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# ler

**LOWER EXTREMITY REVIEW**

May 15 / volume 8 / number 5

## SMOKING & KNEE OA:

From clinical  
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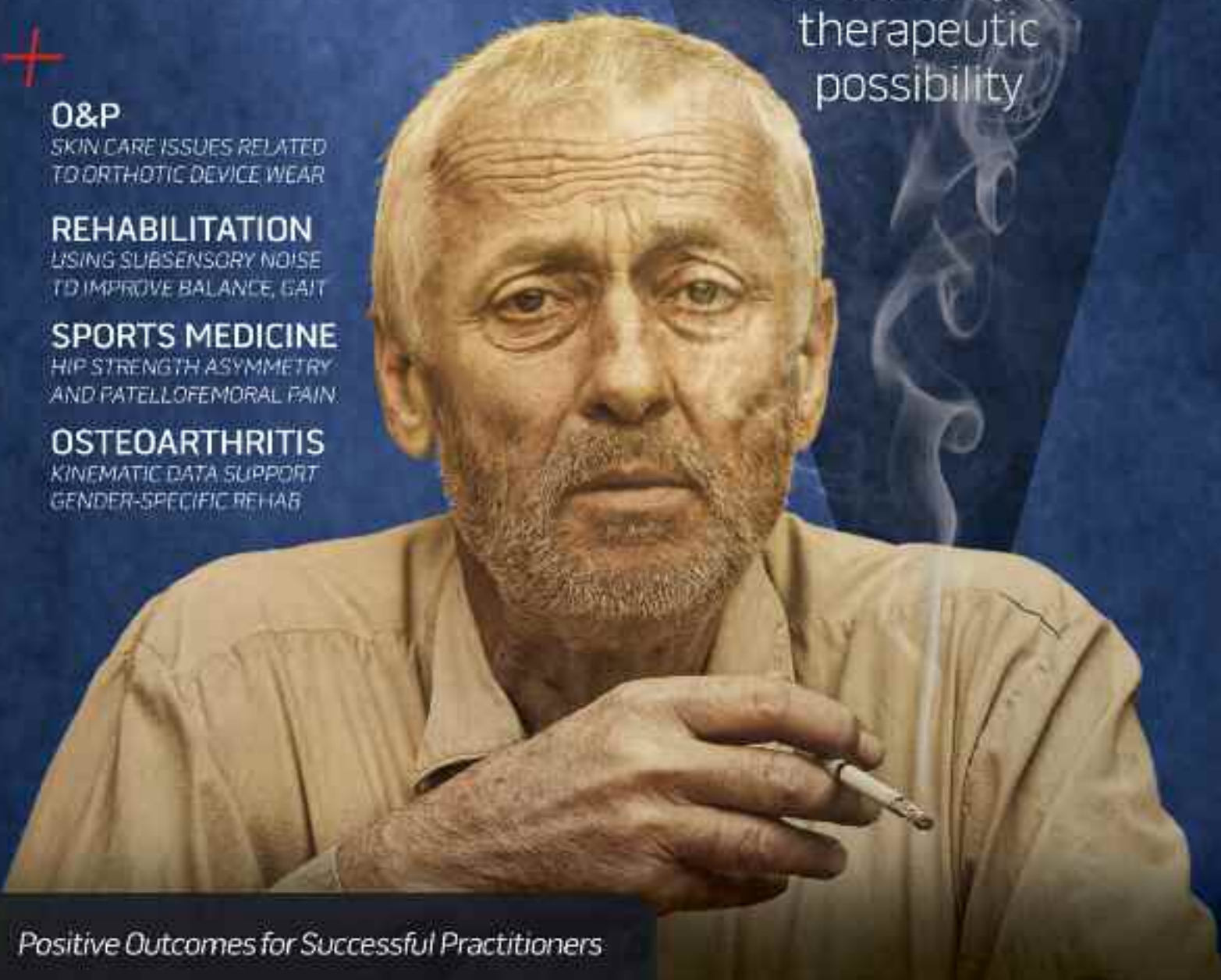
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May 2016

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## Smoking and knee OA: FROM CLINICAL CONTROVERSY TO THERAPEUTIC POSSIBILITY

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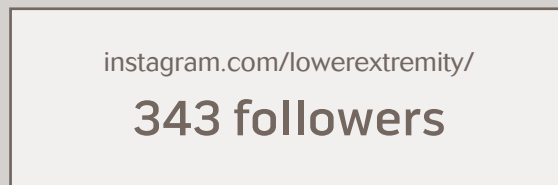
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buzzing about stochastic resonance (SR)?

SR is a process in which introducing low levels of “noise” to a system heightens sensory signal recognition; for example, introducing subsensory electrical stimulation to the plantar surface of the feet via a vibrating insole heightens a person’s sensorimotor perception in ways that have been associated with improvements in balance and gait. Some of the most interesting recent work in this area has been done at the Wyss Institute for Biologically Inspired Engineering at Harvard Medical School in Boston, by authors who have summarized a portion of their work in this issue (see “Using subsensory noise to improve balance, gait,” page 37.)

As you might imagine, the most obvious applications for this type of technology involve people with sensory impairment related to aging or conditions such as stroke or diabetic neuropathy; in those populations it could help reduce the risk of falls and fall-related injury. But the Wyss researchers have found that SR also has positive effects in young, healthy individuals, helping to enhance balance control in response to fatiguing exercise. Since fatigue is associated with increased injury risk in otherwise healthy people, the findings suggest SR could potentially reduce that risk.

Platelet-rich plasma injections. Kinesiology tape. Foam rolling. Compression garments. Blood-flow restriction training. Elite athletes have always been at the leading edge of the latest techniques believed to help speed recovery from injury, often long before they’ve been subjected to rigorous scientific study. So why isn’t the sports world

## out on a limb: Stumping for SR in sports

But it gets better. The Wyss team has also found that the use of SR in young, healthy, recreational athletes is associated with improved performance on an agility task. The .12-second improvement in time may not seem like much, but the authors pointed out that, when the same agility drill was performed at the 2015 National Football League Combine, .13 seconds separated the fastest time from the eighth-fastest time.

Now, I suspect that most sports leagues would consider the use of vibrating insoles during competition an unfair advantage—something I wouldn’t want to be accused of advocating. But the findings also appear to support the idea of using SR to improve rehabilitation of athletes after an injury.

For example, although strength deficits and asymmetries are often associated with poor outcomes after injury, multiple studies have also shown that simply strengthening a weak muscle doesn’t translate to improved biomechanics—the body has to learn how to use that stronger muscle. Doesn’t it seem like using SR to enhance sensorimotor function might be a logical way to try to bridge that gap?

**Stochastic resonance technology might be the best rehab intervention nobody in sports is talking about. At least not yet.**

Granted, SR has not yet been formally studied in elite athletes. But a lack of published evidence has hardly ever stopped elite athletes—and the practitioners they work with—from trying absolutely anything to speed recovery after an injury. And what’s known about SR so far suggests it has the potential to do just that.

It might be the best rehab intervention nobody in sports is talking about. At least not yet.

Jordana Bieze Foster, *Editor*

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## CAI and the CNS

Excitability may influence instability

By Larry Hand

For individuals with chronic ankle instability (CAI), the somatosensory feedback necessary for postural adjustments, walking, and running may be hampered by a decrease in soleus spinal reflex excitability, according to a new study in the *Journal of Athletic Training*.

The findings of the multicenter study add to the body of evidence suggesting that central nervous system (CNS) issues, as well as mechanical joint laxity, contribute to CAI.

"A successful reorganization of the sensorimotor system after an initial ankle sprain is the critical point when individuals suffer chronic ankle instability or become copers [individuals who do not develop chronic instability after an ankle sprain] who break the cycle of recurrent injuries and disabilities seen in CAI," corresponding author Masafumi Terada, PhD, ATC, an assistant professor in the College of Sport and Health Sciences at Ritsumeikan University


## Strength training in runners has bonus benefits for physiological performance

Long-term periodized strength training has physiological performance benefits in distance runners, according to research from the University of Limerick in Ireland.

Investigators randomized 20 competitive distance runners to a control group or an intervention group that completed a 40-week periodized strength-training program. A 20-week preseason training program, with two sessions per week, focused on building maximal and reactive strength. A 20-week in-season training program, with one session per week, focused on maintaining maximal and relative strength while building explosive strength.

Physiology, body composition, and strength were assessed at baseline and at 20 and 40 weeks.

After 20 and 40 weeks, the runners in the intervention group demonstrated significant improvement from baseline for running economy and velocity at maximal oxygen uptake—measures of physiological performance—as well as maximal and relative strength. The runners in the control group had no significant changes from baseline for any of the outcome measures.

The findings were published in April by the *Journal of Strength and Conditioning Research*. 

—Jordana Bieze Foster

Source:

Beattie K, Carson BP, Lyons M, et al. The effect of strength training on performance indicators in distance runners. *J Strength Cond Res* 2016 Apr 21. [Epub ahead of print]



in Kyoto, Japan, told LER by email.

According to this supraspinal modulation theory, the CNS in healthy people and copers modulates neural activity within the motor pathways to prevent the excessive ankle supination that is a mechanism of ankle injury, Terada said. A decrease in soleus spinal

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## fMRI study supports use of multiple exercises to prevent hamstring injury

A multicenter functional magnetic resonance imaging (fMRI) study indicates that no single exercise activates all of the hamstring and synergist muscles in professional soccer players, suggesting a combination of exercises may be optimal for hamstring injury prevention.

Investigators performed fMRI on 36 professional soccer players before and after performing four hamstring exercises: Nordic hamstring curl, flywheel leg curl, Russian belt, and conic-pulley exercise. Each exercise session included four sets of eight repetitions.

The flywheel leg curl was associated with the greatest increase in T2 contrast shift (indicating muscle activation) from pre- to postexercise: T2

increases were seen for the gracilis (95%), semitendinosus (65%), and the short (51%) and long (14%) heads of the biceps femoris. The Nordic hamstring curl was associated with increases in the gracilis (39%), semitendinosus (16%), and the short head of the biceps femoris (14%). The Russian belt exercise was the only one associated with an increase in the semimembranosus muscle (7%).

The findings were published in April by the *International Journal of Sports Medicine*. 

Source:

Fernandez-Gonzalo R, Tesch PA, Linnehan RM, et al. Individual muscle use in hamstring exercises by soccer players assessed using functional MRI. *Int J Sports Med* 2016 Apr 26. [Epub ahead of print]

# in the moment: sports medicine

Continued from page 13

reflex excitability in patients with CAI would suggest the initial ankle injury triggers an alteration in that neuromotor process, he said.

Terada and colleagues conducted a case control study to see if spinal reflex excitability differences exist among individuals with CAI, copers, and controls. They measured ankle laxity in 37 individuals with CAI, 30 copers, and 26 healthy controls using an ankle arthrometer. They also assessed the maximum Hoffmann reflex and maximal muscle response for the soleus muscle in response to electrical stimulation; since slow-twitch fibers involved in the Hoffmann reflex make up most of the soleus muscle, a greater Hmax:Mmax ratio indicates greater spinal reflex excitability of the soleus muscle.

They found that individuals with chronic instability had lower Hmax:Mmax ratios than both copers and healthy controls. However, no difference existed between copers and controls. In addition, there were no significant differences among the groups for anterior-posterior or mediolateral ankle laxity.

The slow-twitch fibers in the soleus muscle are mostly innervated by small alpha motoneurons, Terada explained, so the study findings suggest that some people may restore their ability to reflexively recruit alpha motoneurons after ankle injury, and some may not.

"Therapeutic interventions that can increase the H-reflex in the soleus may help to break the cycle of recurrent injuries and disabilities seen in CAI," he said. "Lower-intensity transcu-

taneous electrical stimulation, joint manipulations, and reflex conditioning protocols may be effective in increasing the soleus spinal excitability."


Without a prospective study, however, it is difficult to know the true neurophysiologic mechanism underlying the between-group differences in soleus spinal reflex excitability, he noted.

Patrick McKeon, PhD, ATC, FACS, an assistant professor of exercise and sports sciences at Ithaca College in New York, told *LER* in a phone interview that the study's findings suggest CAI might be more related to the coordination and control of dynamic stabilizers than the function of static stabilizers.

"It really does fit in well with the body of evidence that's saying chronic ankle instability

seems to be related to a functional deficit as opposed to a mechanical one," said McKeon, who was not involved with the study. "And it lines up well with the idea that we see lots of improvement in people as we have them undergo dynamic interventions."

McKeon echoed Terada's comments regarding possible neurophysiologic explanations for the findings.

"One of the mechanisms that might be driving it is a change in the motor neuron excitability," he speculated. "But this study really can't establish any cause and effect." 

