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From the editor:
Get smart about smart insoles

New technologies, especially those with the potential to allow patients to manage their own health, can leave practitioners wondering about their job security. But smart insoles aren't going to put any clinicians out of work any time soon. In fact, smart insoles won't really be able to help patients unless foot health specialists embrace them as a clinical tool.

This is true for a number of reasons, many of which are discussed in this issue of *LER Foot Health* (see "Smart insoles: Assessing their clinical potential," page 15).

Without a clinician's guidance, patients may not realize smart insoles' potential benefits for specific conditions like diabetic neuropathy. The data generated by a smart insole's embedded sensors won't do a patient any good if those data are too numerous or complex, but an astute practitioner can analyze that information and determine its clinical implications.

Most important, patients who experiment with smart insoles on their own are likely to tire of the technology once the novelty wears off—and long before any significant health benefits have been achieved.

I observed this phenomenon firsthand recently in a number of friends who went through a Fitbit phase. They counted their steps religiously and even chose to walk on occasions when they normally would have driven. It certainly seemed like the technology was on its way to improving their health. But it failed to hold their interest after just a few weeks.

The problem in that case wasn't with the technology. It's just hard for many people to implement lifestyle changes on their own, and that's something even the smartest technology hasn't yet figured out a way around. That's where a clinician's involvement can really make a difference.

Don't worry about smart insoles doing your job for you. Focus instead on how smart insoles can help you do your job better.

Jordana Bieze Foster, *Editor*

Segmental forefoot kinematics could influence risk of ulceration

Metatarsals do not move as a unit

By Katie Bell

Diabetes mellitus and peripheral neuropathy are associated with altered movement in individual metatarsal segments that is not always consistent with movement of the forefoot as a whole, according to research from Chicago that may have implications for foot ulcer prevention.

"We think differences in the magnitude and quality of motion between individual metatarsals may be related to the location of tissue breakdown," said first author Frank DiLiberto PT, PhD, OCS, FAAOMPT, an assistant professor in the Department of Physical Therapy at Rosalind Franklin University of Medicine and Science in Chicago. "Further work should be performed to fully delineate this potential relationship."

The study included 15 participants with diabetic peripheral neuropathy who did not have deformity or ulceration and 15 healthy matched controls. Researchers examined in vivo kinematic angular excursions of individual metatarsal segments and a unified forefoot segment as participants walked barefoot on a level walkway. Specifically, a five-segment foot model that included the first, third, and fifth metatarsals, calcaneus, and tibia was used to investigate relative 3D angular excursions throughout the terminal stance phase of walking.

In the patients with diabetic neuropathy, sagittal plane motion was reduced in all individual metatarsals and the unified forefoot relative to the controls, while only third metatarsal excursion was reduced in the frontal plane. In the transverse plane, participants with diabetic neuropathy had reduced motion in the third and fifth metatarsals and the unified forefoot.

Coupling of individual metatarsals and unified forefoot motion was strong in the sagittal plane in both groups, but variable coupling in the frontal and transverse planes suggests the metatarsals do not collectively function as a unit during walking. The findings were published in October 2015 by *Gait & Posture*.

Although the study authors suggest individual metatarsal kinematics provide further understanding of the diabetic neuropathic process, they recommend additional study to determine if the observed kinematic profile is associated with the development and location of deformity and tissue breakdown in individuals with diabetic peripheral neuropathy.

"The differential motion within the forefoot in people with diabetes mellitus and peripheral neuropathy, or in comparison to normal foot function, may be related to elevated pressures and increased ulceration risk [not specifically assessed in this study]. It is reasonable to continue to use orthotics to address elevated plantar pressures and try to optimize in-shoe kinematics," DiLiberto said. "While I do not know of studies demonstrating the effect of intrinsic strengthening or metatarsal mobilization in people with diabetes mellitus or peripheral neuropathy, it may be beneficial to include these components in preventive protocols."

> It may be more accurate to consider forefoot movement in terms of a medial segment and a lateral segment rather than a single forefoot region.

The differences evident in the magnitude and coupling between motion in the individual metatarsals and the unified forefoot suggest it may be more accurate to consider forefoot movement in terms of a medial segment and a lateral segment rather than a single forefoot region.

"Our data suggest that measuring individual metatarsal motion is not the same as measuring unified forefoot motion," DiLiberto said. "Based on our findings, we recommended the use of a two segment forefoot model to better represent foot function. This recommendation may be the most relevant in the examination of transverse and frontal plane motion. Further work is also recommended to determine the clinical relevance and impact of a more specific modeling approach. More specific modeling may lead to better detection of pathology and guide interventions."

