wearing prescribed offloading devices or to examine ulcer healing by activity status. Two studies reported activity outcomes only; the remaining 6 studies also reported ulcer healing or healing-related outcomes, either as proportion healed, change in size or area, and/or time to healing. None measured

ulcer recurrence. Adherence to the offloading device was reported by 5 studies. Outcomes are reported separately by study design.

RCTs: Physical activity (4 trials; n = 242 participants)

All trials reported that participants wearing total contact casts were less active compared to those wearing other removable devices. Physical activity after 4 to 12 weeks of ulcer treat-

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ment was lower amongst those wearing total contact casts compared to selected other offloading devices (half-shoe, forefoot offloading, healing sandals or removable cast), (SMD -0.45; 95% CI - 0.87 to - 0.04; $P = 0.03$; I2 = 56%; 4 trials, n = 242). Subgroup analysis of difference in physical activity after wearing a total contact cast versus a removable cast walker (2 trials; n = 88) demonstrated higher levels of physical activity in those wearing a removable cast walker after 12 weeks (SMD -0.69; 95% CI - 1.32 to - 0.05; $P = 0.03$; I2 = 53%, n = 88).

RCTs: Ulcer healing (4 trials, n = 242 participants)

Overall, odds of ulcer healing were higher in participants wearing non-removable total contact casts compared to all other removable devices combined after 12 weeks of treatment (OR 2.69; 95% CI 0.97 to 7.45; $P = 0.06$; I2 = 64%; 4 trials, n = 242) (Figure). Subgroup analysis examining differences in ulcer healing between total contact casts versus removable cast walkers also demonstrated greater odds of healing in those wearing a removable cast walker after 20 weeks (OR 3.93; 95% CI - 1.48 to 10.47; $P = 0.006$; I2 = 0%; 2 trials; n = 88).

Observational studies: Physical activity (4 studies; n = 196 participants)


Overall, findings from the observational studies suggested low levels of activity while people wore devices. In a cohort with 13-week follow-up, 40 participants were advised to be completely non-weight-bearing for the first 48 hours after total contact cast application, although most walked on the cast during this early period (median 808 steps over 48 hours). Total step count was low over the remaining observation period (median total 2,083 steps/day). A USA/UK cohort study (n = 79) reported higher daily activity levels in those fitted with a removable cast walker, being active for over 6 hours per day (mean 6.7 hours; SD 3.8) over 6 weeks, with adherence data suggesting the device was worn over half of time while active (59% [SD 22]). In contrast, a cohort study with 20 participants found that even when monitored for only 1 week, adherence to a removable cast walker was poor. Participants were less active while wearing their cast (mean total daily steps 345 [SD 219] vs. 874 [SD 828] when not wearing cast; $P = 0.01$) with only 28% of total daily activity occurring while the cast boot was worn. Similarly, the Jordanian cohort study of 57 participants wearing removable cast walkers also reported poor adherence of 34% of activity time, when monitored for only 1 week.

Observational Studies: Ulcer healing (2 studies; n = 119 participants)

In the multicenter USA/UK cohort, only 19/79 (24%) ulcers healed over 6 weeks, although mean ulcer size reduced from 230mm² to 106mm² ($P = 0.001$). Ulcer healing was associated with better adherence to the offloading device although sample sizes were too small for meaningful analyses. Ulcer healing was higher in the cohort study with longer follow-up, with 32/40 (80%) healed after 13 weeks of total contact cast treatment.

Conclusion

Clinical experts have recently challenged traditional wisdom that activity should be limited during DFU offloading, suggesting that prescribed inactivity may be detrimental to health. Biological tissues respond to the load placed upon them, increasing or decreasing tolerance to stress depending on load. Reduced mechanical loading on the plantar surface of the foot may decrease the ability of tissues to withstand future stress, thereby making tissues more vulnerable to future injury. Recent epidemiological data appears to provide some support for this theory: sedentary time was the strongest predictor of ulcer development and had greater prognostic ability than traditionally recognized risk factors, such as ischemia and neuropathy. International guidelines now recommend that weight-bearing activity can be carefully encouraged in people with diabetic peripheral neuropathy.

Despite the entirely plausible hypothesis that rehabilitation may benefit patients with DFUs, the main finding of this systematic review was that there was no evidence to conclude whether rehabilitation is safe, or clinically or cost-effective. This is a missed opportunity to improve outcomes in people undergoing active ulcer treatment. There is clinical uncertainty and given the scale of the clinical problem, further research is urgently needed to develop and test a targeted rehabilitation package within a high quality, well-designed clinical trial. 

...sedentary time was the strongest predictor of ulcer development and had greater prognostic ability than traditionally recognized risk factors, such as ischemia and neuropathy.

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Nanoparticles and Electrospinning – Emerging Technologies in Wound Healing: A Review

BY JAMES MCGUIRE DPM, LPT, LPED, AND AVNEE J. PATEL, DPM

Chronic wounds affect millions of patients worldwide making wound care an integral part of healthcare. Such wounds pose a significant financial burden upon both patients and the health-care industry and negatively impact the patient's overall quality of life. For this reason, continued innovation within the field of wound dressings and dynamic wound treatment options is of utmost importance. Nanoparticles are a developing component of wound treatment largely in part due to their biocompatibility, ability to function in many ways and environments, and positive impact on chronic wound healing. Here, we review various nanomaterials, their function in wound healing and action as delivery vehicles for actives and look closer at electrospinning – a method of delivering nanoparticles to a wound bed.

Wound Healing Review

Due to the ever-increasing number of patients with wounds, wound healing has grown into a multidimensional subdivision of medicine. While for centuries the majority of wounds were acute in nature, chronic wounds have become a major part of modern healthcare, making the continued investigation into optimizing treatment of chronic wounds paramount.

Poor healing environment, concomitant microbial infection and prolonged inflammation complicate wound healing potential.¹ While acute wounds heal without incident in the expected period of 8-12 weeks, chronic wounds heal slowly, are often associated with underlying disease, and are complicated by other factors such as microbial infection.² The implication of poor wound healing is made abundantly clear in podiatric wound care where poor vascular health, uncontrolled diabetes, neuropathy, and repetitive injury to the lower extremity often result in non-healing or delayed-healing wounds.



Traditional dressings primarily function as a passive part of the wound healing process – preventing continued abrasion or trauma to the wound site or maintaining some degree of moisture as seen with petroleum-impregnated gauze. Alone, though, they neither maintain nor encourage the wound healing cascade, functioning instead to protect an open wound from worsening, but minimally contributing to its improvement. In this paper, we discuss novel materials available for wound treatment, applications to wound healing, and explore electrospinning as a method of wound dressing.

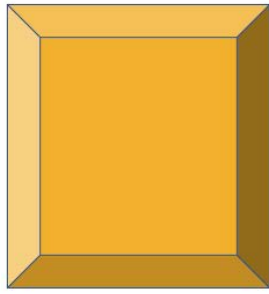
Physiology of Wound Healing and Podiatric Applications

Wound healing has been well-described as having 4 main stages: hemostasis, inflammation, proliferation, and remodeling.^{1,2,4,6} While acute

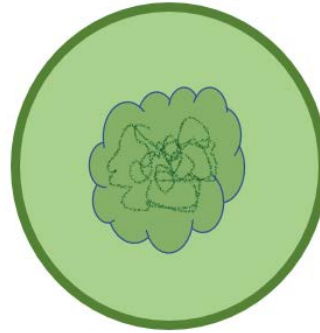
wounds progress through these stages at an expected rate, recruiting the necessary cells, chemokines, and growth factors in a highly regulated fashion, chronic wounds have been described as becoming stalled in the inflammatory stage. Acute wounds heal to produce an ordered extracellular matrix (ECM) and the matrix develops at a rate that exceeds the rate of tissue breakdown at the wound site leading to complete remodeling of the wound.¹ In the setting of a persistent inflammatory response, phenotypically abnormal inflammatory infiltrate disrupts the coordinated cellular response at the wound site resulting in a chronic, non-healing wound.⁴

Integral to podiatric wound healing is avoiding amputation, of which 85% are preceded by non-healing wounds such as diabetic ulcers, venous ulcers, and pressure ulcers.^{2,5,7} Biofilms, which cause persistent inflammation and worsen

Figure 1.