Source:

Bowker S, Terada, M, Thomas AC, et al. Neural excitability and joint laxity in chronic ankle instability, copers, and control groups. *J Athl Train* 2016 Apr 11. [Epub ahead of print]

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## Gender, gait, and knee OA

### Kinematic data have rehab implications

By Katie Bell

Women with and without knee osteoarthritis (OA) demonstrate greater knee abduction and hip adduction during gait than their male counterparts, according to research from Canada that supports the concept of gender-specific rehabilitation in this population.

Gender should be taken into account when studying the biomechanical etiology of knee OA, and the development of gender-specific analysis and rehabilitation protocols are necessary, the authors wrote.

"I believe this study provides very strong evidence that rehabilitation programs and [prevention] strategies need to be subgroup-specific," said study author Reed Ferber, PhD, ATC, an associate professor in the faculties of kinesiology and nursing at the University of Calgary in Alberta.

The study included 100 participants with knee OA (55 women), aged 33 to 72 years, and 43 healthy individuals (25 women), aged


## Leg strength, velocity predict functional issues in older adults with poor mobility

Leg strength and speed of leg movement are predictive of functional decline in older adults with poor mobility, according to research from Boston, MA.

In 391 adults 65 years or older with self-reported mobility modifications, investigators from Harvard Medical School assessed variables related to leg strength, speed of leg movement, knee and ankle range of motion, and trunk stability. The researchers then followed the participants for two years, annually assessing mobility-related function using the Late Life Function and Disability Instrument.

Weaker leg strength, lower trunk extensor endurance, and slower leg velocity at baseline were associated with greater odds of persistently poor func-

tion and declines in function over the two-year follow-up.

The findings, which were epublished in April by the *Archives of Physical Medicine and Rehabilitation*, suggest that interventions targeting these variables—particularly trunk extensor endurance and leg velocity, which may be less familiar to clinicians than leg strength as predictors of mobility-related function—could help to optimize rehabilitation and disability prevention in this geriatric population.  —Jordana Bieze Foster

Source:

Ward RE, Beauchamp MK, Latham NK, et al. Neuromuscular impairments contributing to persistently poor and declining lower-extremity mobility among older adults: New findings informing geriatric rehabilitation. *Arch Phys Med Rehabil* 2016 Apr 4. *IEpub ahead of print*



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40 to 79 years. The OA group had a 100-mm knee pain visual analog scale (VAS) above 20 mm on most days of the week preceding enrollment and a Kellgren-Lawrence (KL) grade less than three, indicating mild to moderate radiographic OA. The researchers assessed 112 kinematic variables as the participants walked on a treadmill at self-selected speeds ranging from 1 m/s to 1.3 m/s.

Women with knee OA had greater knee abduction at touchdown

*Continued on page 16*


## Metabolic activity suggests Achilles tendons are still healing at 6 months

Metabolic activity evident six months after an Achilles tendon rupture—when rehabilitation protocols typically allow running and other high-load activities—suggests the tendon is still healing at that time, according to research from Denmark.

Investigators from Bispebjerg Hospital in Copenhagen used positron emission tomography (PET) and power Doppler ultrasonography to assess Achilles tendon metabolism and vascularization in 23 patients three, six, and 12 months after surgeons repaired their ruptured tendons.

Relative glucose uptake on PET scans, an indicator of metabolic activity, was significantly higher in repaired tendons than intact tendons at all three time

points, and was negatively related to patient-reported outcomes at six months. Glucose uptake was also higher in the tendon core than the periphery at three and six months. Vascular flow activity was significantly higher in repaired tendons than intact tendons at three and six months but had normalized by 12 months.

The findings were epublished in April by the *European Journal of Nuclear Medicine and Molecular Imaging*. 

—Jordana Bieze Foster

Source:

Eliasson P, Coupe C, Lonsdale M, et al. Ruptured human Achilles tendon has elevated metabolic activity up to 1 year after repair. *Eur J Nucl Med Mol Imaging* 2016 Apr 13. *IEpub ahead of print*

# in the moment: rehabilitation

Continued from page 15

and during swing, and a greater maximum peak hip adduction angle during stance, compared with men with knee OA; similar differences were also seen between women and men without knee OA. However, no differences in the discrete variables were evident between healthy men and men with knee OA or between healthy women and women with knee OA. The data were epublished in April by the online journal *BMC Musculoskeletal Disorders*.

"Our classification method shows a maximum classification accuracy of eighty-three percent between OA male and OA female patients. So, a small proportion of males have gait kinematic patterns similar to females and vice versa," Ferber said.

Previous assessments of gender-specific gait patterns in

patients with knee OA have been inconsistent, perhaps in part because a number of characteristics of knee OA—including pain—can affect gait in ways that may obscure other associations; the inclusion criteria in the current study were designed to address some of these issues, he said.

"Certainly, it is well known that higher pain values can influence gait kinematics, and most previous studies have used a mixed cohort of knee OA patients with mild to moderate and severe pain and symptoms," Ferber said. "We tried to investigate a homogeneous cohort so that the influence of pain would be minimized."


Although many knee OA interventions are designed to address frontal plane kinetics

rather than kinematics, Ferber said the gender differences observed in the current study may not extend to kinetic variables. A systematic review and meta-analysis the Calgary group completed in 2013 did not find consistent evidence that external knee adduction moment differs between those with and without knee OA or between disease severity levels.

"In fact, we found that only temporospatial and kinematic gait alterations associated with knee OA increased in magnitude with increasing disease severity," he said.

Cheryl Hubley-Kozey, PhD, a professor in the schools of physiotherapy and biomedical engineering and associate dean (research) in the faculty of health professions at Dalhousie University in Halifax, Canada, agreed

that gender should be a consideration in the study and management of knee OA.

"In general, I think our present state of knowledge is that sex differences should be accounted for in OA gait studies (and indeed in studies involving imaging, biomarkers, strength, etc). We are beginning to uncover different pathomechanical processes for men and women, which, once are established, will help with person-specific interventions," Hubley-Kozey wrote in an email to *LER*. 

Sources:

Phinyomark A, Osis ST, Hettinga BA, et al. Gender differences in gait kinematics for patients with knee osteoarthritis. *BMC Musculoskelet Disord* 2016;17(1):157.

Mills K, Hunt MA, Ferber R. Biomechanical deviations during level walking associated with knee osteoarthritis: a systematic review and meta-analysis. *Arthritis Care Res* 2013;65(10):1643-1665.

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# SMOKING & KNEE OA:

From clinical controversy to  
therapeutic possibility

Experts say perplexing studies suggesting that smoking may be protective against the development of knee osteoarthritis (OA) should not deter clinicians' efforts to discourage smoking—even in patients who are at risk for OA. But, if researchers can pinpoint specific ingredients associated with the protective effect, that could have significant implications for the development of new OA therapies.

By Barbara Boughton



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# Smoking tobacco

has long been recognized as the most preventable cause of morbidity and early mortality in the US.<sup>1</sup> Smoking contributes to many poor lower extremity outcomes, including increased risk of osteoporosis-related fractures, complications following orthopedic surgery, and musculoskeletal pain.<sup>2</sup>

Yet smoking remains a persistent and widespread habit among Americans—including patients who need healthcare for orthopedic and musculoskeletal conditions. In fact, studies have estimated that one out of every five patients who receive outpatient physical therapy smoke or use tobacco.<sup>1,3</sup> Organizations such as the American Academy of Orthopaedic Surgeons (AAOS) have begun to recommend that clinicians should take a more active role in screening patients for smoking and counseling them about smoking cessation.<sup>2</sup>

At the same time, a number of controversial but large review and population-based scientific studies have reported that smoking may be protective against the development of osteoarthritis (OA), particularly knee osteoarthritis. Several large studies in China and Australia have also found that, among OA patients, smokers are less likely than nonsmokers to undergo total knee arthroplasty for severe symptoms.

The research has generated controversy, as well as concern among lower extremity clinicians who are well acquainted with years of research showing poor outcomes among patients with OA who also smoke.

“The research that shows a protective effect of smoking on knee osteoarthritis is intriguing and interesting, but I’m not convinced that there’s enough evidence to support the notion that smoking has a beneficial effect,” said Janet Bezner, PhD, PT, DPT, associate professor of physical therapy at Texas State University in San Marcos. “There really isn’t enough information in the research studies I’ve seen to support the conclusion that smoking has a protective effect on knee osteoarthritis—or to change our advice to patients about the hazards of tobacco.”

Smokers are at increased risk for nonunion of fractures and delayed healing after orthopedic surgery,<sup>2,4-6</sup> said AAOS spokesperson Alan Reznik, MD, an orthopedic surgeon and sports medicine specialist in New Haven, CT, and one of the authors of the recent AAOS statement on smoking.

Since smoking damages the inner walls of arteries and slows down microcirculation, blood flow that aids healing is often compromised, Reznik added. Smokers are also at increased risk for mortality and serious morbidities such as deep infection, heart attack, and stroke and sepsis after surgery, including orthopedic surgery,<sup>7-10</sup> he said.

“Smokers who have other risk factors such as obesity and diabetes are often not candidates for elective orthopedic surgeries such as arthroplasties, because they are at such heightened risk for complications,” he said.

Smokers who quit just weeks or months before surgery appear to reduce their risk for adverse events, and that risk decreases further if the patients quit smoking a year or more before surgery, according to the AAOS statement.<sup>2,10,11</sup>

“The hazards of smoking are well documented,” Bezner said. “We know that smokers are more likely to have back pain and chronic musculoskeletal pain—and smokers heal more slowly from tendon and muscular injuries.”<sup>12-14</sup>

## A protective effect?

Yet in recent years, a great deal of research has begun to show a modest to significant protective effect of smoking on knee OA. No one, of course, is arguing that lower extremity clinicians should encourage their patients to smoke, or refrain from counseling smoking cessation. Researchers hope that learning more about the possible link between tobacco and OA will lead to insights about specific ingredients in tobacco or nicotine that may be protective, so those components could be isolated for the development of new arthritis medications.

In one of the largest recent studies on OA and smoking, published in *Osteoarthritis and Cartilage* in 2014, researchers in Singapore found smokers had a significantly lower risk for severe knee OA resulting in total knee arthroplasty than nonsmokers in a cohort of more than 63,000 Chinese men and women. Smokers had a 51% decreased risk of total knee arthroplasty compared with people who had never smoked.<sup>15</sup>

“Our study is limited in that it used total knee replacement as a surrogate for knee osteoarthritis—so you can’t really say from our study whether smoking was associated with onset or progression of osteoarthritis,” said Katy Leung, MBChB, director of research in the department of rheumatology and immunology at Singapore General Hospital. “Yet, an important strength of our study is that we had very detailed data on patients who quit smoking, and we found that the protective effect of smoking declined quickly after quitting.”



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Recent basic science experiments indicate that nicotine can aid collagen synthesis in chondrocytes,<sup>16</sup> which suggests to Leung and colleagues that there could be practical implications drawn from their study's findings.

"The development of chemopreventive agents from nicotine analogues may provide an effective means to reduce the progression and lessen the burden of severe OA," they wrote in their paper.

That line of thinking, however, is still in the very early stages.



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"There are hundreds of ingredients in cigarettes, so it's not yet appropriate at this time to make any conclusions about which ingredients might have a protective effect," Leung said. "More research on this question needs to be done."

In 2011, researchers performed a meta-analysis of 48 studies and found a significant inverse association between smoking and the development of knee OA.<sup>17</sup> Yet a large population-based study of 9064 Koreans older than 50 years, published in 2016, did not find a significant association between knee and hip OA and smoking or indirect or side stream smoke.<sup>18</sup>

Two large population-based studies conducted in Australia found a beneficial effect of smoking on knee OA, as well. This research concluded smoking decreased the risk for lower limb total joint replacement, and the association held true when the researchers controlled for age, comorbidities, body mass index (BMI), and socioeconomic status.<sup>19,20</sup>

"Both of our studies were consistent in their findings," said lead researcher of both studies George Mnatzaginian, PhD, MPH, an epidemiologist at Australian Catholic University in Melbourne. "There was a protective effect of smoking, and both male and female smokers had less risk for lower limb total joint replacement than nonsmokers. We also found a dose-response effect between years of smoking and reduced risk for having a total joint replacement [with more years of smoking linked to a greater decrease in risk for TKA than fewer smoking years]."

## Contradictory findings

In a 2015 editorial in *Osteoarthritis & Cartilage* that analyzed recent studies and reports on the link between OA and smoking,<sup>21</sup> David Felson, MD, a professor of medicine and epidemiology at Boston University in Massachusetts, noted that a "preponderance of evidence suggests that smokers are modestly protected against developing radiographic OA in the knee and hip." Yet Felson and Zhang also observed that smoking may have contradictory effects on OA. Research such as the 2011 meta-analysis indicated that, while smokers had less OA disease than nonsmokers, they were at "modestly increased risk of painful OA," Felson and Zhang wrote.