The approach taken by DiLiberto and colleagues represents a paradigm shift in research design that could have significant clinical implications for patients with diabetes, said Smita Rao, PT, PhD, assistant professor of physical therapy at New York University in New York City.

"This is a novel approach compared to many existing studies because most current foot models assess the forefoot as a whole," Rao said. "Studying metatarsal motion in individuals with diabetes and neuropathy but no deformity may provide valuable insights that are important to develop targeted intervention that will help prevent deformities in this population."

Rao and colleagues analyzed forefoot motion in terms of its medial and lateral components in a 2010 study of 15 individuals with diabetic neuropathy and 15 controls, but some of their findings differ from those of DiLiberto et al.

"In contrast to our previous work, where we found a rigid first metatarsal segment and less rigid lateral forefoot [in the group with diabetes], DiLiberto et al found a normal first metatarsal and a more rigid third metatarsal," Rao said. "These phenotypes of foot function and their relevance to deformity progression must be investigated in future studies." ler

Katie Bell is a freelance writer based in New York City.

Sources:

DiLiberto FE, Tome J, Baumhauer JF, et al. Individual metatarsal and forefoot kinematics during walking in people with diabetes mellitus and peripheral neuropathy. Gait Posture 2015;42(4):435-441.

Rao S, Saltzman CL, Yack HJ. Relationships between segmental foot mobility and plantar loading in individuals with and without diabetes and neuropathy. Gait Posture 2010;31(2):251-255.

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Shoe Showcase: Help your patients step out in style

Apex Spring Collection

Apex introduces its Spring Collection, designed to offer consummate style, superior comfort, and expert construction. Each pair is crafted with high-quality materials and engineered for agility and durability. The new collection includes a hiking boot version of the Ariya for men in black or brown, and three classic styles for men (the Classic Lace Boat Shoe in black or brown, the Classic Monk Strap in black, and the Classic Strap Boat Shoe in black or brown). Also new for spring is the FitLite Collection of knit athletic shoes, including the Bolt for men and the Breeze for women, in multiple colors.

Apex

800-252-2739

apexfoot.com

revere Comfort Sandals

Sandals from revere Comfort Shoes, designed and developed in Australia, are now available in the US market. Designed in collaboration with foot health experts, all revere sandals have removable polyurethane footbeds, extra depth to accommodate custom foot orthoses, and a cushioned heel. Features such as strap extensions offer adjustability for a personalized fit without taking away from the stylish look of the upper designs. revere sandals available in women's sizes 5-12 and men's sizes 7-14. The Miami for women comes in black, black lizard, white snake, champagne, and red croc (pictured).

revere Comfort Shoes USA

208/720-2100

revereshoes.com

Anodyne Sport Collection

Averaging around 7 oz per shoe (less than half a pound), "light is right" when it comes to Anodyne's sport collection. With 16 different combinations of styles and colors for men and women, the sport collection has something for everyone. In addition to being very lightweight, all of Anodyne's shoes feature a soft, low-shear microfiber lining that helps to prevent heel slippage, extra depth to accommodate edema and orthotic devices, a protective toe box, and a strong shank and heel counter. Available in men's sizes 7.5-14 and women's sizes 5.5-11, in medium, wide, and extra wide widths.

Anodyne

844/637-4637

anodyneshoes.com

Salco 6 Slingback Sandal

Ideal for pairing with breezy summer dresses, the new Salco 6 slingback sandal for women has woven its way into Arcopédico's cork sole collection. The new Salco 6 sandal features multitone interlacing soft nylon knit straps across the vamp along with heel and ankle straps for a secure, comfortable hold. The Salco 6 has a contoured foot bed with reflexology technology designed to enhance comfort and circulation. Featuring a cork and latex footbed and durable, lightweight polyurethane outsole, the Salco 6 sandal is ready for summer. The sandal is available in blue or black; the suggested retail price is $95.

Arcopédico USA

775/322-0492

arcopedicousa.com

Ped-Lite Oliver

The Oliver, new from Ped-Lite, offers the benefits of a therapeutic shoe without sacrificing the appearance of a traditional boat shoe. Customers will initially notice the Oliver's all-leather upper with wrap-around lacing that is typical of a classic boat shoe. The shoe also features 6/16" of extra depth to accommodate custom foot orthoses, but 1/4" of that extra depth is hidden inside the sole of the shoe; the result is an attractive style that looks like a true traditional boat shoe rather than a diabetic shoe. The Oliver, pictured in brown, is also offered in tan and black, with a lace-up or Velcro closure.