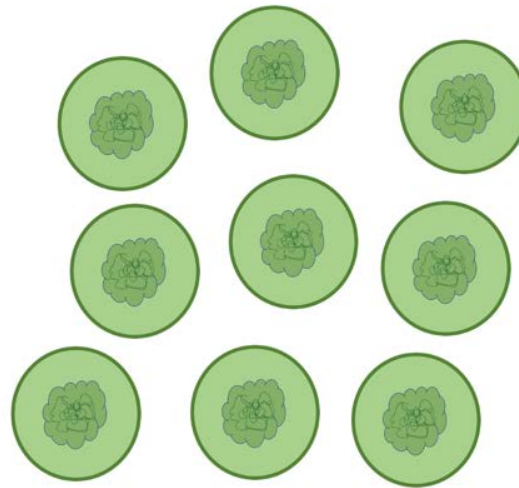
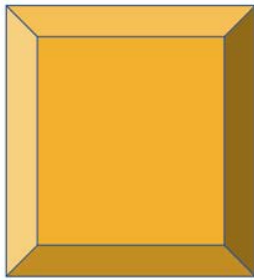


Active Agent



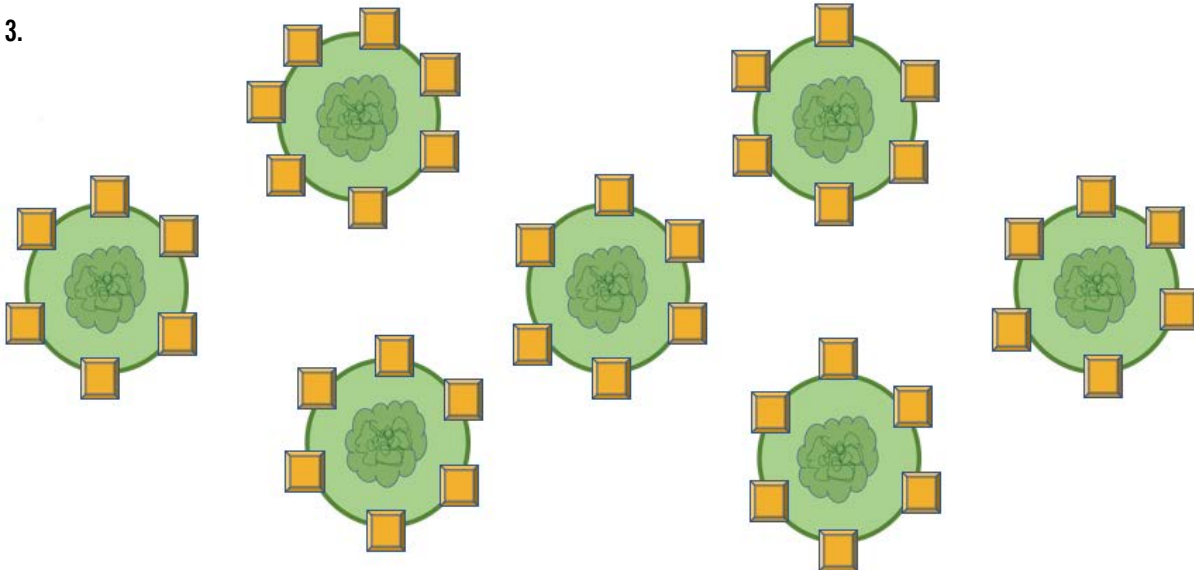
Bacterium

Figure 2.



Large Molecule Size of Active Agent

Figure 3.



Small Molecule Size of a Nanoparticle Active Agent

The small molecule size of the active agent, in the case of nanoparticles, allows for it to contact and react with the bacterial cell wall.

infection risk, are a common complicating factor of chronic wounds which adds to their delayed healing, especially in those who are immunocompromised.^{7,8} Nanoparticle technology possesses the capability to function as an active, biocompatible, non-irritating dressing that is stage-specific and prevents biofilm formation thereby supporting a normal wound healing cascade.^{2,3,9}

Characteristics of the Ideal Wound Dressing

In the podiatric setting, wounds often possess irregular borders and varying depths making active, moldable dressings integral to facilitating healing. Current wound treatment protocols often involve traumatic, painful debridement of the wound bed to granular tissue and application of dressings which often do not conform to the wound bed and border. This may lead to patient discomfort with the dressing, slippage of the dressing, and the requirement for frequent changes. This introduces a significant burden on not only the patient and family, but also the healthcare system with the increased cost of home nursing and additional office visits for dressing changes and follow-up. To promote atraumatic, efficient wound healing, the ideal wound dressing should conform to the wound bed and require infrequent changes.¹⁰ Additionally, the dressing's ability to promote tissue and ECM proliferation is imperative.¹¹

As previously mentioned, the bioburden carried by chronic wounds in the form of biofilms covering the wound bed introduces an additional variable necessitating consideration. In chronic wounds, there is often an increase in exudate comprised of increased levels of inflammatory cells and proteins indicative of infection.⁸ Dressings that maintain a moist wound bed are sufficient for sterile wounds, however necrotic wounds and those which carry a bioburden that is inconsistent with normal dermal flora are best served with active, functional dressings.¹¹ Nanoparticles and other emerging wound healing technologies support the delivery of actives, such as antibiotics, anti-inflammatories, and growth factors, to the wound bed, thus increasing the efficiency and efficacy of wound dressings.

AuNPs are chemically stable, biodegradable, and biocompatible, making them ideal additions to other treatments used for the wound bed.

Wound Treatment Materials, Podiatric Applications, and Mechanisms of Antimicrobial Activity

There is no defined gold standard protocol for the treatment of acute and chronic wounds. There are, however, many effective conventional and adjunctive treatment options including hyperbaric oxygen therapy, negative pressure wound therapy, advanced wound dressings, and new revascularization surgeries which aim to optimize the wound environment in an effort to promote healing.⁵ Key complicating factors for these methods warrant consideration, including but not limited to unaddressed systemic diseases, nutrition, access to available dressings or therapies, insurance coverage, and patient adherence issues – all of which ultimately delay wound healing.^{2,5} Especially in podiatric wound care, where persistent chronic wounds often plague patients with key comorbidities, such as diabetes and vascular disease, development of a multispecialty, dynamic, and targeted wound treatment plan could prove invaluable.

External pathogenic contamination of chronic wounds, commonly polymicrobial in nature, necessitates the use of an aggressive wound hygiene program and antimicrobial dressings. Wound dressings including gold, zinc, and silver have been well-studied and shown to have antimicrobial properties.^{1,2,5,6,11} Conventional antimicrobial agents, such as oral and topical antibiotics, pose contraindications and complications in the setting of chronic wounds. Specifically, bacterial resistance due to antibiotic-overuse, dermatitis, and other adverse cutaneous reactions

to topical agents could pose an issue. Antimicrobial nanoparticles could circumvent these potential complications by delivering bioactives on biologically inert molecules.¹¹

Nanomaterials in Wound Healing

Nanomaterials can target specific stages in the wound healing cascade, have antimicrobial and anti-inflammatory properties, and promote angiogenesis – making them a novel technology to be considered in the world of wound healing.^{1,3} Nanoparticles are up to two-times more potent than pure ionic forms, largely in part due to their high surface-area-to-volume ratio allowing for greater elution of bioactive compounds. Additionally, their small size allows them to better attach to and infiltrate the target cell walls of bacteria. In the setting of biofilms, this may allow for more efficient targeting of the involved bacteria. Importantly, molecular differences exist, underscoring the importance in molecule selection in the treatment of individual wounds.

Gold

Gold nanoparticles (AuNPs) are well-studied and have many applications to wound healing, largely in part due to their bacteriostatic and bactericidal properties.^{3,6,11} Additionally, they have been shown to have antioxidant properties.^{11,12} AuNPs impart their bacteriostatic activity by binding bacterial DNA and inhibiting DNA uncoiling to ultimately decrease bacterial DNA replication; they convey their bactericidal activity by directly targeting bacterial cell walls, making it especially helpful in locally targeting multi-drug resistant bacteria.¹¹ In the setting of chronic wounds, which are commonly seen in patients with underlying pathology, directed local antimicrobial therapy to the affected sites may be the preference, considering the physiological toll systemic antimicrobial treatments often have. In addition, AuNPs have been shown to have a stimulatory effect on angiogenesis and epithelialization leading to faster wound closure.^{1,6,11-13}

Among the keys to more efficient wound healing are targeted therapies such as AuNPs. In a rat model, full thickness excisional wounds

showed decreased inflammatory cells and increased fibroblasts in the granular tissue of the wound bed after AuNP and silver nanoparticle (AgNP) topical application.¹³ In this example, AuNPs and AgNPs directly acted upon the inflammatory and proliferative phases of the wound healing cascade to optimize and accelerate the healing process. Complete re-epithelialization and development of a collagen scaffold was seen in 14 days with topical application of AuNPs.¹³

AuNPs are chemically stable, biodegradable, and biocompatible, making them ideal additions to other treatments used for the wound bed.^{3,11,14} The intrinsic anti-inflammatory and antioxidant capabilities of AuNPs may be enhanced by combination with anti-inflammatory or antioxidant medications to specifically target the angiogenic and inflammatory phases of the wound healing cascade.³ In doing so, chemical and pharmacotherapeutic modulators are directly targeted to the wound bed to elicit greater affect. For example, when conjugated with AuNPs, vancomycin had greater activity against vancomycin-resistant enterococcus and gram-negative bacteria.¹⁴ Reactive oxygen species which potentiate inflammation and lead to delayed wound healing have also been treated with AuNPs.¹² In combination with photo biomodulation therapy (PBMT), a light therapy that improves cell migration thereby promoting actions such as epithelialization and angiogenesis, AuNPs were shown to efficiently target inflammation at the wound bed to promote augmented wound healing.¹²

Zinc

Zinc is an essential mineral metal oxide element. Zinc nanoparticles (ZnNPs) are commonly used in skin creams and antiseptic topicals primarily due to anti-inflammatory properties, biocompatibility, hemostatic ability, and the element's mechanical strength and tensile properties.^{1,6,15} Zinc induces bactericidal activity by disrupting cell membrane activity and causing bacterial cell death after adsorption into the bacterial cytoplasm.^{1,11} In addition to its bactericidal activity, when incorporated into hydrogel-based dressings, it may be used as a resorbable template to induce keratinocyte migration to encourage epithelialization at the wound bed.^{6,11,15} In the

setting of chronic wounds, where the wound bed is sequestered in a constant inflammatory cycle, a topical dressing that promotes epithelialization is paramount. For this reason, it is important to note that there is toxicity associated with ZnNPs – namely that it produces reactive oxygen species to damage bacterial cell membranes. However, this is also known to be associated with keratinocyte dysfunction which may potentiate the inflammatory cycle at the wound bed.^{1,11} ZnNPs have been found to have size-dependent bactericidal activity at the wound bed surface, with 8nm showing greater than 95% of *S. aureus* growth inhibition as compared to 50nm showing 40% bactericidal activity.¹ This should be taken into consideration when embedding ZnNPs in wound dressings.