A recent study highlighted the contradictory and complex effects of smoking on knee OA.<sup>22</sup> In 2250 patients with radiographic evidence of knee OA, researchers from the University of Massachusetts Medical School in Worcester studied the effect of smoking history on knee pain, stiffness, physical function, and OA progression as indicated by joint space width. Changes in knee-specific symptoms, such as pain, stiffness, and physical function were measured at baseline and annually over 72 months. Joint space width was evaluated by x-ray at baseline and annually over 48 months. In their analyses, the researchers controlled for potential confounders, such as age, gender, education, income, race, BMI, symptom-related multijoint OA, alcohol consumption, and Short Form-12 physical and mental health scores.

In a cross-sectional analysis performed at baseline, the researchers found patients with a history of greater than 15 pack-years of smoking had worse pain and stiffness than patients who had never smoked. Their findings also revealed a contradictory result: Patients with less than 15 pack-years of smoking at baseline had better joint space width than patients who never smoked—but they had worse overall function.

The researchers also measured changes in WOMAC (Western Ontario and McMaster Universities Arthritis Index) symptoms from baseline to 72 months, and changes in joint space width from baseline to 48 months. This more robust longitudinal analysis found no association between smoking history or pack-years of smoking and changes in OA symptoms or joint space width.

"We suspect that the small and conflicting findings from the cross-sectional study are [less reliable and] due to residual confounding," the researchers wrote in their paper.

"Our study showed clearly that there was no relationship between smoking and knee osteoarthritis," said lead author Catherine

Continued on page 22



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Dubé, EdD, research associate professor in the Department of Quantitative Health Sciences at the University of Massachusetts Medical School. “We do not believe there is a protective effect of smoking on osteoarthritis.”

Dubé acknowledged that previous population-based studies had found a strong association between smoking and reduced prevalence of knee OA, as well as a reduced risk for total knee arthroplasty.

“It’s difficult to assess the quality of these studies, and the generalizability of their results,” she said.

Dubé also noted a number of studies have actually found that, because smoking has a negative effect on bone mineral density, the habit can cause increased cartilage loss.<sup>23,24</sup>

“Chronic smoking also creates a pro-inflammatory state, and since inflammatory mediators play an important role in osteoarthritis, one would expect that smoking would have an overall negative effect on symptoms and disease progression,” she said.

In their paper, Dubé and colleagues noted that, while some chemical exposures in cigarette smoking could be beneficial, it might be almost impossible to narrow down which ingredients were protective.

Cigarettes have hundreds of ingredients associated with at least 69 known carcinogens, and more than 7000 chemicals when burned, Dubé and colleagues noted in their study.

Still, it’s important for research to provide more clarity about the relationship between smoking and OA, so that smokers do not find a reason to continue smoking, Dubé said.

## Cessation counseling


Other clinicians interviewed by *LER* also emphasized the importance of continuing to counsel OA patients who smoke about the health hazards of their habit. A discussion about smoking before elective surgery, such as total knee arthroplasty, presents an opportunity to intervene and discuss smoking cessation methods and programs, said V. Franklin Sechriest II, MD, chief of orthopedic surgery at the Minneapolis Veteran Affairs Health Center System.





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"It's crucial to discuss the risks of smoking with any patient undergoing surgery," Sechriest said. "If patients can't quit smoking before undergoing surgery, then it's vital to aggressively counsel them afterward about tobacco cessation. I usually tell my patients that, if they want a good outcome after surgery without complications, it will help to quit smoking."

Sechriest also noted that smokers should be monitored more closely than nonsmokers after orthopedic surgeries to ensure healing.

Bezner emphasized the important role that physical therapists

can play in helping patients to stop smoking.


"We should be screening patients for smoking, and asking if we can help with quitting," she said. "Although we can't prescribe stop-smoking medications, we can refer patients to stop-smoking programs."

But Bezner has found that physical therapists often don't take advantage of opportunities to address smoking cessation with their patients.<sup>1</sup>

"Physical therapists have reported that they do not feel prepared to provide smoking cessation counseling, although they feel that they should ask patients about smoking habits and provide advice to stop smoking," Bezner wrote in a 2015 review article on promoting health and wellness in physical therapy.<sup>1</sup>

Bezner advises taking an educational approach to patients who smoke, and informing them about the risks of smoking, as well as the benefits and rewards of quitting. Patients should also be asked to identify any barriers or roadblocks they've encountered when trying to quit, and advised about ways they might be able to overcome these roadblocks, she added.

If an OA patient is both obese and a smoker, or if an obese patient who smokes is at risk for OA, it's often best to start by advising them about starting an appropriate exercise program—as long as they can handle physical activity.

"Once they take that first step and start exercising," Bezner said, "they realize pretty quickly how much smoking is limiting them." 

*Barbara Boughton is a freelance writer based in the San Francisco Bay Area.*

References are available at [lermagazine.com](http://lermagazine.com).



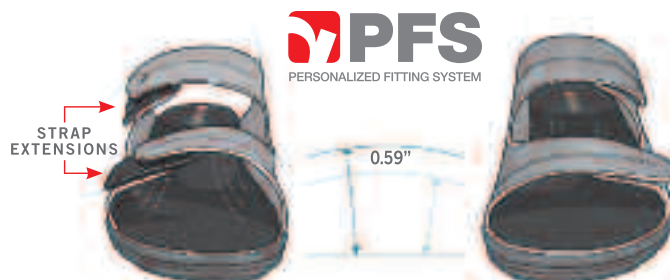
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## Managing metatarsalgia in athletic populations

By Howard Kashefsky, DPM, FACFAS

Metatarsalgia is a common foot disorder. The term metatarsalgia refers to a pain syndrome in the forefoot and not to a specific diagnosis.<sup>1</sup> Pain is confined to the area across the plantar forefoot, including the second through fourth metatarsal heads. However, it is frequently accompanied by deformity of the first and fifth rays, as well as the toes.<sup>2</sup>

Many different diagnoses have been identified as the cause of the painful forefoot. Excessive stress may result in ligamentous strain, synovitis, capsulitis, stress fracture, or degenerative arthritis. Metatarsalgia may be associated with a tight Achilles tendon (equinus), cerebral palsy, stroke, multiple sclerosis, or other neurological diseases. Metatarsalgia also results from pathological alterations in forefoot structure due to hallux valgus, hallux limitus, rheumatoid arthritis, osteomyelitis, or osteochondrosis (Freiberg disease). Circulatory or metabolic disorders may also be associated with metatarsalgia.<sup>3-8</sup> Brachymetatarsia, an arrest of normal metatarsal growth and development with a resultant short ray, may cause symptoms.<sup>9</sup> A Morton neuroma or other nerve injuries may be associated with forefoot pain.<sup>10</sup> Hammertoes can occur in association with joint dislocation, and may contribute.<sup>11</sup>

Cavus foot and pes planus foot types have both been associated with metatarsalgia. Cavus foot type as well as pes planus with hypermobile first and fifth rays have been associated with increased shearing at the forefoot.<sup>12,13</sup> Metatarsal weightbearing is increased with the cavus foot because a disproportionate amount of weight is borne by the heel and forefoot. It is not uncommon to observe retracted or clawed toes with cavus feet, which decreases the ability to unload the metatarsals at push-off.<sup>14</sup> The pes planus foot type (resulting from genu valgum, rearfoot valgus, or forefoot varus) remains pronated during midstance and inhibits proper supination, which compromises the propulsive function of the forefoot.

Although plantar fat pad loss makes sense intuitively as a cause of metatarsalgia, a study by Waldecker suggests the two may not be associated; more research needs to be done.<sup>15</sup> Unintended iatrogenic metatarsalgia after bunion surgery can be the result of a short first metatarsal or elevation of the first ray.<sup>16,17</sup>

### Classifications

Helal et al classified metatarsalgia as either primary or secondary.<sup>18</sup> Primary metatarsalgia is structural—an anatomical abnormality

resulting in increased pressure under the metatarsal heads. Examples include hallux rigidus, long or short metatarsal bones, and possibly pes cavus. Treatment should be focused on offloading the metatarsal heads and should mechanically direct force away from the point of pressure.

Secondary metatarsalgia is defined as pain that does not originate within the metatarsal area. Conditions such as rheumatoid arthritis, sesamoiditis, and equinus can all lead to localized pain at the ball of the foot. The origin of metatarsalgia can be multifactorial. Scranton found that 31 of 98 patients had two or more mechanical etiologies for primary metatarsalgia, and that often, primary and secondary metatarsalgia existed together.<sup>19</sup> Effective treatment will address the area of pain, the function of the foot, and, if necessary, the systemic disease.

Scranton found 23 different diagnoses of metatarsalgia in 98 patients. Forty-five patients had primary metatarsalgia, 12 of whom had static disorders and 12 of whom had iatrogenic (postoperative) etiologies. Thirty-three patients had secondary metatarsalgia, 11 of whom had rheumatoid arthritis and 10 of whom had sesamoiditis. Twenty patients experienced pain under the forefoot.<sup>19</sup>

Viladot has classified metatarsal pathomechanics as an overload of anterior support or an irregular distribution of the metatarsal load.<sup>20</sup> Irregular metatarsal load syndromes are further separated into four groups: first ray overload, first ray insufficiency, central ray overload, and central ray insufficiency.

### Metatarsalgia in athletes

Metatarsalgia is common in sports, including rock climbing, running, and cycling. A potential cause of these injuries is excessive plantar pressure in the forefoot region.<sup>21,22</sup>

In particular, pain associated with metatarsal stress fracture has plagued military personnel throughout history but has now become more common in the civilian population with the increasing popularity of recreational long-distance running, aerobics, and jumping sports.<sup>23,24</sup> Metatarsal stress fractures and metatarsalgia also are fairly common among competitive athletes, especially runners.<sup>25-27</sup> Buda et al identified metatarsalgia in 12.5% of 144 rock climbers.<sup>28</sup>

Cycling is associated with metatarsalgia.<sup>29</sup> Carbon fiber cycling shoes have become popular for their stiffness, but the stiffer material is also associated with 18% higher peak plantar pressures in

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the forefoot, leading Jarboe and Quesada to recommend that competitive or professional cyclists suffering from metatarsalgia or ischemia should be especially careful not to aggravate these foot conditions.<sup>30</sup>

## Treatment

Multiple studies support the use of treatment focused on reducing forefoot plantar pressure.<sup>31-34</sup> Postema et al reported a reduction in forefoot plantar pressure and force impulse both with a rocker sole and with custom foot orthoses in individuals with a history of metatarsalgia.<sup>32</sup> Individuals with current pain preferred a custom-molded insole more often than those without pain.

The efficacy of rocker shoes for reducing forefoot plantar pressure during walking has been well documented in both healthy individuals and patients with forefoot problems such as metatarsalgia.<sup>35-39</sup> Sobhani et al found that running in rocker shoes was associated with a significant reduction in all pressure parameters in the central and lateral forefoot as well as reduced force time integral and maximum mean pressure in the medial forefoot.<sup>40</sup> Although the study participants (all healthy runners) found the rocker shoes less comfortable than standard running shoes, the authors concluded rocker shoes might be beneficial for runners who are recovering from metatarsalgia or stress fractures in the forefoot region.

Treatment with metatarsal pads is a common standalone therapy for metatarsalgia. A 1990 study by Holmes and Timmerman used pedobarography to determine the effect of metatarsal pads on pressure under the metatarsal heads in 10 asymptomatic volunteers.<sup>41</sup> They found that the met pads were associated with significantly reduced pressure at the second metatarsal head for all participants; pressure reduction with met pad use decreased for each subsequent lesser metatarsal head lateral to the second metatarsal.

Another study of metatarsal pads, published in 1994, expanded on this idea by measuring the intervention's effect on peak pressures in eight discrete plantar locations on the hindfoot, midfoot, and forefoot.<sup>42</sup> In 10 asymptomatic individuals, met pad use was associated with statistically significant increases in plantar pressure at the metatarsal shaft region, suggesting offloading of the metatarsal heads. Although there were no statistically significant changes in any other plantar region, there was a mild decrease in

pressure at the first and second metatarsal heads and slight increases laterally. In addition, contact duration decreased at all metatarsal head locations, and pressure-time integral (PTI) decreased at the first, second, third, and fourth metatarsals.

Location of met pads seems to be crucial for plantar pressure reduction, as a research group in Taiwan demonstrated.<sup>43</sup> Metatarsal pads, each measuring 55 mm in length, 36 mm in width, and 10 mm in height, were uniformly used in 10 individuals with a history of primary metatarsalgia. The greatest pressure reduction was achieved when the metatarsal pad was placed just proximal to the site of peak metatarsal head pressure. The study revealed positional differences as small as 4 mm could influence the metatarsal pad's ability to reduce plantar pressures at the metatarsal heads. However, for clinicians to use the same type of assessment to place a metatarsal pad for each patient is impractical.