Ped Lite
219/756-0901
pedlite.com

Mephisto Maryse Sandal

New to the Mobils by Mephisto line of comfort footwear is the Maryse sandal for women, a slingback wedge sandal with a polyurethane outsole, nubuck upper, and three adjustable Velcro straps. A key feature of all Mobils footwear is the all-over soft padding—cushioning between the lining and the soft leather upper that is designed to pillow the feet. Mobils footwear also features soft-air technology in the midsole to minimize shock, which has benefits for the more proximal musculoskeletal structures in addition to the feet. The Maryse sandal is available in dark taupe, in sizes 5-12 (whole sizes only).

Mephisto USA
800/775-7852
mephistousa.com

Samuel Hubbard Shoes

Lightweight, comfortable, and crafted from high-quality leathers and materials from around the world, Samuel Hubbard shoes are designed for people who move, walk, work, live, and play. The generous design and toe box, silky glove leather lining, and easily removable memory foam insole make these shoes well suited for individuals who wear custom foot orthoses. The Market Cap (pictured), part of the Go to Work Collection, works well with both dress slacks and blue jeans. It features a smart cap toe design distinguished by very fine broguing. Available in black or cognac, in men's sizes 7-14.

Samuel Hubbard Shoe Company
844/482-4800
samuelhubbard.com

Vionic Contoured Sandals

Vionic's contoured sandals, according to a recent peer-reviewed study, are comparable in effectiveness to the company's prefabricated foot orthoses for the short-term treatment of heel pain. The same study also found that Vionic contoured sandals offer more effective relief of heel pain than standard flat flip flops. The contoured footbeds of Vionic sandals feature Orthaheel technology, including a firm but flexible midsole, biomechanically designed arch support, and a deep heel cup. The Bella sandal for women (pictured), a toe post design with a feminine bow, is available in sizes 5-11 and in seven colors.

Vionic Group
415/492-2190
vionicshoes.com

Pilgrim Shoes P3020

This spring Pilgrim Shoes introduces style P3020, a new addition to the company's men's and women's Areni One collections. These shoes come with our signature stretchable leather uppers, combining the aesthetic appeal and durability of leather with the ability to accommodate forefoot deformities. Breathable panels along the sides of the shoe help promote air circulation to maintain a healthy in-shoe climate. Style P3020 is available in black, in sizes 5 -11, and in three widths. Pilgrim Shoes manufactures diabetic footwear in the US for better quality control and to facilitate a faster turnaround time.

Pilgrim Shoes
410/277.8855
pilgrimshoes.com

Delmar Bootery:

After 78 years and three generations, it's still all about the fit and the fix

By Catherine M. Koetters

Chances are, if asked to describe a shoe repair shop, you probably wouldn't use the words "pretty" or "refined." But Gail Sundling, owner of the Delmar Bootery, might convince you otherwise.

When asked to take the reins of her parents' Delmar, NY, store after her mom broke her neck in a 1976 car accident, Sundling—then 24 years old and pregnant—pondered her next move.

"One of the first things that I did, instinctively, was to upgrade the store's image, only because I didn't like to work in clutter, and I needed things organized," she recalled. "As I was doing that, the response of the customers was, 'Oh, I love coming in here. It's so warm. It's so beautiful.' Then I thought, 'Why can't shoe repair be as elegant as any other business?'"

That's when Sundling expanded her vision for the 425-square-foot store—which had been physically connected to her childhood home in the Albany suburb of Delmar since opening in 1938. That vision was realized in 1988, when Sundling opened a second Delmar Bootery—this time in a stylish Albany outdoor mall where the business continues to operate today, surrounded by art galleries, restaurants, jewelry stores, a salon, and a spa.

"The finest plaza that we have in Albany is Stuyvesant Plaza, and I felt if I could get in there, I would have achieved my goal," she said.

But the mall's manager, clinging to common perceptions about what a shoe repair place would look like, took some convincing.

"I explained to him what my concept was and that only Stuyvesant Plaza was upscale enough to handle what I was going to do," Sundling said.

The warm, rich wood interior and inviting atmosphere of this 1500-square-foot shop is intended to reflect the high-quality comfort shoes sold here, as well as the staff's focus on customer service. Delmar Bootery carries a variety of men's and women's shoe lines, including Drew, Alden, Aetrex, Dansko, Sanita, New Balance, Sebago, and Tauer & Johnson.

Mandy Sundling Young, Delmar's vice president and the owner's daughter, said they select shoe lines that come in numerous widths and can be successfully modified and repaired. This isn't as simple as it used to be, Sundling and Young agree.

"Manufacturers do not make it easy for us to repair items," said Young, referring to the increasing number of low-cost, fast-fashion shoes. "Glues won't adhere to a lot of materials that they're using. A lot of times the shoes are injection-molded, so, if we try to take apart the soles, we can't always get the shoe put back together the way it was supposed to be."