Embedded ZnNPs have properties which promote wound healing. As a part of hydrogels, collagen dressings, and cellulose sheets, ZnNPs have been shown to exhibit antibacterial activity and promote tissue regeneration.¹ Additionally, ZnNPs have been shown to be compatible with other materials commonly seen in wound dressings. Balaure et al explored combining collagen, one of the most abundant extracellular matrix proteins, with Zinc to exploit its antibacterial activity in combination with the ability of collagen to act as a wound bed scaffold.¹⁵ They found that 1% orange essential oil functionalized zinc oxide NPs (ZnO@PorT) which were not only biocompatible, but also accelerated wound healing and prevented bacterial bioload at the wound bed of third degree burns.^{11,15} Similarly, Koga et al explored crosslinking an alginate-alo vera gel with ZnNPs and found that although this gel did

not show accelerated healing, there was greater degree of exudate absorption.¹⁶ This underscores the versatility of ZnNPs in wound dressing technology and its ability to have stage-specific applications to the wound healing cascade.

Silica

Silica, an inorganic compound, is known for having highly specific surface area and functional capabilities. It has been described as biocompatible and cytocompatible, and has the ability to enhance cell proliferation.^{3,17-19} Additionally, silica nanoparticles (SiNPs) can be easily produced, which is particularly important considering the significant financial burden wound care presents to many healthcare systems.¹⁹ Silica does not innately harbor wound healing capacity; however, its ability to function as a scaffold allows it to have diverse applications to wound healing.¹⁷ In combination with platelet lysate (PL), porous silicon microparticles (PSi) were examined for their ability to promote wound healing and in vitro assays found PL-modified PSi induced a significant proliferative effect when compared to positive and negative controls.¹⁸ Similarly, it has been shown that when PSi are coated with biopolymers, such as chitosan or hyaluronic acid, they may be loaded with antibiotics such as vancomycin to provide a local controlled release of the drug.^{18,20,21} The local delivery of drugs is key to reduction of multi-drug resistance in bacteria and decreasing the systemic burden of oral medications on patients, especially in the setting of chronic wounds and those with active infection in addition to considerable comorbidities.

Silver, a common component of commercial wound dressings, has been shown to be stable in combination with silica, with silica acting as a scaffold for silver, forming Ag-MSNs (disulfide bond-bridged nanosilver-decorated mesoporous silica nanoparticles).¹⁷ Ag-MSNs showed both antibacterial and adhesive activities and increased the rate and efficiency of wound closure compared to sutures with little local and systemic toxicity.¹⁷ In a nanoparticle solution, silica functions as an adhesive by forming a hydrogel which functions alongside tissues without changing in permeability or rigidity, allowing it to conform to the wound bed.²² This nano-adhesive Ag-MSN

As a part of hydrogels, collagen dressings, and cellulose sheets, ZnNPs have been shown to exhibit antibacterial activity and promote tissue regeneration.

Continued on page 36

Ag-MSNs showed both antibacterial and adhesive activities and increased the rate and efficiency of wound closure compared to sutures with little local and systemic toxicity.

system showed antibacterial activity against *S. aureus* and *E. coli*, two common flora present on chronic wound beds and were shown to act as an effective and efficient system to close wound edges.^{17,22}

SiNPs have been shown to act as suitable scaffolds for the delivery of other nanoparticles and drugs, however it is important to note that particle size and surface chemistry determined cytotoxicity.^{18,21} As a drug delivery system, SiNPs have been studied extensively in systemic chemotherapeutic transport. Transcutaneously, SiNPs were shown to penetrate the epidermis without causing skin damage or organ toxicity.²¹ Despite silica adhesion strength increasing with increase in particle size, wound bed size and surface area should be taken into account because an increase in surface area of SiNPs have been found to be generally more cytotoxic.^{21,22} Considering the versatility of the compound and its ability to be modified to specifically target flora and promote epithelialization, and with appropriate consideration to their size, SiNPs could be especially beneficial to those patients suffering from chronic wounds which carry a bioload.^{18,19} (18,19).

Copper

Copper is an essential element which is known to be widely bactericidal.^{1,6,23,24} Additionally, it is known to promote angiogenesis, fibroblast proliferation, collagen formation, and ECM cross-linking.^{24,25} In studies of copper-impregnated wound dressings, six days after application of the sterile dressing, wound size was measured to be significantly smaller compared to the control group. There was an increase in proangiogenic factors seen at one day after dressing application and angiogenic effects, including increased oxygenation of the tissues and decreased inflammation of the wound bed, were observed.^{24,25} This

is consistent with the ability of copper ions to increase gene expression to promote angiogenesis and ultimately, wound closure. CuNPs have been shown to have a high rate of absorption, adsorption, penetration, and availability and have wide activity to microbes commonly seen in the setting of diabetic ulcers, such as *S. aureus*, *E. coli* and *P. aeruginosa*.^{6,23,26,27} Additionally, CuNPs and topical copper applications are known to be safe to humans. CuNPs exert their bactericidal properties by releasing ionic copper which disrupts the bacterial cell membrane causing cytoplasmic degradation and bacterial cell death.^{1,26,27}

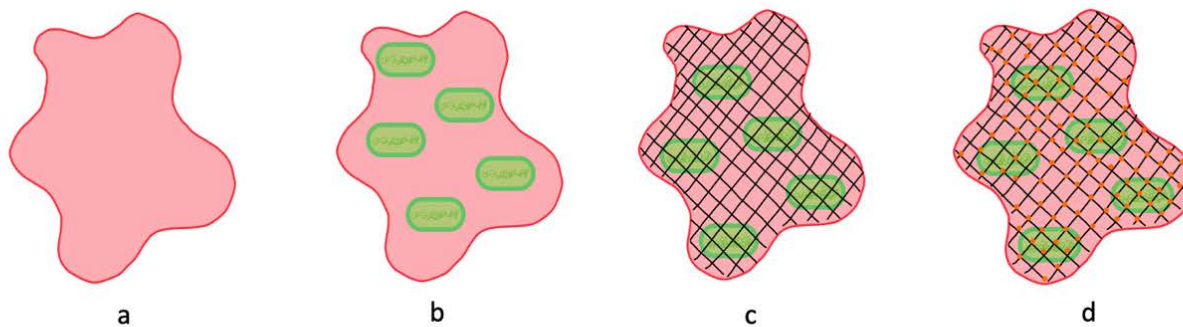
Copper also harbors the ability to act as a scaffold, allowing it to exert dual action with other active molecules. While typically unstable in physiologic proteins, copper metal-organic frameworks (Cu-MOFs) allow it to perform in combination with other molecules.^{28,29} In combination with nitrous oxide (NO), a Cu-MOF was electrospun to contain a NO core resulting in a delayed CuNP release over an extended period of time.³⁰ This presents an alternate approach to wound treatment – rather than stage-specific nanoparticle action, nanoparticles may sustain ion release over time thereby extending their action. This is especially important in the setting of biofilms, where bacteria in the colony may be present in variable stages of cell division. It was seen that MRSA and *E. coli* biofilm cells were almost completely dead four days after exposure to CuNPs and *S. aureus* biofilm was reduced by 50% after 48 hours.^{23,27} In combination, CuNP's many traits – biocompatibility and bactericidal action, innate ability to promote wound healing by stimulating anti-inflammatory effects and angiogenesis, and ability to act as a scaffold for other actives with a delayed release of ions – could be beneficial in the treatment of chronic and infected wounds.

Silver

There are commercial silver-based wound dressings which have been shown to have a positive impact on wound healing.^{3,11} In addition to their bactericidal properties, AgNPs allow for a higher surface area-to-volume ratio compared to topical silver compounds.^{1-3,11,31} This accommodates for innate silver cytotoxicity, a key consideration in its use, by requiring a lower concentration of silver to be used to augment wound healing.^{1,3,11} Silver creates action by promoting granulation tissue, collagen deposition, and wound contractility by differentiation of myofibroblasts from normal fibroblasts.^{2,6,11} Silver exercises its antimicrobial activity by deactivating respiratory enzymes after uptake into cells to generate reactive oxygen species to disrupt cellular processes.³¹ This ultimately controls biofilm growth.³² In combination with pharmaceutical antimicrobial agents, silver is able to exert additional antimicrobial activity as evidenced by accelerated healing seen in two different studies when in combination with tetracyclines and gentamicin.^{6,11}

Inflammation is a key component of the wound healing cycle – chronic wounds are described as being caught in this phase. Silver is a key modulator of anti-inflammatory cytokines in addition to retaining antimicrobial activity.^{6,11} Silver has been shown to have activity against multi-drug resistant bacteria, making it a valuable wound care treatment in the setting of chronic wounds where patients have often exhausted conventional antibiotic treatments.^{2,6} Additionally, AgNPs have activity as part of dressings and dermal substitutes.³³ In a murine study looking at in vivo infection rates, 72 hours after application of the AgNP-loaded dressing, there was a decrease in bioburden to the wound.³⁴ As previously stated, this was similarly seen in a rat model, where

Figure 4.