Because one of the most important outcomes of treatment is pain relief, in 2006 the same Taiwanese research group assessed the correlation between the use of a metatarsal pad and subjective symptoms.<sup>44</sup> Thirteen patients with secondary metatarsalgia wore metatarsal pads positioned under and just proximal to the second metatarsal head for two weeks. Improvements in visual analog pain scores were statistically correlated with reduction in PTI and, more strongly, with reduction in maximum peak pressure.

Additional studies of secondary metatarsalgia have focused primarily on pain relief with the use of met pads in combination with foot orthoses in patients with rheumatoid arthritis.<sup>45,46</sup> These studies found that metatarsal pads were associated with statistically significant decreases in peak plantar pressures, pressure-time intervals, and patients' pain, along with increased quality of life. These studies also found the use of a custom orthosis without the pad provided a frequent decrease of peak pressures and decreased metatarsal pain in varying amounts.

In a 2006 study of 20 patients with diabetes, Mueller et al found that both a total contact insert and a metatarsal pad were associated with statistically significant reduction of pressure under the metatarsal heads.<sup>47</sup> Patients were analyzed while wearing just a shoe, a shoe with total contact orthoses, and a shoe with the same orthoses but with a metatarsal pad added. The total contact orthoses in this study increased the foot contact area by an average of 27%, primarily in



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*Continued on page 26*

the arch. The orthoses reduced metatarsal peak pressures by 19% to 24% and PTI by 16% to 23%. The addition of a metatarsal pad, although it did not increase contact area, reduced peak pressure by an additional 15% to 20%, and PTI by an additional 22% to 32%. The authors reported that adding the metatarsal pad increased the pressure peak at the second metatarsal shaft by an amazing 308%, indicating that, although the pad did not increase the surface area, it redistributed pressure from the metatarsal head to the shaft.

Treatment of metatarsalgia with foot orthoses alone has also been researched. The purpose of orthotic therapy is to increase the patient's tolerance of weightbearing, facilitate proper foot function, and normalize gait. The orthosis should balance weight distribution across the metatarsals by correcting or compensating for any biomechanical malalignments that alter foot biomechanics.

## Orthotic design considerations

Orthotic design should be tailored to each individual case. The disproportionately high weightbearing areas in the cavus foot can be reduced by adding support along the lateral and medial longitudinal arches.<sup>14</sup> The pes planus foot requires control of forefoot or rearfoot varus by medial posting.<sup>48</sup> Medial column instability due to excessive rearfoot pronatory motion often leads to dorsiflexion of the first ray and subsequent overloading of the second, limiting the first metatarsophalangeal joint motion.<sup>49</sup> A wide orthotic plate made from a cast with the first ray plantar flexed helps maintain contact with the more medial aspect of the foot, allows greater motion of the big toe, and enhances weightbearing under the first metatarsal head, decreasing pressure under the second metatarsal head.<sup>49</sup>

In general, the following steps<sup>14</sup> established in 1985 are still valid for orthotic management of metatarsalgia:

1. Perform a complete clinical examination;
2. Establish a diagnosis;
3. Determine which orthotic features will help achieve treatment goals;
4. Fabricate the device from the correct materials;
5. Determine the therapeutic benefit of each of the device's features;
6. Analyze the effect of the device on the patient's gait; and
7. Reevaluate the orthosis periodically.



Custom versus ready-made orthoses for metatarsalgia have been studied. Kelly and Winson found both custom and prefabricated insoles were associated with reduced plantar forefoot pressure in patients with lesser metatarsalgia, however, the custom group reported a 16% higher compliance rate and greater self-reported symptom improvement.<sup>50</sup>

Ki et al found orthoses with minimum arch fill were far more effective than flat insoles for redistributing peak plantar pressures in 30 healthy volunteers.<sup>51</sup> They also demonstrated that, the greater the contact in the arch area, the greater the decrease in rearfoot and forefoot pressures. The paper also revealed that custom devices made using either CAD-CAM technology or foam impression were far superior to flat insoles for reducing forefoot plantar pressures.

Orthotic therapy should be used only with suitable footwear. Metatarsalgia patients should use shoes with a low heel, stiff sole, and large, rounded toe box.<sup>14,52-54</sup>

A variety of orthotic approaches may be used to alter the weightbearing load at the metatarsals. Shaft padding relieves the symptomatic metatarsal head by transferring the load to the proximal metatarsal shaft. The first, second, and fifth metatarsals can be padded with flexible materials, while the third and fourth metatarsals can be supported with pear-shaped metatarsal pads.<sup>55-57</sup> The success of shaft padding requires placing the support just proximal to the metatarsal head and not underneath it.

A topcover and a forefoot extension can be used to add cushioning, which dampens force. Research suggests softer top-

cover materials give patients more comfort and increase their tolerance of orthotic devices,<sup>58</sup> which may have implications for multiple pathologies. Materials such as closed-cell neoprene, plastazote, and Poron can add shock absorption under the forefoot.

Topcovers require periodic replacement, dependent on patient weight, moisture, and frequency of use. Since compression of very soft materials over time negates the benefits of shock absorption the patient needs, noncompliance and loss of effectiveness can result if these materials are not replaced. Poron extensions that maintain their ability to cushion the metatarsal heads also attenuate pressure by delaying compression. (ler)

*Howard Kashefsky, DPM, is the director of podiatry services at the University of North Carolina Hospitals in Chapel Hill.*

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## Skin care issues related to orthotic device wear

The care and prevention of skin issues may not get as much attention in orthotics as in prosthetics, but such issues can significantly affect patient outcomes. Here, lower extremity experts share the tips and tricks they use to manage dermatological challenges related to orthotic devices.

By Lori Roniger

Modern orthotic devices are designed to fit more intimately than in the past, a development that allows for more effective biomechanical correction. But this evolution has also led to an increase in the incidence of lower extremity skin issues related to structural or environmental stresses.

Other trends, such as a greater number of people living with type 2 diabetes, diabetes-related peripheral neuropathy, and stroke, have increased the population of patients using ankle foot orthoses (AFOs) and other lower extremity orthotic devices who are susceptible to skin breakdown and other issues. And those with spinal cord injuries and decreased sensation in their lower extremities can present skin-related challenges for practitioners.

"You really didn't have too many skin-related issues in the past," said Harry "JR" Brandt Jr, CO, LO, BOCO, director at Collier Orthotics and Prosthetics in Pleasant Hill, CA, of older-style devices.

Brandt, who has worked as an orthotist for 35 years, pointed out that socks and silicone liners are often discussed in prosthetics and in relation to protecting the existing limb, but there's less of that type of discussion with regard to orthotic devices. He noted, however, that practitioners are increasingly utilizing thermoplastic orthotic devices with more contact points, which can provide greater control but also lead to more skin issues.

"It's important to manage that tissue correctly to reduce or eliminate the forces involved," he said.

Josh Ahlstrom, CPO, an orthotist and prosthetist with Midwest Orthotics and Technology who is based in Indianapolis, IN, focuses on the pediatric population and encounters skin issues in some of his patients.

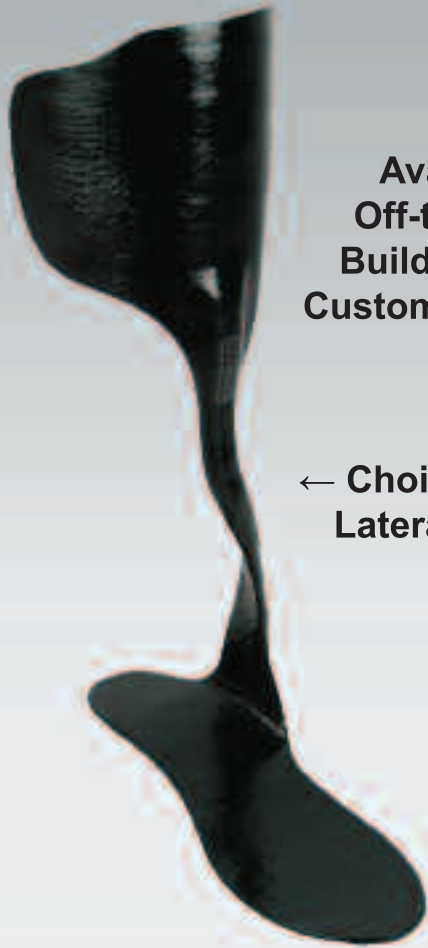
"One of the problems that leads to skin irritation is trying to take a mobile object and put it in something that doesn't let it move," Ahlstrom said.

The goal, he said, is to equalize pressure distribution all around the foot and to put patients in a brace that moves when the foot moves. An AFO-SMO (supramalleolar orthosis) combination is a

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total contact brace that allows the foot to have natural movement, he said.

Skin issues that practitioners see and seek to prevent in patients who use lower extremity orthotic devices include pressure and diabetic ulcers, blisters, calluses, fungal infections, and problems related to perspiration and edema. At the very least, these issues can negatively impact patient's quality of life and compliance with device wear; at worst, they can significantly increase the risk of amputation.

## Sock watch

One of the key ways clinicians help patients protect their skin is by recommending they wear appropriate socks. While there's some variety in the type of socks and sock material that practitioners prefer and recommend, they all strive to help keep patients' skin dry.

"You can have the best-fitting AFO that you've ever seen, and if you get them in a thin nylon sock [or any sock that doesn't provide effective perspiration wicking] and an ill-fitting shoe, it basically negates what you've just accomplished through this wonderful fitting, and you end up back in the office with pressure sores around the toes," Brandt said.

He recommends athletic socks that contain padding and are made of acrylic fibers and yarns, polyesters, nylon, and wool. Brandt said these socks help to wick away perspiration and keep skin dry and less susceptible to shear forces. He usually recommends a boot sock or uniform sock with some compression.

He also tells patients lacking sensation to wear white socks so that if a sore starts to blister it will show on the sock.

David Misener, CPO, who practices at Clinical Prosthetics and Orthotics in Albany, NY, said that, even in patients with normal skin integrity, perspiration is a significant issue that can affect the skin where the orthotic device makes contact. This can affect all types of patients and present problems during any season of the year where he practices. Although complaints about perspiration can come from almost any patient, he said, they can be much more of a problem with total contact designs that don't allow air to circulate or moisture to evaporate.

Misener suggests patients wear wicking clothing, socks that contain wool blends, or good quality athletic socks.

"I find more often than not that the patients have a particular preference," he said.

Ahlstrom, who noted that his pediatric population can experience skin irritation, blisters, increased reddening, and calluses with lower extremity orthotic devices, recommends that socks fit appropriately and don't have wrinkles or creases that can create pressure points on the skin. Although there are some great AFO socks, he said, those can be relatively expensive, and a well-fitted cotton athletic sock can do the trick in most cases.

Ahlstrom also advises his young patients, some of whom have "particularly sweaty little feet," to change socks during the day around lunchtime.

"Changing socks throughout the day can do wonders for reducing blisters," he said.

Sean McKale, CO, an orthotist with Midwest Orthotics in Chicago, doesn't get fancy with his sock recommendations, telling patients to go for cotton versus acrylic socks.

"They wear what they want to wear," McKale said. "Some patients wear taller socks and some ankle socks. There doesn't seem to be too much of a problem."

Jason Jennings, CPO, area clinic manager with Hanger Clinic in Houston, also recommends cotton socks, as well as changing them at least every eight hours year-round, in part because of the Texas heat.

Likewise, the sock recommendations of Chris Toelle, LCO, regional area clinic manager for Hanger in Sarasota, FL, are influenced by the warm, humid climate there. He said thick nylon and wool socks for AFOs are "intolerable" there, but socks made of cooling materials, blends, and military-inspired materials are good choices. He said a traditional sock can be very hot under a lower extremity orthotic device and cause skin to break down and look like it has just emerged from a pool.

For feet that are slipping or uncomfortable in orthotic devices, Tracey Vlahovic, DPM, an associate professor at Temple University School of Podiatric Medicine in Philadelphia who focuses on skin issues, recommends socks containing copper or silver fibers.<sup>1,2</sup>

"It won't cure sweaty feet, but it can certainly make them more comfortable," Vlahovic said. The embedded fibers can also be deodorizing or antimicrobial, which can help with athlete's foot.

*Continued on page 32*

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## Dry ideas

Although choosing the right socks to wear under lower extremity orthotic devices and changing them frequently can help reduce perspiration problems, some practitioners, like Vlahovic, also recommend other strategies for keeping their patients dry.

Sweaty feet are probably “the biggest thing” she sees related to orthotic devices, she said.

She noted that leather orthotic topcovers can increase sweating in some patients or make it feel like the foot is slipping, so using a different topcover material can be helpful.