- a) Irregularly-shaped wound
- b) Bioburden on wound surface
- c) Electrospun nanofiber scaffold molds to wound surface and takes into consideration irregular wound borders
- d) Electrospun nanofiber matrix serves as a scaffold for active nanoparticles to take antimicrobial action at the bacterial cell surface

there was a decrease in inflammatory cells and increased fibroblast differentiation in granular wound beds after AgNPs topical application.^{13,34}

In addition to the ability of AgNPs to be transferred to dressing materials without requiring chemical processing, silver may be combined with materials such as AgNO₃ and reduced during the electrospinning process to AgNPs to have the aforementioned antimicrobial activity.³⁵ AgNP-based dressings have few complications when applied to the wound base for extended periods of time, and showed compatibility with collagen scaffold.^{11,33} Similarly, on a copper-based framework, sustained release of silver ions generated reactive oxygen species leading to enhanced wound healing.²⁹

Electrospinning

Electrospinning is a technique that permits control over the application of nanomaterials during the production of scaffolds, allowing them to retain properties similar to the extracellular matrix.^{3,9,11} It is a simple, cost-effective, flexible, and modifiable method of developing wound dressings from both synthetic and natural polymer solutions.³⁶⁻³⁸ Electrospinning is performed by an electrical potential being applied to a polymer liquid. At a critical voltage, the fluid is ejected and solvent evaporates leaving fibers ranging from 2nm to several micrometers in diameter. These fibers are then collected to form the electrospun nanofiber scaffolding used in active therapeutic dressings.³⁶⁻⁴⁰ As previously mentioned, in addition to being compatible with

the wound bed surface, electrospun dressings are also versatile, allowing bioactive molecules and therapeutic agents to be incorporated into the nanofiber matrix.

Bioactive molecules and other therapeutic agents, such as antibiotics, may be combined with polymers by blending, surface modification, coaxial spinning, and emulsion processing.^{36,41} Blending requires that the drug is dissolved or dispersed in the polymer solution which encapsulates the bioactive therapeutic agent. The emulsion is then processed to develop the electrospun nanofiber. Depending on the interaction between and polarity of the bioactive agent and the polymer in solution, the active agent may be dispersed through the polymer or localized to the periphery resulting in a slow release or burst release, respectively.³⁶ Surface modification involves the bioactive agent being adhered to the fiber surface, which makes it biochemically and structurally like native tissue and allows for a slow, controlled delivery. This is ideal in the setting of growth factors or other agents which act at stage-specific timepoints necessitating pulsed release.³⁶ Co-axial electrospinning produces fibers with a core-shell appearance; the core is composed of the therapeutic agent and the shell is the polymeric matrix.^{36,41} This is especially beneficial in cases where sustained, local delivery of a therapeutic agent is desired; however, generating these complex structures poses a challenge. Emulsion electrospinning has the therapeutic agent and polymer emulsified together and electrospun in conjunction as compared to alone

in co-axial electrospinning.^{36,41}

An ideal drug delivery system should enable the therapeutic agent to have action and enhance its ability to act at the wound bed. Nanofibers have been successfully used as a drug cargo delivery vehicle for therapeutic agents such as antibiotics, metal nanoparticles, carbon materials, peptides, and natural extracts.⁴² Electrospun scaffolds are versatile – their innately small structure mimics the structure of the extracellular matrix and ability to be combined with bioactives augments their action at the wound bed.^{37,38,40} Electrospun nanofibers have select features which make them effective scaffolds for therapeutic agents including high surface area, high porosity, small pore size, morphological similarity to the extracellular matrix, and mechanical strength allowing for ease of handling.^{3,9,41,43}

Electrospinning creates porous polymeric nanofibers which promote fibroblast adherence in wounds.^{3,11,39,40,43} One key advantage of electrospun dressings is the application process. Electrospun dressings are placed directly on the wound bed without having to touch the wound bed. Studies in porcine and rat models have found that, in combination with active nanomaterials, such as silver, copper and gold, electrospun dressings offer low cytotoxicity, antibacterial activity, and reduced inflammation, which together promote wound healing.^{11,14} Electrospun dressings may also be used as a network in which cellular markers are encapsulated to act at the wound bed. One such example is growth factors.⁴⁴

Lai et al investigated a staged release of

Continued on page 39

growth factors by an electrospun nanofiber dressing in the management of chronic wounds.⁴⁴ A collagen-hyaluronic acid skin equivalent was designed to release various growth factors to promote epithelialization and re-vascularization of the wound bed. There was slow controlled release over one month which saw accelerated wound closure and more histologically normal collagen deposition. Leung et al confirmed that the ability to control the rate of drug release from a wound dressing by manipulating the release mechanisms allowed electrospun nanotechnology to play an active role in the wound healing process.⁹ Application of electrospun dressings in cases of chronic dermal ulcerations confirmed that nanofiber scaffold dressings can behave as both therapeutic and bioactive delivery vehicles.

As previously discussed, metal and metal oxide nanoparticles harbor the ability to disrupt bacterial cell membranes and ultimately cellular processes by generating reactive oxygen species. There is also some evidence to support loading these metal nanoparticles on to electrospun scaffolds as a means of delivery to the wound surface.⁴¹ There are biocompatible natural and synthetic polymers which are often combined to draw upon their individual benefits.^{3,9,38} With such actives in addition to the innate benefits of electrospun dressings, these combined dressings have antimicrobial effects, promote wound healing, induce angiogenesis, re-epithelialize, and promote granular tissue and collagen synthesis – all of which are key to the normal progression of wound healing and inhibiting wounds from being confined to the inflammatory stage of wound healing leading to chronicity.^{3,9,41,43,44}

Natural polymers are derived from sources, such as silk fibroin, collagen, and polysaccharides found in the extracellular matrix of cells. Silk fibroin is a natural biopolymer fiber from silk-worms and spiders with a repetitive amino acid sequence which allows it to form a biomaterial matrix.^{2,3,38} Wang et al investigated nerve regeneration using an electrospun silk scaffold. Their assessment of the scaffold's ability to mimic a native ECM and provide support for regeneration of cells showed that silk fibers are biocompatible, biodegradable, and result in a low inflammatory

response.^{2,45} The scaffold was also shown to have high levels of fibroblast cell attachment and to promote cell growth when functioning as a peripheral nerve graft.⁴⁵ However, as a wound dressing, it is important to recognize that the solvent in which the silk is constituted during the electrospinning process is key to its success as a scaffold.^{38,45} For example, a previous study by the same authors found that in combination with a lactic acid backbone, silk was successfully electrospun into a matrix.^{45,46} When electrospun, nanofibers increase total surface area of an active molecule and allow for contact guidance for cell migration. In the setting of tissue regeneration, silk scaffolds have shown promising results in neural tissue, vascular tissue and epidermal tissue regeneration making it an ideal candidate in the dressing of chronic wounds.³⁸ The unique properties of biocompatibility, biodegradability, flexibility, adherence, and absorption of exudates with minimal inflammatory reaction make silk a very promising material for wound dressings.²

Soy is a naturally derived plant-based biomaterial which has been successfully electrospun to form a functional scaffold. Soy has many reactive groups making it a strong candidate for chemical, physical, and enzymatic modification able to act at the wound bed.³⁷ In a pig model, full thickness excisional wounds showed signs of re-epithelialization compared to the control group at two weeks after application of the electrospun soy scaffold dressing.⁴⁷ Importantly, especially in the setting of chronic wounds, there was a decrease in the number of inflammatory cells noted. Dermal appendages, such as sweat glands and hair follicles, were present in the soy-treated wounds and absent in the control on histological exam, demonstrating that although electrospun soy scaffold did not accelerate wound healing, the quality of wound healing was augmented.⁴⁷

In a comparison of polyethylene oxide (PEO) emulsions versus soy protein isolate emulsions, it was found that depending on the concentration of the mixture, the ability to be successfully electrospun changed.³⁷ Soy + PEO scaffold showed significant upregulation in markers indicative of ECM deposition and remodeling.⁴⁸ The scaffolding supported fibroblast

adhesion, spread, growth, and proliferation in vitro.^{47,48} This study confirmed that trace amounts of PEO allowed for soy proteins to be successfully electrospun into a functional hydrolysis-resistant scaffold that supports wound bed healing and skin regeneration.^{37,48}


Applications of Nanomaterials and Electrospinning

Nanoparticle-based treatments and therapies have been of recent interest largely due to their versatility. The ability of electrospun fiber dressings to be loaded with therapeutic nanoparticles allows them to function as a bioactive dressing tailored to address the deficiencies inherent in chronic wounds.⁹ There is a growing list of multi-drug resistant bacteria, and a high percentage of chronic wounds have a biofilm where resistance is transferred from bacteria to bacteria.⁵² The need for multifunctional dressings designed to target biofilms and reduce the formation of surface bioburden is great.