If the underlying cause of sweaty feet is hyperhidrosis, however, the use of topical aluminum chloride solution (Drysol) under a physician’s direction can be effective at reducing sweating, she said. If that doesn’t control the problem, Botox injections are another reasonable treatment.<sup>3</sup>

Jennings, working in Texas, recommends simply applying commercial antiperspirant directly on lower extremity skin.

To reduce friction caused by sweaty feet and wet socks, Ahlstrom likes to apply thin, adhesive, low-friction interface material manufactured with polytetrafluoroethylene (PTFE) film directly to the inside of a brace. It can be cut into any shape and can reduce shear forces and prevent tackiness even if a sock is wet, he said.

McKale said that, for some of his patients who wear a molded inner boot that controls side-to-side motion and experience greater sweat accumulation, he modifies their boots by adding small air holes, each the size of a belt buckle hole, using a hand punch tool.

Jennings noted that fungal infections, like athlete’s foot, can occur anywhere on the body, including the ankles and thighs, but are sometimes mistaken for a rash. If an over-the-counter antifungal medication doesn’t help, patients should be referred to a physician.

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## Put a shoe on it

Although it's important for socks and lower extremity orthotic devices to work well together in order to protect skin, Brandt emphasized the importance of helping patients select appropriate footwear when initially evaluating them, so that all components work together as a unit.

"A large percentage of patients wear shoes that are too big or small or ill-fitting," Brandt said.

When fitting the orthotic device, he'll sometimes recommend shoes that are a half-size bigger or a different type of shoe, such as styles with a deeper toe box or athletic shoes that come in a range of widths that can accommodate extra volume.

## Pros and cons of contact

Practitioners also noted the type of lower extremity orthotic device used and proper fitting are also key for avoiding skin issues.

McKale, who tends to fit patients with carbon-fiber AFOs that have an open design, says this style is less problematic for the skin than total contact polypropylene AFOs that have less air flow.

"I don't deal with a lot of skin issues," McKale said. "The advantage of a carbon-fiber system is less total contact."

He noted some AFOs come with removable liners that can be washed, which may help avoid skin issues.

A total contact AFO, however, can be a good choice for some patients. If, for example, a posterior-leaf type design creates skin issues at high-pressure areas, the total contact design can help distribute that pressure, Brandt said.

## Modifications

Brandt noted that certain modifications to improve the fit of an orthotic device can be helpful for preventing skin issues. He recommends paying special attention to bony prominences, taking time

*Continued on page 34*

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to identify those areas appropriately when casting, and wrapping them with elastic bandages to accentuate them and compress the soft tissue evenly.

"The challenge of course goes up exponentially if there are skin or [muscle] tone or vascular issues," Misener said.

Pressure issues, sores, and abrasions can occur when there is too much pressure over a specific area, he said.

"Our goal is to reduce the peak pressures at that point," Misener said.

Design changes or dynamic stopping can help realign the anatomy in ways that minimize the risk of skin issues, he said. For example, stroke patients who develop pressure sores when using a brace dynamically can benefit from a structure created within the device to address pronation or supination.

Toelle, who sees a large population of young and old patients with diabetes in southwest Florida, said he prefers to fit lower extremity orthotic devices for people with diabetes in the afternoon, when they're at their worst in terms of edema. If the device ends up a little too big at times when the edema is less severe, padding or socks can help. A removable diabetic insert can help adjust pressure to the bottom of the foot over time while using the same brace.

Toelle said he sees a lot of skin issues related to AFO use in patients with drop foot from multiple diagnoses, such as stroke, diabetes, or cardiac or blood flow issues. He also uses a lot of stance-control devices and knee ankle foot orthoses (KAFOs) in stroke patients with weaknesses in the extremities; because these devices cover a larger area of the leg, they are even more likely to be associated with skin issues than lower-profile devices.

Working with children, Ahlstrom uses a lot of very flexible plastic.





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He said this can wrap around the foot to create total contact and even pressure distribution and help avoid common hot spots. Overpronation in children can produce redness at the navicular, medial malleolus, the lateral portion of the calcaneus, and the fifth metatarsal head.

## Change is good

Sometimes patients require a change in device; for example, a teenaged patient with spina bifida who came to Brandt after an old solid-ankle AFO had created a large pressure wound. To address the pressure issue, he fit the patient with a total contact two-piece AFO that distributed pressure over a larger area. To provide an intimate fit, a cast was custom-made for the patient. He noted the patient was at a key developmental point at which the orthotic solutions that had worked in the past might not work in the future.

Patients with an existing wound typically need to transition to a CROW (Charcot restraint orthotic walker) boot or another type of walker until the wound heals. In particular, diabetic ulcers and pressure ulcers should be offloaded immediately, which can be done by creating room in the orthosis or padding around the area, Jennings said.

Ahlstrom recalled a child with cerebral palsy who had been getting bigger, heavier, and more difficult to manage in terms of tone and pronation. He wore a traditional AFO of rigid plastic but was developing a significant callus over the navicular bone. He was then switched to an SMO, fit into the AFO, to address the callus issue with a more forgiving material without sacrificing stability.

"A lot of times skin irritation is a result of trying to get the body to do something that it maybe doesn't want to do," Ahlstrom said. "The goal in orthotics is to try to put the body in better alignment so it can function the way it's designed to function. It's good to move forward with techniques and materials that work with the body and not against it." 

Lori Roniger is a freelance writer based in San Francisco, CA.

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## Using subsensory noise to improve balance, gait

Using specially designed insoles to deliver stochastic resonance to the plantar surface of the feet has the potential to significantly improve static balance, dynamic balance, and gait mechanics in healthy, young individuals as well as elderly people and others with somatosensory deficits.

By Daniel Miranda, PhD; Wen-Hao Hsu, ScD; and James Niemi, MS

The existence of noise (in this context, a random, unwanted signal) in most systems or environments is typically considered a problem. In fact, engineers and scientists have spent decades pursuing ways to reduce or eliminate noise in a range of applications. Noise-cancelling headphones and photo-processing software are two examples of applications in which reducing noise is critical to obtaining crisp sounds and sharp images, respectively.

However, physicists and scientists from the 1980s to the mid-1990s reported applications for which the introduction of nonlinear noise to certain systems or environments enhanced the detection and transmission of weak signals.<sup>1</sup> This phenomenon, coined stochastic resonance (SR), indicates that the flow of information through certain systems is improved by the inclusion of a specific level of noise. At the time, it was hypothesized that the sensory systems and perceptual processes may be able to take advantage of this phenomenon to improve the detection of weak stimuli.<sup>2</sup>

Collins and colleagues confirmed this hypothesis in a series of experiments involving human participants, in which subsensory SR noise improved tactile sensation by acting as a suitable pedestal for enhancing the detection of weak, normally undetectable, stimulations (Figure 1).<sup>3</sup>

### Early insoles and standing balance

This was an exciting finding because it suggested the introduction of SR to the human sensory system might enhance the detection of weak stimuli in persons with sensory deficits caused by normal aging, stroke, diabetes, or other neurological disorders in addition to individuals with intact, normally functioning systems.<sup>4</sup> From a clinical perspective, in the lower extremities, this sensory feedback provides important information to the human balance control system that, when diminished, is associated with an increased risk of falling.

Collins hypothesized that the application of SR to the soles of the feet might improve standing balance, with eventual applications in walking and fall prevention.<sup>5</sup> To test this hypothesis, Priplata and

Introducing stochastic resonance to the human sensory system enhances the detection of weak stimuli, which can help improve balance and reduce fall risk.

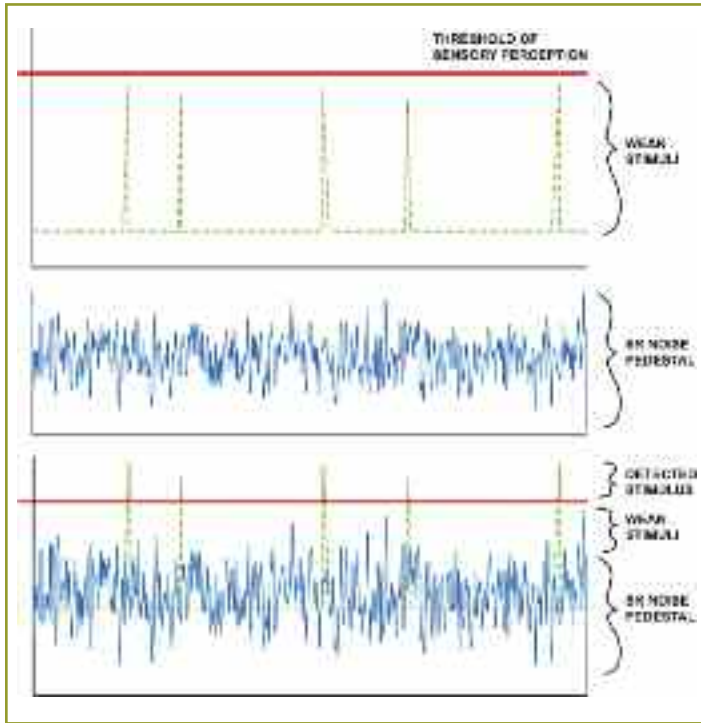


Figure 1. The theory behind how stochastic resonance (SR) may improve tactile sensation is illustrated here. A weak stimulus below an individual's threshold of perception is enhanced by the inclusion of subsensory stochastic resonance noise. The subsensory SR noise acts as a pedestal from which the transmission capabilities of stimuli are enhanced, allowing the human sensory system to detect subthreshold stimuli.

colleagues designed a series of experiments using a pair of large stationary devices modeled after insoles (Figure 2A).<sup>6-8</sup>

Their experiments measured sway parameters during quiet standing in young participants, elderly participants, patients with diabetes, and patients with stroke. Their findings indicated that application of SR to the plantar surface of the feet was associated with reduced postural sway parameters in each of the tested populations. Interestingly, differential effects of SR were observed between young people and those with sensory deficits (eg, elderly people, patients with diabetes, patients with stroke).

The authors suggested the young, healthy participants were already operating at a near optimum level of sensory function. Therefore, the capacity for improvement in standing balance with SR appears to depend on the baseline level of sensory impairment. The observed balance improvements lead to the question of whether the SR phenomenon would be effective in enhancing performance of activities involving dynamic balance, such as walking.

The vast majority of falls and fall-related injuries in persons with sensory deficits occur while walking or doing walking-related activities.<sup>9,10</sup> Therefore, the early stationary SR devices needed to be redesigned for in-shoe use in order to perform studies investigating dynamic balance activities. Actuators were first placed in sandals to permit walking and then tethered with cables to the signal electronics and batteries (Figure 2B). This new iteration provided a platform to investigate the effects of SR on gait in healthy and at-risk patient populations.

## Spatiotemporal parameters of gait

Certain spatiotemporal gait characteristics, which are quantifiable measures of gait function, have been associated with fall risk in people with sensory deficits. These characteristics have been traditionally separated into two categories: those associated with the rhythmic stepping parameters of gait, such as stride length and stride time; and those associated with the balance control parameters of gait, such as stride width and double-support time (the time both feet are in contact with the ground).<sup>11</sup>

High variability in the rhythmic stepping parameters of gait is generally associated with gait instability and fall risk, as is high variability in the sway parameters measured during standing balance.<sup>12,13</sup> Interestingly, both high and low variability in the balance control parameters of gait have been associated with gait instability, with the understanding that some moderate level of variability is required for stability.<sup>12,14,15</sup> For example, some step-width variability is important biomechanically because it provides a certain level of adaptability to limb movements and allows an individual to adapt and maintain stability during walking.

With low step-width variability, there is no flexibility to respond to perturbations. On the other hand, high step-width variability is typically associated with crossing one foot in front of the other during walking, which can narrow and offset the base of support and is a clinical indicator of unsteady walking.

## Using SR to improve dynamic balance

From a clinical perspective, SR applied to the plantar surface of the feet could improve dynamic balance during gait in two ways: first, by reducing high variability in the rhythmic stepping parameters of gait; and second, by increasing the variability in the balance control parameters of gait for the least variable walkers or decreasing the variability for the most variable walkers.

Using a tethered sandal device similar to the pair shown in Figure 2B, Galica and colleagues aimed to evaluate the effects of SR applied to the plantar feet on the rhythmic stepping parameters of gait in healthy young adults, elderly nonfallers, and elderly fallers as they walked at a self-selected pace on a circular track.<sup>13</sup>

At baseline, the elderly fallers had the highest variability in rhythmic stepping parameters (stride time, stance time, swing time), followed by the elderly nonfallers and the healthy, young participants. With the introduction of SR to the plantar surface of the feet, reductions in variability were observed for each of the rhythmic stepping parameters in all three participant populations. Moreover, the largest reductions were observed in the most variable walkers (elderly fallers), followed by the elderly nonfallers, and then the young participants (these participants did not experience statistically significant reductions).

This was the first study to show that SR applied to the plantar feet during the gait cycle can reduce rhythmic stepping variability in elderly participants who are at risk of falling.

Although rhythmic stepping parameters are important for the clinical potential of SR technology, it's generally accepted that balance control parameters of gait are more closely associated with falls and better predict fall risk. As mentioned, affecting the balance control parameters is a two-way proposition. That is, the most variable walkers may need to reduce their variability to steady their

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walking, and the least variable walkers may need to increase their variability to introduce a certain level of adaptability in limb movements while walking. Therefore, proprioceptive improvements from SR that would push certain individuals into a more optimal state differ from the proprioceptive improvements that would be effective in other individuals, depending on their baseline level of balance control variability.

In a follow-up study, Stephen and colleagues set out to test whether SR exerted a baseline-dependent effect on the balance control parameters of gait in elderly participants.<sup>12</sup> Using the same tethered sandals, similar to the pair shown in Figure 2B, the authors investigated the effect of SR on stride length and stride width while participants walked at a constant speed on a treadmill. Confirming their hypothesis, the results indicated a baseline-dependent effect of SR, where the least variable walkers demonstrated more variability, and reductions in variability were observed in those who were most variable at baseline.

## Our recent work

To this point, the vast majority of research has focused on elderly individuals or patients with diabetes or stroke who have the potential to benefit most from the sensory improvements gained from SR applied to the plantar surface of the feet. Moreover, the observed improvements appear to be greatest for the individuals with the largest sensory deficits. This trend appears to be consistent from the standing balance studies through to more recent gait studies. Despite this, the few studies that have involved healthy, young individuals have reported only small or trending balance and gait

improvements associated with SR in that population.<sup>6,13</sup>


During normal locomotion, healthy young persons are not at risk for falls or fall-related injuries, and their somatosensory systems are likely operating at an optimal state with a limited capacity to improve. This eliminates the need for sensory-enhancing SR technology during typical daily activities. However, sensory deficits do occur in healthy, young people performing vigorous activities that cause fatigue.<sup>16-18</sup> These sensory deficits can place them at higher risk for slip-, trip-, and fall-related injuries when they are competing in long, strenuous athletic activities or military marches.

With a newly designed three-quarter-length insole device that uses a tethered control program (Figure 2C), we set out to test the effect of fatigue. We induced fatigue through a task simulating a strenuous recreational hike or military march and measured its effects on spatiotemporal gait parameters.<sup>19</sup> Our goals were to determine if sustained vigorous walking on an inclined surface while carrying a backpack load destabilizes gait, and if SR applied to the planar surface of the feet has a stabilizing effect.

We fitted participants with a backpack weighing approximately 30% of their body weight and fitted their standard athletic shoes with the new insole devices. We then asked them to walk at a self-selected pace on a treadmill and tracked their foot position with a motion-capture system. The protocol started the participants at level ground and increased the incline by 2% every five minutes until participants reached volitional exhaustion, after which the treadmill was returned to level ground.

Throughout the protocol we applied SR to the plantar surface of the feet in a random fashion, such that pairs of trials were recorded

*Continued on page 42*



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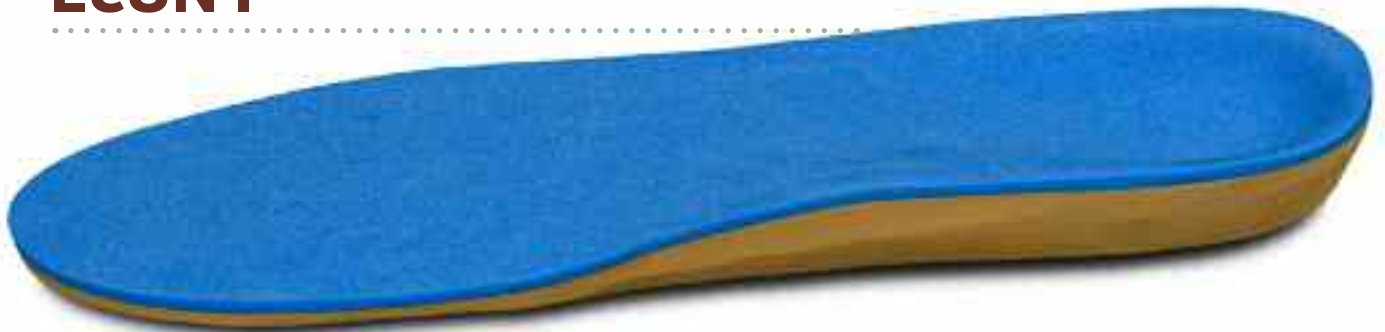
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Figure 2A-2D. Evolution of stochastic resonance (SR) vibrating insoles. A. Stationary SR devices modeled after insoles, designed by Priplata and colleagues.<sup>6-8</sup> B. Actuators were first placed in sandals (pictured) to permit walking and then tethered with cables to the signal electronics and batteries.<sup>12,13</sup> C. A newly designed three-quarter-length insole device that uses a tethered control program.<sup>19,20</sup> D. A prototype of an SR device containing the vibrating elements, battery, and electronics that charge the device wirelessly and allow it to communicate with a computer or smartphone.

in which SR was on for one minute and off for one minute. As in all the experiments, the subsensory level of the SR signal blinded participants the stimulus condition. We extracted spatiotemporal gait characteristics for SR-on and SR-off conditions during the baseline level-ground walking period, the period just prior to reaching volitional exhaustion, and the end level-ground walking period.

Our results indicated that, without SR, vigorous activity increased the variability in the rhythmic stepping and balance control parameters of gait. Not surprisingly, our healthy, young participants had relatively low overall baseline variability. We concluded the undesirable increase in rhythmic stepping variability led to a compensatory increase in balance control variability.

We believe this is a compensatory response, in which the relatively low baseline variability is pushed to a heightened state of adaptability to stabilize each participant's gait during vigorous activity. If so, we hypothesized, the introduction of SR would enhance stimulus detection while fatigued, resulting in a reduction in rhythmic stepping variability and an increase in balance control variability.

We observed no effect during any part of the task when SR was on compared to when it was off for the rhythmic stepping parameters. However, we did observe an increase in the variability of the balance control parameters throughout the task when SR was turned on compared to the off condition, independent of fatigue state. Therefore, applying SR resulted in additional benefits to balance control parameters of gait that may improve stability in healthy,

young individuals who are experiencing vigorous activity and fatigue.

Finally, these results suggest that other athletic populations that become fatigued during training or competition may get injury prevention or performance benefits from a sensory-enhancing device, though additional research is needed.

## Outstanding questions

We have substantial evidence that SR applied to the plantar surface of the feet improves sway parameters during quiet standing and spatiotemporal gait parameters during walking in elderly people, people with somatosensory deficits, and healthy, young individuals. In parallel, we have seen substantial engineering effort put into the sensory improvement devices. They have evolved from bulky static gel insoles to a form factor modeled after a standard three-quarter-length insole device. Despite the research promise and device development, additional research questions remain, and a fine-tuning of the device design is needed to bring this technology to the clinic or sports equipment store.

From a research standpoint, questions about the longevity of beneficial effects, as well as the amplitude range of subthreshold stimulation, still remain. Each study mentioned in this review used a level 10% below each participant's sensory perception threshold.

Continued on page 44



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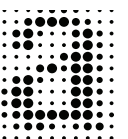
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However, would 15% or even 30% below the threshold still provide the desired effect? It is also unclear if the sensory benefits are acute or persist over a long duration. Furthermore, not much is known about how stable an individual's sensory perception threshold is. Does the threshold vary throughout the day or over the course of multiple days? Most importantly, all of the research to date has been limited to measurements quantifying sway and spatiotemporal gait parameters. These metrics are associated with falling and injury risk, but it is still unclear if SR technology will translate to actual reductions in falls and injury rates among at-risk elderly people, patients with sensory deficits, athletes, or military personnel.

Some of these questions have been addressed in a recent study from Lipsitz and colleagues, who tracked a small group of elderly persons using the shoe-mounted three-quarter-length insoles (shown in Figure 2C).<sup>20</sup> The investigators sought to determine whether the balance and gait improvements would persist throughout a day, whether sensory thresholds were consistent, and whether different levels of SR could still achieve the same beneficial effect.

The study provided strong evidence that individual sensory perception thresholds are relatively stable and that SR technology is not an acute phenomenon. Furthermore, SR levels set at 15% and 30% below the perception threshold were equal to each other in effectiveness. These findings suggest SR is not an acute phenomenon, and greatly simplify setting the subsensory threshold stimulation level of a future, commercially available device.

## The future of SR devices

From a device development standpoint, recent advancements in battery, charging, and microelectronic technology could make a self-contained insole device possible in the near future. A device similar to the prototype shown in Figure 2D could contain the vibrating elements, battery, and electronics that charge the device wirelessly and allow it to communicate with a computer or smartphone. Such a device would appear indistinguishable from the replacement insoles found on drugstore shelves and sports equipment stores.

Most importantly, this device could be deployed in large clinical studies to establish a direct link between SR and injury risk in people with sensory deficits as well as in healthy individuals. The hope is that, soon, people will be able to come to the clinic or store, have their sensory threshold determined, and then be fitted with a device that improves their sensation with just a little bit of noise. 

*Daniel Miranda, PhD, is a technology development fellow; Wen-Hao Hsu, ScD, is a postdoctoral research fellow; and James Niemi, MS, is a lead senior staff engineer at the Wyss Institute at Harvard University in Boston.*

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## Hip strength asymmetry and patellofemoral pain

Hip strength asymmetry has been observed in patients with existing patellofemoral pain syndrome (PFPS) and potentially could be used to screen for at-risk individuals. However, new findings suggest this type of asymmetry does not appear to be associated with early stage PFPS.

By Franklin Caldera, DO, MBA; and Christopher Plastaras, MD

Patellofemoral pain syndrome (PFPS) is one of the most common overuse knee injuries seen in sports medicine and orthopedic clinics. Here, the term “overuse” injury refers to the effects of repeated minor trauma to the knee joint. The trauma is usually from recreational or competitive jumping or running as a sport or part of a sport. The injury occurs gradually and symptoms may not at first interfere with participation.<sup>1</sup>

The most common symptom of PFPS is diffuse anterior knee pain around the patella. Individuals have difficulty describing the location of the pain and when doing so may place their hands over the anterior patella in a circular motion (the “circle sign”).<sup>2</sup> Pain usually occurs when the knee extensor muscles experience load, such as when ascending or descending stairs or when doing slopes, squatting, kneeling, or running; it can also occur following prolonged sitting with flexed knees (the “theater sign”).<sup>3</sup>

PFPS can be seen in both men and women who participate in running and running-related sports. It accounts for approximately 25% of all knee injuries.<sup>4</sup> Reliable clinical diagnostic tests have not been developed yet, so diagnosis is typically made based on a clinical exam and exclusion of other causes, such as intraarticular pathologies, patellar tendinopathy, and plica syndrome.<sup>5</sup>

### PFPS and hip abduction in women

Many studies have shown that women are at higher risk of developing PFPS than men.<sup>6</sup> One study reported the ratio of female to male patients with PFPS is as high as three to one.<sup>7</sup> Many factors have been suggested as possible causes of PFPS, including an increased Q angle, patella alta, abnormal or excessive foot pronation, vastus medialis muscle weakness, hip abductor weakness, decreased flexibility of the hamstring muscles, and malalignment of the femur.<sup>8,9</sup> It has also been suggested that anatomic, hormonal, and neuromuscular factors contribute to women’s greater risk of developing PFPS.<sup>10</sup>

Several studies have reported that hip kinematics during running

The easiest way to identify hip strength deficits associated with PFPS—to facilitate early intervention—would be to assess between-limb hip strength symmetry.

differ between healthy men and women, and these differences may help explain the gender differences in PFPS incidence. In their landmark paper on the condition, Powers et al noted that women exhibit greater internal rotation of the femur and larger hip adduction during running than men.<sup>11</sup> Ferber et al reported significantly greater peak hip adduction and hip internal rotation during the stance phase of running in female recreational runners compared with their male counterparts.<sup>12</sup> Willson et al also found female runners had greater hip adduction than male runners both at initial contact and at the time of peak vertical ground reaction force.<sup>13</sup>

Studies of female runners have also reported that hip kinematics differ between runners with PFPS and healthy individuals. Noehren et al found greater peak hip adduction and hip internal rotation during running in women with PFPS than in healthy controls;<sup>14</sup> in a prospective study, the same group found female runners with greater hip adduction at baseline were the ones most likely to develop PFPS.<sup>15</sup> Souza and Powers also found greater peak hip internal rotation in female runners with PFPS during multiple activities than in healthy controls.<sup>16</sup>

Cichanowski<sup>17</sup> and Ireland<sup>18</sup> theorized the kinematics of the lower extremity associated with PFPS might change as a result of deficits in hip muscle strength. Gluteal weakness has been implicated in other knee pain syndromes, such as iliotibial band syndrome.<sup>19</sup> In female athletes with unilateral PFPS, Cichanowski et al found less hip abduction strength and hip external rotation strength in the affected leg compared with the unaffected leg and compared with the corresponding limb of healthy controls. Ireland et al also reported that young women with PFPS were more likely than controls to demonstrate weak hip abductors and external rotators. In their aforementioned study, Souza and Powers found that female runners with PFPS had less hip abductor strength and hip extensor strength than healthy controls, as well as altered kinematics.<sup>16</sup>

The success of hip-strengthening programs in individuals with PFPS also supports the theory that deficits in hip muscle strength contribute to PFPS development. Dolak et al found that improvement in hip abductor strength was associated with improvement in symptoms in women with PFPS.<sup>20</sup> Khayambashi et al found similar symptom improvement associated with increased hip strength in

women with PFPS, and that the symptom improvement was sustained six months after the strengthening intervention.<sup>21</sup> Ferber et al observed that increased hip strength was associated with reduced pain in individuals with PFPS. Those improvements were not associated with any change in lower extremity kinematics, but the study included both men and women with PFPS.<sup>22</sup> Those findings contrast with those of Baldon Rde et al, who found that improvement in gluteus medius strength had a mediating effect on frontal plane trunk and hip kinematics in female athletes with PFPS.<sup>23</sup>

It would be clinically useful to be able to identify hip strength deficits in the early stages of PFPS so that strengthening interventions could be implemented before symptoms become severe. The most convenient way to do this would be to compare hip strength in the affected and unaffected limbs, based on the assumption that hip strength would be more symmetrical in healthy individuals than in individuals with or at risk for PFPS. We conducted a study to address this issue.