During production of nanoparticle-loaded electrospun fiber scaffold dressings a key consideration is the mechanism by which the therapeutic agent is released. Modifications to the electrospinning process to slow or pulse the release of the bioactive agents were previously mentioned. For this reason, it is imperative that the type, properties, and composition of the polymer used for electrospinning be considered when determining the active agent with which to combine its action.⁵⁰ It is also important to note the effect of the nanoparticle upon healthy cells. While it is advantageous that many metallic nanoparticles induce bacterial cell death by generating reactive oxygen species to interfere with normal cellular processes, the effect upon surrounding healthy cells cannot be ignored. Ultimately, the goal of active dressings – in this case, bioactive-loaded electrospun nanofiber dressings – is to promote healing of the wound, highlighting the importance of understanding the toxicology associated with these novel materials. Of importance when considering these for use are the nanoparticle's size, surface chemistry, surface physiology, the dose which is present in or on the dressing, the degree to

which it produces free radicals, and its chemical components.⁵¹

Summary

Chronic wounds impose a heavy burden on our healthcare system and in concert with the bioburden these wounds carry, treatment proves challenging and expensive.⁵¹ The goal in treatment with nanoparticles, nanocomposites, coatings, and scaffolds is to provide a viable matrix for tissue reconstruction, increase the selectivity and efficacy of antimicrobials utilized, and to decrease the amount of patient exposure to strong, sometimes toxic anti-microbials.^{11,40} The ability to deliver therapeutic agents directly to the wound surface, reduce the concern for systemic exposure and toxicity, and promote the rate at which wounds epithelialize are all enhanced with the use of nanomaterials whether in particle or fiber form. Novel treatment options using bioactive therapeutic nanomaterials and electrospun nanofiber scaffolds are increasing in use and present a necessary and beneficial solution to the problems of toxicity and overall effectiveness. 

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Fireworks-Related Lower Extremity Injuries Treated at United States Emergency Departments

BY MATHIAS B. FORRESTER, BS

Background: Fireworks are commonly used in the United States (US) for festive or recreational purposes. Consumer fireworks sales have increased over the last several decades. Injuries, some of which may be potentially serious, can occur to both the individual using the fireworks and spectators or bystanders. This study characterized fireworks-related lower extremity injuries treated at US emergency departments (EDs).

Methods: An analysis was performed of fireworks-related lower extremity injuries using data from the National Electronic Injury Surveillance System (NEISS) of the US Consumer Product Safety Commission (CPSC) during 2000-2021.

Results: An estimated 33,770 fireworks-related lower extremity injuries treated at US hospital EDs during 2000-2021 were identified, representing 15.0% of the total estimated fireworks-related injuries. While the annual estimated number of injuries ranged between 855 and 1,694 (mean 1,343) during 2000-2015, the estimated annual number of injuries was higher during 2016-2021, ranging between 1,856 and 2,347 (mean 2,048). 87.9% of the estimated injuries were treated during June-August with 78.2% treated during July. Patients age 0-19 years accounted for 48.6% of the estimated injuries; 56.0% of the patients were male. Thermal burns were reported in 58.8% of the estimated injuries, and 91.4% of the patients were treated or examined at the ED and released.

Conclusions: The number of fireworks-related lower extremity injuries have increased during 2016-2021. The majority of these injuries were treated during June-August, particularly July, and most injuries involved children and males. The majority of the injuries were thermal burns, and most patients were treated or examined at the ED and released.



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Fireworks are devices designed to produce visible or audible effects by combustion, deflagration, or detonation.¹ They typically consist of a casing filled with combustible material; the devices can be handheld (e.g., sparklers) or can be detonated from a distance.² Fireworks are commonly used in the United States (US) for festive or recreational purposes.³ The American Pyrotechnic Association reported that estimated consumer fireworks sales in the United States increased during 2000-2021, reaching a total of \$2.2 billion in 2021.⁴ Fireworks consumption likewise increased from 152.6 million pounds in 2000 to 428.8 million pounds in 2021.⁵

Injury can occur to both the individual using the fireworks and spectators or bystanders in the vicinity.⁶ These injuries can be serious,

resulting in pain and permanent disability. Fireworks are responsible for thousands of hospital emergency department (ED) visits each year.^{1,3,5,7-9} The majority of persons injured are children and male.^{1-3,6-9,10-15}

Although the body part most often injured by fireworks is the hand, followed by the head and face, the lower extremities also may be injured.^{1,6,7,9,11,15} The objective of this study was to characterize fireworks-related lower extremity injuries treated at US EDs.

Methods

Data for this retrospective epidemiologic study was obtained from the National Electronic Injury Surveillance System (NEISS) at <https://www.cpsc.gov/cgibin/NEISSQuery/home.aspx>. Operated by the US Consumer Product

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Table 1. Time period and patient demographics of fireworks-related lower extremity injuries treated in United States emergency departments, National Electronic Injury Surveillance System, 2000-2021

Variable	No.		Est.		
	No.	%	No.	%	95% CI
Treatment 3-month period					
December-February	58	6.6	2,351	7.0	1,398-3,303
March-May	26	3.0	1,065	3.2	-
June-August	772	87.6	29,676	87.9	23,382-35,971
September-November	25	2.8	678	2.0	-
Treatment day of week					
Saturday-Sunday	323	36.7	12,806	37.9	95,80-16,031
Monday-Friday	558	63.3	20,964	62.1	16,207-25,722
Patient age (years)					
0-5	174	19.8	5,853	17.3	4,067-7,640
6-12	196	22.2	5,971	17.7	4,158-7,784
13-19	143	16.2	4,575	13.5	3,079-6,072
20-29	140	15.9	6,041	17.9	4,213-7,869
30-39	99	11.2	4,631	13.7	3,122-6,141
40-49	68	7.7	3,349	9.9	2,145-4,553
50+	61	6.9	3,348	9.9	2,144-4,552
Patient sex					
Male	509	57.8	18,911	56.0	14,528-23,293
Female	372	42.2	14,859	44.0	11,236-18,482
Total	881		33,770		26,777-40,763

No. = Number.

Est. = Weighted estimate (sum of the Weight numeric field in the National Electronic Injury Surveillance System database). The numbers in the Weight field are not whole numbers but include decimals. As a result of rounding to whole numbers when performing analyses, the sum of the estimates for a given variable might not equal the total. The Consumer Product Safety Commission considers an estimate unstable and potentially unreliable when the number of records used is <20 or the estimate is <1,200.

95% CI = 95% confidence interval. Not calculated if the estimate is <1,200.



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Safety Commission (CPSC), the NEISS collects data on consumer product-related injuries from the EDs of a stratified random sample of 100 hospitals from the more than 5,000 hospitals in the US. The random sample is stratified by hospital size, geographic location, and hospital type (general and pediatric hospitals). Professional NEISS coders view the medical charts at participating hospitals and, for patients with injuries that meet NEISS inclusion criteria, collect and code information such as treatment date; patient age, sex, and race; injury diagnosis and body part injured; discharge disposition; consumer product(s) involved in the injury; location where the incident occurred; and a brief narrative describing the incident.^{16,17} Previous studies have used NEISS data to examine fireworks-related injuries; however, these studies examined injuries to all body parts,^{1,6,7,11} included only pediatric patients,^{9,15} or focused on body regions other than the lower extremity.^{2,3,10,12-14} Data are publicly available

and de-identified; thus, the study is exempt from institutional review board approval.

Cases were fireworks-related lower extremity injuries reported to the NEISS database during 2000-2021. The publicly available NEISS database contains three numeric fields for coding the product involved in the injury (Product_1, Product_2, Product_3). These three fields were searched for the product code 1313 (fireworks). That the injury involved a lower extremity was based on either the Body_Part or Body_Part_2 numeric fields containing codes for a lower extremity (upper leg, knee, lower leg, ankle, foot, toe). The NEISS Coding Manual indicates that the Product_3 and Body_Part_2 fields were added in 2018,¹⁷ although these fields do not appear to have been used until 2019.

The variables examined were treatment year, month, and day of week; patient age and sex; location where the incident occurred; type of injury (diagnosis); affected body part;

and disposition. As with the Product_3 and Body_Part_2 fields, the NEISS Coding Manual indicates that the Diagnosis_2 field was added in 2018 but not used until 2019.¹⁷ Diagnoses and body parts documented in these second sets of fields during 2019-2021 were included in the analysis.

Analyses were performed using Microsoft 365 Personal Access and Excel (Microsoft Corporation, Redmond, Washington, US). The distribution of cases and national injury estimates were determined for each variable. National injury estimates were calculated by summing the values in the Weight numeric field in the publicly available NEISS database, and 95% confidence intervals (CIs) were calculated for the estimates. The CPSC considers an estimate unstable and potentially unreliable when the number of records used is <20 or the estimate is <1,200.¹⁶ For those variable subgroups where the estimate was <1,200, 95% CIs were not calculated.



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Results

During 2000-2021, 881 fireworks-related lower extremity injuries were reported to a sample of US hospital EDs, resulting in a national estimate of 33,770 such injuries, representing 15.0% of the 224,989 total estimated fireworks-related injuries involving any body part. Figure 1 (page 51) shows the annual estimated number of fireworks-related lower extremity injuries. The estimated number of injuries varied from year to year with no clear trend over the 22-year period. However, while the annual estimated number of injuries ranged between 855 and 1,694 (mean 1,343) during 2000-2015, the annual estimated number of injuries was higher during 2016-2021, ranging between 1,856 and 2,347 (mean 2,048).

Table 1 (page 44) presents the distribution of fireworks-related lower extremity injuries by time period and patient demographics. Almost 90% of the injuries were reported during June-August with 676 (76.7%) of the cases

and 26,421 (78.2%) of the estimated injuries treated during July. While the single age group with the highest proportion of estimated injuries was patients age 20-29 years, patients age 0-19 years accounted for 48.6% of the estimated injuries. The majority of patients were male. Of the 19,708 estimated injuries where the location of the incident was recorded, 14,637 (74.3%) occurred at home, 2,104 (10.7%) at other public property, 2,012 (10.2%) at a place of recreation or sports, 804 (4.1%) at a street or highway, 136 (0.7%) at a farm or ranch, and 15 (0.1%) at school.

Table 2 (page 49) provides the distribution of fireworks-related lower extremity injuries by type of injury, body part, and patient disposition. Thermal burns accounted for the majority of injuries. The most commonly affected part of the lower extremity was the foot followed by the lower leg. Most of the patients were treated or evaluated in the ED and released. No deaths were reported.

Discussion

This study examined fireworks-related lower extremity injuries treated in US hospital EDS over a 22-year period. While lower extremity injuries account for only a fraction of all fireworks-related injuries (15% in the present study), fireworks result in an estimated 1,000-2,000 lower extremity injuries each year.

Although US consumer fireworks sales and consumption increased during 2000-2021,^{4,5} the estimated number of fireworks-related lower extremity injuries did not demonstrate a similar increase during 2000-2015. However, the mean annual estimated number of injuries during 2016-2021 was 53% higher than during the previous time period. This increase might be due to the increase in fireworks sales and consumption. It also may be due to the addition of a third product code field and a second field for documenting an injured

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Table 2. Type of injury and disposition of fireworks-related lower extremity injuries treated in United States emergency departments, National Electronic Injury Surveillance System, 2000-2021

Variable	No.		Est.		
	No.	%	No.	%	95% CI
Type of injury (most common)					
Thermal burns	547	62.1	19,857	58.8	15,301-24,413
Laceration	75	8.5	2,990	8.9	1,874-4,105
Strain or sprain	58	6.6	2,791	8.3	1,726-3,857
Contusion or abrasion	63	7.2	2,711	8.0	1,666-3,756
Fracture	37	4.2	1,542	4.6	806-2,279
Body part affected					
Foot	257	29.2	10,509	31.1	7,739-13,278
Lower leg	233	26.4	9,294	27.5	6,772-11,815
Upper leg	205	23.3	7,120	21.1	5,056-9,183
Ankle	96	10.9	3,411	10.1	2,192-4,631
Knee	61	6.9	2,461	7.3	1,480-3,442
Toe	38	4.3	1,296	3.8	628-1,964
Disposition					
Treated or examined and released	789	89.6	30,882	91.4	24,381-37,384
Treated and admitted for hospitalization	59	6.7	1,445	4.3	736-2,155
Treated and transferred to another hospital	17	1.9	956	2.8	-
Held for observation	2	0.2	10	0.0	-
Left without being seen/against medical advice	13	1.5	461	1.4	-
Not recorded	1	0.1	16	0.0	-
Total	881		33,770		26,777-40,763

Please see full footnote on Table 1.

During 2000-2018, a record could have only 1 body part and diagnosis coded. During 2019-2021, a record could have 2 body parts and diagnoses coded.



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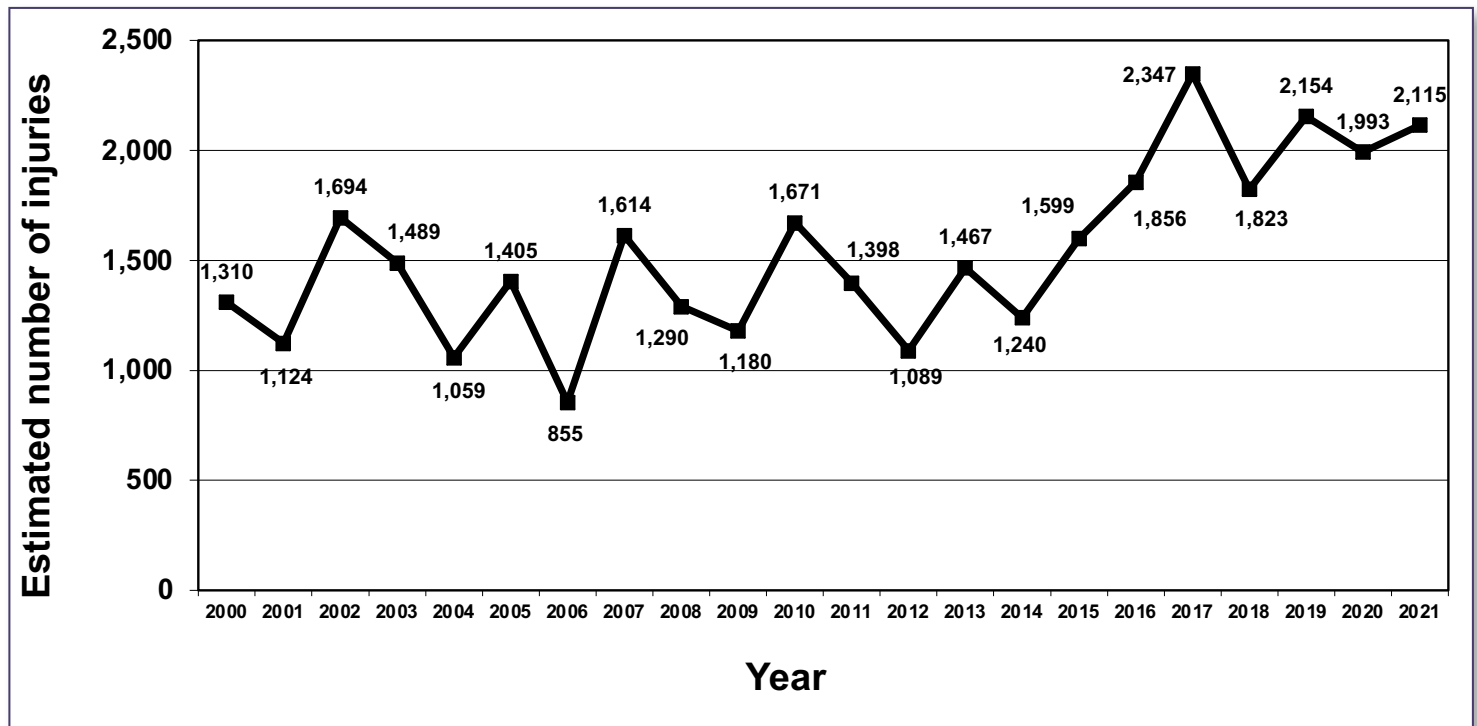
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Figure 1. Annual estimated number of fireworks-related lower extremity injuries reported to the National Electronic Injury Surveillance System



During 2000-2018, a record could have 2 product codes documented. During 2019-2021, a record could have 3 product codes documented. The United States Consumer Product Safety Commission considers an estimate unstable and potentially unreliable when the estimate is <1,200.

body part. However, these changes affected records collected during 2019 and later while the increase in injuries started 3 years earlier. Furthermore, of the 152 cases treated during 2019-2021, none had the product code for fireworks in the Product_3 field, only 20 would have been excluded if the second body part field had not been included in the analysis.

This study found that most of the injuries were treated during June-August, particularly July. Furthermore, fireworks-related lower extremity injuries most commonly affected children and males. This is consistent with the literature.^{1,3,6-9,10-15} However, most of these previous studies likewise used data from NEISS, although they examined all fireworks-related injuries or injuries to other parts of the body, so the similarities in patterns might be expected.


Approximately 60% of the injuries were thermal burns, with smaller proportions involving lacerations, strains or sprains, contusions

or abrasions, and fractures. Previous studies reported similar patterns of injuries.^{1,7,9,12-15} Although thermal burns can be potentially serious, approximately 90% of the patients were treated or examined in the ED and released.

There are ways to prevent fireworks-related injuries. The Center for Disease Control and Prevention (CDC) recommends that fireworks only be used by trained professionals and that no individuals attempt to use firework explosives at home.¹⁸

There are several limitations to this study. The NEISS database only includes injuries treated at an ED. Studies that include information on injuries not evaluated at hospital EDs would provide a more complete view of fireworks-related lower extremity injuries. In addition, state laws regarding the regulation of fireworks vary throughout the US.² Therefore, the pattern of fireworks-related injuries may vary from state to state. However, the

publicly-available NEISS database does not provide information on the state where a particular injury occurred. As a result, this study was not able to examine state differences in fireworks-related lower extremity injuries. As mentioned in the Methods, the Product_3, Body_Part_2, and Diagnosis_2 fields were only added and used after 2018; thus, more cases were included in 2019-2021 than if these fields were not included in the analysis.

In conclusion, the number of fireworks-related lower extremity injuries have increased during 2016-2021. Most of these injuries were treated during June-August, particularly July, and most affected patients were children and males. The majority of the injuries were thermal burns, and most patients were treated or examined at the ED and released. 

Mathias B. Forrester, BS, is an independent researcher in Austin, Texas. He has been involved in public health research for 38 years.

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Although the body part most often injured by fireworks is the hand, followed by the head and face, the lower extremities also may be injured.