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## Our research

In designing our study, we considered studies such as Magalhaes et al<sup>24</sup> and Robinson and Nee.<sup>25</sup> These studies investigated hip abduction strength symmetry in female patients with PFPS and

Continued on page 50



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reported 12% and 22% reduction, respectively, in hip strength of the leg with PFPS compared with the unaffected side. Both studies included control groups. Magalhaes et al reported that the hip abductors, lateral rotators, and flexors and extensors on the injured side of those with unilateral PFPS were significantly weaker than in those without the pain syndrome; only the hip abductors, however, were significantly weaker on the injured side than the uninjured side in those with PFPS (20%,  $p < .05$ ).

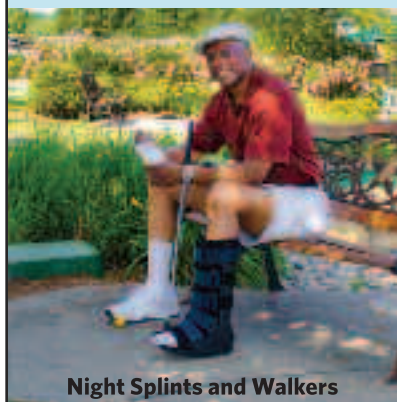
In a secondary analysis, Robinson and Nee found that the symptomatic limbs of participants with PFPS had less hip extension strength ( $p < .001$ ), less hip abduction strength ( $p = .007$ ), and less hip external rotation strength ( $p = .04$ ) compared with the control's weaker limb. Cichanowski et al also showed less hip abduction, external rotation, and extension strength in female patients with PFPS than in healthy controls.<sup>17</sup>

Our study was prospective. We recruited 21 study volunteers (female runners with early PFPS) and 36 healthy controls using flyers and recruitment in the vendor section at local road races, half marathons, triathlons, and running club meetings in a metropolitan area. The participants were women aged between 18 and 45 years who ran at least 10 miles per week. We defined early PFPS with the following criteria: a report of unilateral anterior knee pain associated with running once per week for at least six weeks, pain with a single-leg squat, compression of the patella into the femoral condyles, and pain with palpation of the anterior surface of the patella.

Continued on page 52

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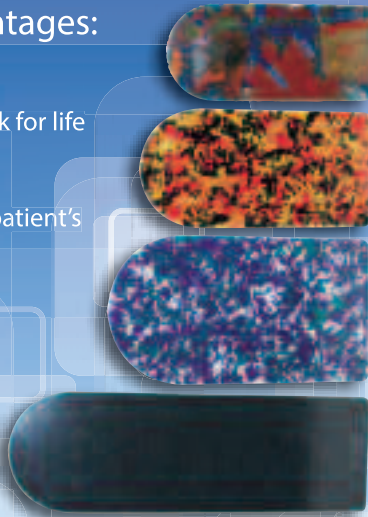
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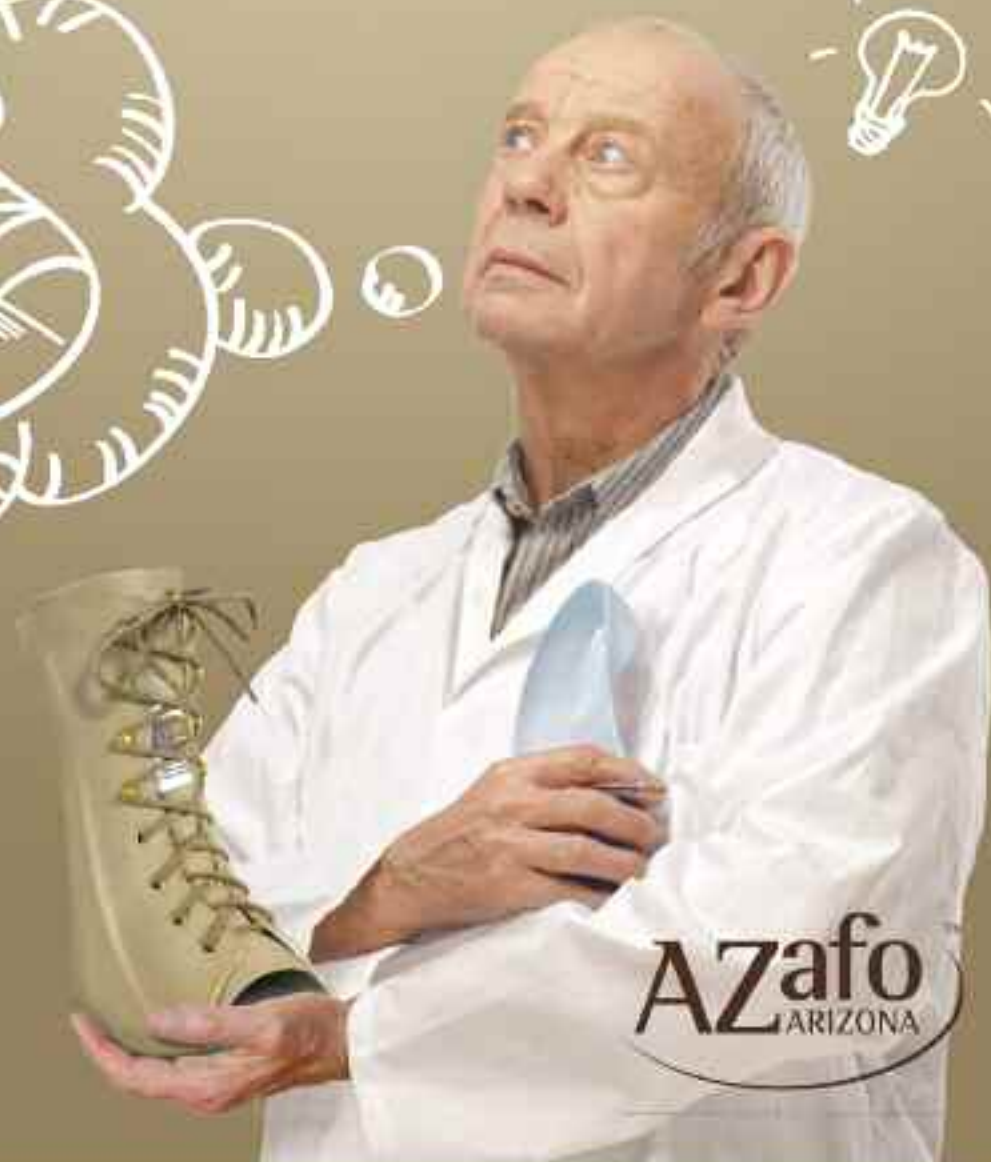
After telephone prescreening, we did an assessment using four stations to gather further data needed to include or exclude patients. First-station participants filled out an autobiographical questionnaire. At the second station, participants underwent bilateral hip strength testing by a single trained examiner blinded to the groups. Hip strength was tested in a neutral position to recruit the tensor fasciae lata muscle and in an extended position to recruit the gluteus medius muscle.<sup>19</sup> At the third station, an examiner blinded to the group measured participants' height, weight, and leg length discrepancy. At the fourth station, participants underwent a focused physical examination of the knee by another examiner blinded to group assignment.

Analysis of baseline characteristics of the group of women with early unilateral PFPS and controls did not show significant differences between the two for height, weight, age, leg length discrepancy, or weekly running mileage.

We calculated hip abductor strength complex asymmetry using the Hip Strength Asymmetry Index (HSAI). P values greater than .05 were considered statistically significant. Female runners with early symptoms of PFPS did not appear to have clinically significant hip abduction strength asymmetry compared with healthy controls. HSAI values for the hip abductors with 95% confidence intervals did not differ significantly between the runners with PFPS and the controls ( $p = .2272$  when tested in the neutral position,  $p = .6671$  when tested in extension).

Our study found the affected PFPS limb was stronger than the weaker limb of the controls (in the neutral position) and not signifi-

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cantly different from the unaffected limb in the PFPS patients. Both findings were unexpected and in contrast with previous studies. The asymmetry may be theoretically explained by the fact that the tensor fascia lata and the gluteus medius are engaged during strength testing in the neutral position. The tensor fascia lata may be engaged more significantly in early stages of PFPS; this would help to unload stress on the knee, leading to stronger abductors on the affected side when tested in neutral. Our findings of no significant asymmetry in the PFPS patients could indicate that the imbalance takes time to develop, and therefore may not be measurable until the later stages of PFPS.

## Clinical implications


Studies have shown that women with PFPS have less hip abduction strength on the affected side compared with the hip strength in the asymptomatic controls.<sup>26</sup> Dolak et al<sup>20</sup> showed strengthening of hip abductor muscles during rehabilitation in early phases of PFPS decreases symptoms more quickly, so, if weakness or asymmetry associated with worsening of PFPS could be identified early, then interventions could be implemented before symptoms progress to clinical relevance. We performed our study to develop a prescreening tool for female athletes in the early stages of PFPS, but did not find any evidence of hip abduction strength asymmetry at this early stage.

Accepting that hip strength testing is difficult to quantify, we believe our methods were the best that are currently available. However, our results indicate that, unlike PFPS patients seeking medical care, women with early PFPS do not appear to have significant hip abduction strength asymmetry.

## Conclusion

During our literature review we came across multiple studies that showed weakness in hip muscle strength in patients with PFPS. However, it remains unclear if the deficit in hip abduction strength is a cause or effect of PFPS; it's the classic "chicken or egg" question—which came first, the symptoms or the underlying hip weakness? Herbst et al's<sup>27</sup> prospective study showed that female athletes who develop PFPS may actually have greater hip abduction strength at baseline than those who do not develop PFPS, which seems to suggest that any subsequent strength deficits are more likely to be an effect of PFPS than a cause.

Further studies are needed to dissect out which mechanism leads to PFPS. Furthermore, no studies have yet assessed hip muscle endurance and PFPS, which may be important as the syndrome occurs predominantly in endurance sports.

The cause of PFPS is still poorly understood and the mechanism of injury needs further study to facilitate development of clinically useful screening tests. Further study of the evolution of patellofemoral pain may help to prevent the occurrence of this pathology. 

*Franklin Caldera, DO, MBA, and Christopher Plastaras, MD, are assistant professors in the Department of Physical Medicine and Rehabilitation at the University of Pennsylvania Perelman School of Medicine in Philadelphia. Plastaras is also director of the Spine, Sports, & Musculoskeletal Medicine Fellowship at the University of Pennsylvania.*

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Vantage Camera  
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Vicon's new flagship camera, Vantage, combines technology with accessible design to open up motion capture to a broader audience. The camera's individual components have been designed to work together to provide up-to-the-minute information so the user can make adjustments in real time. A host of new sensors continuously monitors performance, providing visual feedback through the on-board camera display, the software, and the new Control tablet application. The Vantage offers 16-MP resolution and includes completely re-engineered processing algorithms and tracking capabilities.