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Physical Examination of Possible Biomechanics Involved

BY RICHARD BLAKE, DPM

Whatever your base in Biomechanics, whether it is Root based or not, there are basic biomechanics that should be taught in all podiatry schools. Chapter 4 will go over the basic components of a podiatric biomechanical examination that I find most useful day to day treating patients. You may have other techniques of value to you in helping patients. The physical examination findings in biomechanics are only useful if you use them. Students should practice the exam techniques to develop reliability in their hands and then check with others. We are trying, of course, to make a diagnosis and reverse the stresses on that structure. And, there are so many ways to do it, but we have to be thinking of the possible mechanics involved. The general biomechanics listed here will be re-emphasized in the chapters on individual patient problems, like sesamoiditis. The basic requirements of knowing a patient's biomechanics concerns the following:

1. Are the joints involved over flexible or too limited/dysfunctional?
2. Are the tendons surrounding the sore area strong enough to help the rehabilitation?
3. Are the bones involved in a good position, or out of normal position (stacked up correctly)?
4. Do the overall lower extremity biomechanics somehow put stress on the injured area?
5. How do the biomechanics of the injured area somehow put stress on the injury?

In the practice of biomechanics, there is no definite time frame of discovery. The two patient examples below could not walk at their first visit, so not a lot of biomechanical data could be collected. The full biomechanical exam, which I still do at times of non-acute orthotic workups, should not be the only time

biomechanics is investigated. You will be making biomechanical observations, and biomechanical treatments, throughout your whole intervention with the patient, which sometimes takes months. Look at how biomechanics is used from day one for the two patients below.

Measure Early and Often

Let us use an example of how this works. Your historical review of a patient showed an acute injury to the big toe joint. The patient had swelling, pain on the tibial sesamoid, and the inability to walk which dictated that you place them in Phase I of Rehabilitation, the Immobilization Phase. So, you place the patient in a removable boot, start them icing and contrast bathing, get X-rays which are inconclusive, and consider an MRI based on how the patient is doing at 2 or 4 weeks.


The sesamoid pain and inability to walk demand the tentative diagnosis of sesamoid stress fracture as you have to take the side of caution when a possible severe injury presents. You cannot get anything about the overall biomechanics from gait at this time, but you can examine the big toe joint for its mechanics. You find an incredibly plantarflexed first metatarsal, normal extensor and flexor strength, a negative Lachman maneuver for joint instability, but a loose midfoot suggesting the possibility of pronatory instabilities. When a patient pronates onto a plantarflexed first metatarsal there is an overload of big toe joint tissue. You place a ¼-inch dancer's pad in the removable boot to start protecting the sesamoid even in Phase I. Remember you must attempt to get the pain between 0-2 at every level of rehabilitation as soon as you can. You will be designing an insert with arch support and sesamoid relief (called dancer's padding) during the middle of Phase 1 so it is ready as you enter Phase 2, the Re-Strengthening Phase.

You are thinking through the biome-



chanics right from the start. You will need the patient, whom you will be seeing a lot of, to bring in old running shoes to see the wear patterns, and you can question them regarding their previous knowledge of their biomechanics, and tight calves or hamstrings. An equinus force can place incredible force downward onto the metatarsals.

Practical Biomechanics Question #56: From the first visit with a patient, getting some handle on the overall mechanical problems and specific biomechanics of the area involved is important. How does a patient with acute sesamoid pain and a plantar flexed first metatarsal get treated in a removable boot ideally?

...To learn about the second patient, an avid hiker with right metatarsal pain, check out Dr. Blake's book, page 40. 

Richard Blake, DPM, MS, is adjunct faculty at the California School of Podiatric Medicine. He has practiced podiatry at the Sports and Orthopedic Institute of St. Francis Memorial Hospital in San Francisco, CA. His book, Practical Biomechanics for the Podiatrist, Book 1, is available from Amazon.com and Barnesandnoble.com, as well as from the publisher at bookbaby.com. The is excerpt appears with his permission.

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CYCLONE BIKE FOOT



The Cyclone™ Bike Foot was designed without compromising durability. The innovative design eliminates energy lost to weight caused by a foot shell and shoe, and provides unmatched energy transfer while pedaling. It also eliminates energy loss to deflection caused by the flex of the shoe and foot shell. In addition, the short foot length design increases pedal stroke efficiency. The adjustable pyramid allows the foot to be either right or left. The cleat bracket can be used with 2- or 3-hole cleats, and the bike foot mount is adjustable as well. The Coyote Cyclone Bike Foot (FB1) was designed for K3–K4 level ambulators who desire a lightweight, durable, and rigid foot. It is designed to give optimal power stroke, fit, and alignment for cycling.

Coyote
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IN MEMORIAM: RUDOLF B. BECKER

Rudolf (Rudy) B. Becker III, president and CEO of Becker Orthopedic Appliance Company, has passed away. He was 73 years old. Becker was born July 17, 1949, in Detroit, to Lucille and Otto Becker. He received his Bachelor of Science degree at the University of Hartford in Connecticut. While there he met and fell in love with Carolyn Martin, who would later become his wife. He attended the University of Nebraska where he received a Master's degree in zoology, and then studied

law at Tulane University School of Law in New Orleans, where he graduated at the top of his class.

In 1977, Becker returned to Detroit to help run the family business, Becker Orthopedic Appliance Company. He was president and CEO from 1980–2023, and founded Becker Metal Works in 1986. Becker was the president of the American Orthotic & Prosthetic Association from 1994–1995 and in 2011 was honored with the American Orthotic & Prosthetic Association Lifetime Achievement Award.

For nearly 4 years, Becker battled brain cancer. Despite his illness, he continued his unwavering commitment to the orthotics and prosthetics field to help ensure a positive future for the company, profession, and patients.

IMPLANTABLE KNEE SHOCK ABSORBER



The US Food & Drug Administration has recently authorized marketing of an implantable shock absorber aimed at load reduction for people with refractory knee osteoarthritis (OA) who are not appropriate candidates for arthroplasty. Dubbed the MISHA Knee System, the device is specifically indicated for patients with medial knee OA whose pain continues to interfere with daily life despite prior treatment, including surgery or non-surgical approaches, and are ineligible for, or unwilling to undergo, joint replacement due to age or absence of

advanced OA. Implanted subcutaneously in the medial extra-capsular space, the device is affixed to the tibia and femur with screws—a procedure that can be performed in the outpatient setting.

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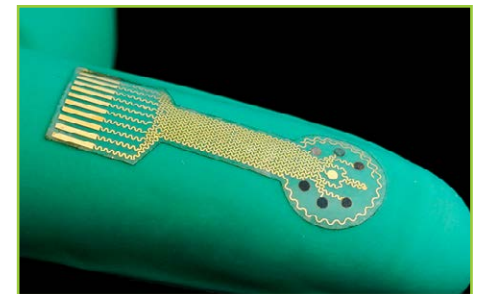


Photo of the smart bandage courtesy of CalTech.

A new kind of smart bandage developed at California Institute of Technology (Caltech) may make treatment of chronic wounds—such as burns and diabetic foot ulcers—easier, more effective, and less expensive. These smart bandages were developed in the lab of Wei Gao, PhD, assistant professor of medical engineering, Heritage Medical Research Institute Investigator, and Ronald and JoAnne Willens Scholar.

The smart bandages are made from a flexible, stretchy polymer containing embedded electronics and medication. The electronics allow the sensor to monitor for molecules like uric acid or lactate and conditions like pH level or temperature in the wound that may be indicative of inflammation or bacterial infection.

The bandage can respond in 1 of 3 ways: First, it can transmit the gathered data from the wound wirelessly to a nearby computer, tablet, or smartphone for review by the patient or a medical professional. Second, it can

deliver an antibiotic or other medication stored within the bandage directly to the wound site to treat the inflammation and infection. Third, it can apply a low-level electrical field to the wound to stimulate tissue growth resulting in faster healing.

In animal models under laboratory conditions, the smart bandages showed the ability to provide real-time updates about wound conditions and the animals' metabolic states to researchers, as well as speed healing of chronic infected wounds similar to those found in humans.

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Sensoria® Health has collaborated with Padula Rehabilitation Technologies to launch the NeurOpTrek™ powered by Sensoria, an innovative new wearable system designed to improve vision and help reduce the risk of falls. NeurOpTrek is a pioneering solution to assess and quantify center of mass dynamically and improve balance, gait, and coordination, reducing the risk of falls by helping a clinician to select the most appropriate yoked prism lenses. Distinguishing this new wearable solution for optometry practices is a comprehensive package, anchored onto the Sensoria smart socks, instrumented with textile pressure sensors and microelectronics to provide real-time gait and balance data. The smart socks are paired with

a dedicated Android tablet with proprietary algorithms and software, along with technical and clinical training and ongoing support.

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VERO ANKLE BRACE



The Vero Ankle™ brace is an innovation designed to help ankle-injury patients rehabilitate and restore mobility and independence, while having the ability to reduce the incidence of acute ankle injuries. The brace combines cutting-edge materials, patent-protected design features, and over a century of combined orthopedic ankle surgery expertise. The finished product is a dynamic, modular, and adjustable brace that seeks to meet the needs of patients at each step of their rehabilitation journey. By using Biomemory™ elastomeric bands, the brace replicates the normal anatomical support of a healthy ankle joint. Elastomeric hinges offer ease of movement and modular stirrups enable the patient to adjust the level of rigidity and support.

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ANKLE EXOSKELETON ALGORITHM HANDLES CHANGES IN PACE, GAIT

Ankle exoskeletons that can help people extend their endurance are a step closer to reality with a new control algorithm, developed at the Uni-

versity of Michigan (U-M), that could enable future exoskeletons to automatically adapt to individual users and tasks. The new control algorithm demonstrates the ability to handle different speeds, as well as changes in gait between running and walking. This would reduce or eliminate the need for manual recalibration.

The control algorithm directly measures how quickly muscle fibers are expanding and contracting to determine the amount of chemical energy the muscle is using while doing its work. Then, it compares that measurement with a biological model to determine the best way to assist. Measuring muscle physiology directly is a key departure from current methods, which use broader measures of motion. Going straight to the source of motion could result in more accurate measurements over a larger range of movements with far less computing power required.



Jacqueline Hannan, a PhD student in industrial and operations engineering, demonstrates walking with an ankle exoskeleton. Photo courtesy of Brenda Ahearn U-M Engineering.

Human testing is an important next step and will require the measurement of muscle fibers in real time using ultrasound. While much work and refinement remain, the researchers are confident that the new avenue of research will one day help people on the ground.

“This has the potential to help just about anyone,” said Paul Pridham, PhD, U-M senior research area specialist in industrial and operations engineering. “From someone who walks a lot for their job, to individuals in the military that perform tasks for long periods of time, to people with muscular disorders that need some extra assistance, and the elderly who need help day-to-day.”

BASEBALL TRAINING SHOE



The SQAIRZ Baseball Training Shoe allows players to maximize their ability to have foot-to-ground contact and optimize their kinetic energy transfer to the ball. In early studies at the Louisville Slugger Hitting Science Center, players were able to increase their exit velocity by an average of 2.6 mph when wearing the shoe over wearing a traditional round-toe shoe. The wide base of the shoe promotes better balance, stability, and braking power. Silicon painted Sta-Put laces comfortably form the shoes to the top of each foot and secure them in place. The patented square toe design gives toes and the ball of the foot more space to properly align in the shoe, which allows for better balance and stability, and more efficient energy transfer. The wider toe box, waterproof design, EVA cushioning, and foam-padded collars and tongues offer comfort.

SQAIRZ

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STUDENTS ENGINEER SOCKS FOR ON-THE-GO NEUROPATHY TREATMENT

A wearable electrical-stimulation and vibration-therapy system designed by a team of Rice University (Rice) engineering students could help people experiencing foot pain and balance loss due to diabetic neuropathy. The team designed a sock, dubbed the StimuSock, with a smart insole that can deliver both transcutaneous electrical nerve stimulation (TENS) and vibration therapy that blocks pain signals to

the brain and provides haptic feedback to help with balance issues, respectively. The device is also user-controllable and easy-to-use.

A lot of the team's effort went into making the device as low-profile as possible. "The intent is for the patient to be able to wear the device for the whole day," said team member Yannie Guo. "Even when everything's off and they don't want the electrostimulation or haptics effect, they can still wear their device."



StimuSock team members (clockwise, from left) Yannie Guo, Kelly Xu, Abby Dowse, Andrei Mitrofan, and Sarah Park display their device. Photo courtesy of Jeff Fitlow/Rice University.

Patients use a smartphone app to control the type, intensity, and duration of the desired therapeutic stimulus. The system has 3 regions that allow users to target a specific area of the foot—the front of the insole, the middle of the insole, and the back of the insole.

The team anticipates the device's final form will have sufficient battery life to provide the recommended maximum of 4 30-minute sessions of TENS therapy per day and operate on standby the rest of the day.

NO-SHOW COMFORT SOCKS

Nekkid Comfort® no-show socks leverage a superior hypoallergenic silicone oval that grips the back of the heel and y-gore construction that firmly hugs the bottom of the heel, so they stay in place, even during vigorous exercise. In addition to exceptional staying power, these socks feature a spiral-woven mesh air vent top



panel and silver-ion treated moisture-wicking Micro-Nylon and LYCRA® Spandex materials to keep feet comfortable and blister-and-stink-free. Like most OS1st® socks, the Nekkid Comfort no-show line is anatomically designed to fit the wearer's feet more properly with specific left and right socks. The socks also feature 360-degree blister protection with a slight compression around the arch that promotes a better fit. The seamless toe design prevents the uncomfortable sensation of the toe seam rubbing against the top of the foot.

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HANGER ANNOUNCES NEW CEO

Hanger, Inc., announced that Pete Stoy, formerly the company's president and chief operating officer (COO), has assumed the role of Hanger's chief executive officer (CEO), effective immediately. He will also serve on the company's board of directors.

Stoy's appointment was announced in January as part of a multi-year succession plan and follows the retirement of Vinit Asar who held the CEO position for more than a decade. Asar will serve as executive chairman of Hanger's board.

Since Stoy joined Hanger as COO in November 2020, he has made a significant impact, contributing to a number of growth initiatives, operational efficiencies, and business improvements. He has over 20 years of healthcare experience with leadership in large,

complex organizations, and holds a designation as a Fellow of the American College of Healthcare Executives (FACHE).

MINIMAL OXFORD MEN'S SHOES



The Hamilton minimal tuxedo-toe Oxfo is designed to keep feet healthy, balanced, and moving comfortably. The shoe is not without compromises such as omitting a raised heel, potentially excluding it from certain formal venues. However, the overall profile of the shoe and leather construction more than compensates. The shoe is constructed with a genuine hand-sewn method informed by the company's moccasin expertise, creating an especially light and comfortable dress shoe. The primary goal of the shoe design was to promote foot health via wide toe boxes, a flexible and lightweight sole, and a zero-drop design for natural foot function and neutral posture. Finally, the shoe is durable, resoleable, breathable, lightweight, and compact for travel.

Softstar Shoes

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BIOPRINTED SCAFFOLD COULD IMPROVE HEALING OF DFUS

Researchers at Queen's University Belfast have designed a new bandage treatment, known as a scaffold, to treat diabetic foot ulcers (DFUs), which is cost-effective while improving patient

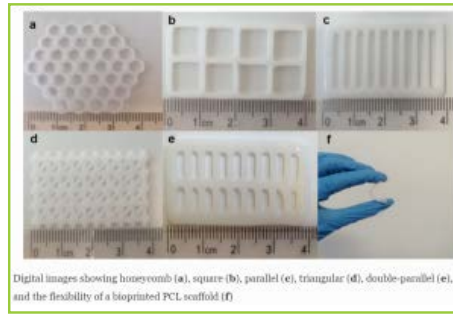


Image courtesy of the research team.

outcomes. Produced by 3D bioprinting, the scaffolds slowly release antibiotics over a 4-week period to effectively treat the wound. This new research demonstrates outcomes with significant implications for patient quality of life, as well as decreasing the costs and clinical burden in treating DFUs. Additionally, the scaffolds can easily be modified to the size of the wound.

"These scaffolds are like windows that enable doctors to monitor the healing constantly. This avoids needing to remove them constantly, which can provoke infection and delay the healing process," said Dimitrios Lamprou, PhD, a professor of biofabrication and advanced manufacturing at Queen's School of Pharmacy. "The 'frame' has an antibiotic that helps to kill the bacteria infection, and the 'glass' that can be prepared by collagen/sodium alginate can contain a growth factor to encourage cell growth. The scaffold has 2 molecular layers that both play an important role in healing the wound."

MICRONEEDLING DEVICE FOR ANKLE JOINT PRESERVATION



The SmartShot[®] microneedling device is a new option for ankle joint preservation that is shown to be 67% less disruptive to subchondral bone and provide improved healing compared to traditional marrow stimulation techniques. This marrow access device was designed specifically to address the unique needs of ankle joint preservation and to promote healing and improve access in the ankle. SmartShot uses a patented mechanism to create deep, microneedle channels into bone to stimulate the patient's own natural healing reaction. The penetration of the outer layers of bone allows blood and stem cells from within the bone marrow to activate cartilage, ligament, and tendon healing. The platform SmartShot marrow access device is indicated for treatment of injuries in the knee, hip, shoulder, ankle, wrist, and elbow.

Marrow Access Technologies

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COUNTERING JET LAG

Reference: Garbellotto et al. JSCR 2022



Designed by @YLMSportScience

6 professional athletes were recruited to assess the effects of a phase advance before a 7- hour eastward flight followed by a strategy of resynchronization at destination on sleep and physical performance

The study was divided into 4 periods:



Images provided by PresentMedia

Melatonin pills and light therapy were administrated during the phase advance and phase adjustment



- 1** Bedtime was advanced by 2.9 hours at the end of the phase advance
- 2** Bedtime was similar at destination compared with baseline
- 3** Total sleep time and sleep composition were unchanged at the end of the phase advance or at destination, compared with baseline
- 4** Physical performances were maintained after phase advance and at destination

CONCLUSION

Coaches and support staff can propose a gradual advance of sleep-wake schedules, followed by a phase adjustment with evening melatonin administration and bright light upon waking, to prepare their athletes before an eastward flight

This strategy is effective, without altering sleep and physical performances



Source: Garbellotto L, Petit E, Brunet E, et al. Gradual advance of sleep-wake schedules before an eastward flight and phase adjustment after flight in elite cross-country mountain bikers: effects on sleep and performance. J Strength Condition Res. 2023;37(4):p 872-880. DOI: 10.1519/JSC.0000000000004348

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