Vicon  
303/799-8686  
vicon.com



Jellyfeet  
Foot Covers

Jellyfeet occlusive foot covers are reusable, multiuse products that offer protection, aid in treatment, and enhance moisturization. They serve as a barrier between the skin and dirt or other harmful agents on the ground. Because they are water resistant and impermeable to lotions and creams, they are suitable for wearing after the application of ointments, topical medications, or lotions. These foot covers are nonallergenic, and their durability allows them to be used repeatedly indoors and outdoors. Jellyfeet covers provide a slight amount of compression to the foot, but do not cut off circulation.

Jellyfeet  
844/411-FEET (3338)  
jellyfeet365.com



Cloudflyer  
Footwear

The Cloudflyer from Swiss footwear company On features a low-profile outsole, a wide platform, and an active wedge in the medial heel and lateral forefoot to give pronation guidance without static features such as posting and dual-density foam. A star lacing system helps alleviate pressure points across the forefoot. All On shoes feature CloudTec cushioning, which is designed to adapt to an individual's preferred movement pathway, reducing energy expenditure. The Cloudflyer is designed to be lightweight without compromising support and cushioning. Available in women's sizes 6-11, men's sizes 7-14.

On  
503/222-0691  
on-running.com



Coral Bone  
Supplements

Coral, a leading brand of coral minerals, now offers Coral Complex3 and Daily D, two supplements to help support healthy bones. Daily D provides 500 IU (1250% DV) of the "sunshine vitamin", vitamin D3. In addition, it provides 100 mg of coral calcium per capsule. Coral Complex3 delivers 900 mg (90% DV) of bioavailable coral calcium per serving, along with 1200 IU (300% DV) of vitamin D3 (as cholecalciferol). Coral Complex3 is excipient free, non-GMO, and available in easily digestible and absorbable vegetarian capsules. It also contains 72 additional trace minerals that are important for healthy body functions.

Coral LLC  
800/882-9577  
coralcalcium.com

## AOPA continues to fight amputee coverage limitations at policy forum

The Washington, DC-based American Orthotic & Prosthetic Association (AOPA) on May 2 wrapped up its 2016 Policy Forum with its first-ever O&P Legislation-writing Congress.

Former Nebraska governor and senator Bob Kerrey led the congress, at which attendees authored a bill to address problems that are undercutting quality of care for O&P patients who are Medicare beneficiaries, according to an AOPA release.

Rep. Renee Ellmers (R-NC) was the opening keynote speaker for the Policy Forum, and Sen. Mark Warner (D-VA) and Rep. Tammy Duckworth (D-IL) provided insight on the congressional perspective. All three legislators shared their concerns about the proposed LCD (local coverage determination) and other restraints that hinder advanced and timely patient care.

Kerrey also met with eight senators to explain the bill and how to "rectify the problems and injustices unnecessarily burdening Medicare beneficiaries and the O&P professionals committed to providing care for those patients," AOPA reported. And, on April 27, 135 O&P providers and patients spent the day on

Capitol Hill in more than 400 meetings with legislators, seeking their support for the new bill and related proposed legislation.

Less than a week before, on April 21, AOPA reported in a conference call with the media that private insurers are exploiting the proposed LCD to deny coverage to amputees for previously approved medical care and devices.

During the call two amputees told reporters about their experiences with United Healthcare coverage denials. AOPA also produced a February letter from six groups, including the Amputee Coalition, urging Cigna to reverse a late 2015 coverage statement that is being used by the company to deny coverage to amputees.

AOPA offered thanks to its 2016 Policy Forum sponsors: WillowWood, Spinal Technology, Ottobock, Becker Orthopedic, Fillauer, Cascade Orthopedic Supply, Townsend Design, Össur Americas, Anatomical Concepts, PEL, Knit-Rite, KISS Technologies, Freedom Innovations, Allard USA, SPS, TRS, Cailor Fleming Insurance, Tamarack Habilitation Technologies, and Ability Dynamics. (ler)

## IOF evaluates osteoporosis medications

The International Osteoporosis Foundation (IOF) Fracture Working Group in April published its conclusions on the effect of osteoporosis medications on fracture healing.

Key conclusions included: Delayed fracture healing is common and practitioners should strive for early recognition and treatment; antiresorptives such as bisphosphonates may delay fracture healing, but the risk is low; and anabolic agents such as teriparatide that enhance osteoblastic bone formation may have a beneficial effect on fracture healing.

The panel concluded there was no negative effect of osteoporosis medications on fracture healing, and that it is safe to start osteoporosis medications as soon as possible after both vertebral and nonvertebral fracture. However, the panel agreed that, after the occurrence of an atypical femur fracture, bisphosphonate therapy should be stopped. Treatment with an anabolic agent such as teriparatide should be considered to improve healing.

*Osteoporosis International* republished the statement on April 25. (ler)

## BOC to drop O&P, pedorthic certifications

The Owings Mills, MD-based Board of Certification/Accreditation (BOC)'s Board of Directors in May approved a plan to sunset the acceptance of new applications for its orthotist (BOCO), prosthetist (BOCP), and pedorthist (BOCPD) certifications.

The decision will lead to greater growth opportunities for the organization and streamline

the professions' credentialing options, according to a BOC release that also noted the organization will continue to provide assistance to all BOC-certified professionals in meeting continuing education requirements, renewing their certifications, and helping them deliver the highest level of quality patient care. (ler)

## Homisak joins OHI central casting

Hauppauge, NY-based OHI on May 3 announced the appointment of Lynn Homisak, PRT, CHC, as central casting program consultant for the company's on-demand pedorthic service.

Homisak, principal owner of Seattle-based SOS Healthcare Management Solutions, is an award-winning consultant and management coach known for developing and facilitating successful practice management

strategies for podiatrists and their staffs. She won the 2010 Podiatry Management Lifetime Achievement Award and is in the *Podiatry Management* Hall of Fame.

OHI's central casting program, launched in 2014, is available in 20 states, and, according to the company, contributed more than \$8 million in revenue to participating practices in 2015. (ler)

## Nolaro24 continues live web series

Middlebury, CT-based Nolaro24 in May announced dates for its upcoming live webinar series on biomechanics. The six new webinars, which the ABC (American Board for Certification in Orthotics, Prosthetics, & Pedorthics) has approved for 1.5 contact

hours each, are scheduled through June 20. Each course costs \$75, and Nolaro24 is offering discounts for those who register for multiple courses.

Go to [nolaro24.com/education.html](http://nolaro24.com/education.html) for complete webinar descriptions and agendas. (ler)

## ING gives \$60K to fund RMPI tuition

The Elwood, IN-based Robert M. Palmer, MD, Institute of Biomechanics (RMPI) reported that OrthoSleeve brand maker ING Source has committed to a second year of scholarship support for students of the nonprofit institute.

ING Source, based in Hick-

ory, NC, donated \$60,000 to reduce RMPI's published tuition for some of its pedorthic precertification courses from \$4000 to \$2500 annually. To qualify for the reduced tuition, submit applications at [rmpi.org](http://rmpi.org) before May 31. (ler)

## Book focuses on pain biomechanics

Stuart Goldman, DPM, a board-certified foot and ankle surgeon who practices at Help for Your Feet in Owings Mills, MD, recently published his book, *Walking Well Again: Neutralize the Hidden Causes of Pain*.

The book emphasizes recognizing the root cause of conditions such as arthritis, fibromyalgia, and spinal stenosis, and reducing pain through improved gait mechanics.

The book is for sale on Amazon. (ler)

*Continued on page 62*

## Össur's new hip OA brace reduces pain

Results from a small study of Reykjavik, Iceland-based Össur's new Hip Unloader brace published in April showed nine of the 14 participants with unilateral symptomatic hip osteoarthritis (OA) reported an immediate reduction in pain with application of the device.

The brace, which Össur launched in the US in May (see "Össur Unloader Hip OA Brace," page 59), also significantly decreased peak hip abduction moment on the OA side as well as peak hip adduction and internal rotation angles during stance.

The study authors, from the University of Iceland in Reykjavik, concluded the brace appears to reduce compressive joint reaction force at the femoroacetabular interface and may offer an alternative for hip OA patients not ready for hip replacement.


*Prosthetics and Orthotics International* republished the results

of the study on April 26.

For its patient with lower limb loss, Össur on May 4 launched #MyWinningMoment, an online contest celebrating mobility.

Adults with lower limb loss can share their stories via photo or video on the mywinningmoment.com website through May 31 for a chance to win a four-day, three-night trip for two people to Reykjavik.

Entries will be judged based on story, originality, proper use of prosthetic, composition, and subject. Entrants must be 18 years or older with lower limb loss and able to travel before the end of 2016.


Get more information and submit entries for free at mywinningmoment.com. Entries are being continually refreshed on the website, and Össur is also showcasing submissions on its social media channels. 

## Diabetes drug *Invokana* under scrutiny

Beerse, Belgium-based Janssen Pharmaceutical's top-selling diabetes drug *Invokana* (canagliflozin) continued to come under scrutiny in April and May with new lawsuits filed, along with questioning from the European Medicines Agency (EMA) about serious potential adverse effects.

Lawsuits in the US and Canada allege that patients weren't warned about serious risks, including diabetic ketoacidosis, of the drug, a sodium-glucose cotransporter-2 (SGLT2). In addition, the EMA's Pharmacovigilance Risk Assessment

Committee has asked Janssen for more information about whether *Invokana* triggered a spike in lower-limb amputations. An ongoing clinical trial of about 4000 patients with type 2 diabetes treated daily with either 100 mg or 300 mg of *Invokana* or a placebo has so far has shown higher rates of lower limb amputation in the *Invokana* groups.


The Food and Drug Administration in 2015 strengthened *Invokana*'s label warning to include information about an increased risk of bone fractures associated with use of the drug. 

## Freedom Innovations taps new CEO

Freedom Innovation's Board of Directors on April 26 named David A. Smith chair and CEO of the Irvine, CA-based company.


Former chair and CEO Maynard Carkhuff will assume the role of vice chair and chief innovation officer and chair the

board's Technology and Product Portfolio Committee.

Smith most recently served as partner at San Francisco-based Health Evolution Partners. Before that he was chair and CEO of PSS World Medical in Jacksonville, FL. 

## JAS acquires Empi Advance ROM line


Effingham, IL-based Joint Active Systems (JAS) reported on May 3 that it has acquired the Empi Advance ROM line of dynamic braces from Empi, a subsidiary of San Diego-based DJO Global. JAS plans to reintroduce the Empi Advance ROM line by July.

JAS is adding the Empi Advance ROM product line to its Static Progressive Stretch (SPS) Range of Motion (ROM) therapy to reinforce its role as a single-source provider for ROM therapy, according to a company release. 

## Spenco runs social media contest

Waco, TX-based Spenco Medical is honoring May as National Physical Fitness and Sports Month by offering an incentive to people who share their fitness journey on social media.

Spenco, which in April posted a new video to support foot care awareness ([youtube.com/watch?v=yO8w3-3Vff4](https://www.youtube.com/watch?v=yO8w3-3Vff4)), will award a \$100 product voucher each week during May

to one winner. To enter, use the hashtag #SpencoJourney and post a photo, video, or written statement to share your fitness journey on Twitter, Facebook, or Instagram. The President's Council on Fitness, Sports & Nutrition sponsors National Physical Fitness and Sports Month. During May, all adults are challenged to get 30 minutes of daily physical activity. 

## Vorum, Nia join for 3D-printed devices

Vancouver, Canada-based CAD-CAM software company Vorum in May announced a partnership with Nia Technologies to deliver 3D-printed orthotics and prosthetics to children in developing countries.

Nia Technologies, a Canadian nonprofit based in Toronto, will integrate Vorum's Canfit 3D design software into its 3D PrintAbility solution. 3D PrintAbility is a digital toolchain designed to significantly reduce the time required to produce customized O&P devices for young people in the developing world. Large


productivity gains are crucial in low-income countries like Uganda, where it is estimated that only 12 practicing orthopedic technologists serve more than 90,000 disabled children in need of O&P devices, according to a press release from the companies.

Clinical trials of 3D PrintAbility for transtibial prosthetic sockets and ankle foot orthoses are scheduled to begin in coming months at CoRSU (Comprehensive Rehabilitation Services in Uganda) Rehabilitation Hospital in Kisubi. 

## Bauerfeind teams up with Mavs' Nowitzki

Tampa, FL-based Bauerfeind USA in April hosted healthcare professionals and business partners in Dallas for a two-day event featuring Dirk Nowitzki, star forward for the Dallas Mavericks and Bauerfeind global brand ambassador.

About 50 attendees came to the event, which included the relaunch of the updated Spinova back brace product line, a show-

case of Bauerfeind's GenuTrain knee braces, and seats at a game between the Dallas Mavericks and Houston Rockets. In a close game, Nowitzki provided a critical blocked shot to lead the Mavericks to an 88-86 win. Nowitzki met for a Q&A session with the Bauerfeind team and spoke about the impact that Bauerfeind's GenuTrain knee brace has had on his career. 

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