Still, the Delmar Bootery, which closed its original location in 2000, does between 20,000 and 30,000 repairs a year, including fixing heels and soles; adding sole guards; stretching shoes and cleaning, polishing, patching, and stitching them; replacing hardware and zippers; shortening purse straps and belts; and treating leather. The store's closest competition for repairs is an hour away, said Young, who estimates only about a half dozen shoe repair shops remain in New York's 2200-square-mile Capital Region.

On the retail side of the business, the staff spends at least 45 minutes with each new client.

"We're not there to sell shoes, we're there to fit shoes," Sundling emphasized. "That's crucial to our business."

New employees are trained for six months before they are allowed to fit a customer alone, she says. Staff also educate customers on the many ways high-quality shoes can be repaired, saving them money in the long run.

Young describes Delmar's typical customer as "at the end of her rope," unable to find a single pair of comfortable shoes and unwilling to give up fashion.

"We're therapists here a lot of times," she said.

All the challenges, both old and new, remind Sundling of something her father, Delmar Bootery founder Jack Leonardo, used to say more than a half century ago: "We're not craftsmen. We're magicians." ler

Catherine M. Koetters is a freelance writer in the Los Angeles area.

Foot Dynamics:

A clinical approach to quality shoes for an active community

By Kristine Thomas | Photos by Nancy Bateman

Too often when a person has issues with their feet, they are treated for their symptoms rather than the underlying problem, said Jeffrey Jacobs, BOCPed.

"My goal is to address their problem," Jacobs said. "I believe the key to solving foot problems begins with wearing the right shoes."

The owner of Foot Dynamics in Boise, ID, Jacobs describes his store as a place to find quality footwear. The store also has an on-site lab for orthotic fabrication and shoe modifications.

First-time customers visiting Foot Dynamics are given a foot evaluation by a foot specialist—either Jacobs or podiatrist Janice Farron, SRCh. Customers are asked questions about their activities and current footwear. Their information is kept on file for future visits.

"We recommend a shoe, and they walk out feeling better," Jacobs said. "We are able to solve foot problems with quality footwear. We believe in matching our clients with the appropriate shoe."

A competitive skier at both the collegiate and master's levels, Jacobs said being an athlete led him to pursue a career helping people with orthopedic issues. A graduate of the pedorthics training program at the Orthotics and Prosthetics Center at Northwestern University Medical School in Chicago, he has owned Foot Dynamics since December 1989.

The combination of athletic and clinical experience that Jacobs brings to his business makes Boise an ideal location.

"Boise is a small town with lots of doctors who are cyclists, skiers, and runners. We help them and help their patients solve their foot problems," Jacobs said.

Jacobs believes a significant contributor to foot injuries—particularly in runners—is wearing a shoe with a heel-to-toe incline, "resulting in an epidemic of equinus in our society."

"The foot is not meant to be at an angle," he said, adding he's an advocate of zero-drop footwear. "Heel elevation in footwear may be the most fundamental and significant cause of foot pathologies in our society."

Eager to find a zero-drop shoe to sell at Foot Dynamics, he discovered the Altra running shoe.

"These shoes are designed so there is no elevation of the heel; the ball of the foot and the heel are on the same level," he said.

In 2009, he purchased eight pairs, which quickly sold. He bought another eight, then 12, and then 15. He has now sold more than 6000 pairs.

What Jacobs stresses to his employees is the importance of educating their clients. It's not just about selling a shoe or orthotic devices. It's about providing clients with the tools—or shoes—so they can continue to ski, cycle, walk, or run while reducing their susceptibility to injuries or pain.

"We discuss their foot problems and why they are having them, we look at the footwear they are using, and we discuss orthotics," he said. "The really key reason why we are successful is because we educate our clients, and they trust us with our recommendations."

Laughing about turning 65 years old in June, Jacobs said there are often misconceptions that therapeutic shoes are only for older people and that they have to look like "an ugly, gray Oxford that everybody knows came from an orthopedic shoe store."

His mission is to change those public perceptions.

At Foot Dynamics, clients will find fashionable and athletic footwear, including Altra Drop Zero, Birkenstocks, Keen, Naot, Sanita, and Alegria. The store's inventory includes comfortable styles appropriate for work, walking, bicycling, hiking, or running.

"We get most of our clients by word of mouth. When we help one person, they tell another," Jacobs said. "If you don't walk out our door raving about your experience, we haven't done our job. If someone asks you about your experience and you say 'good,' we haven't done our job. We want people to have a great experience."

Kristine Thomas is a freelance writer based in Silverton, OR.

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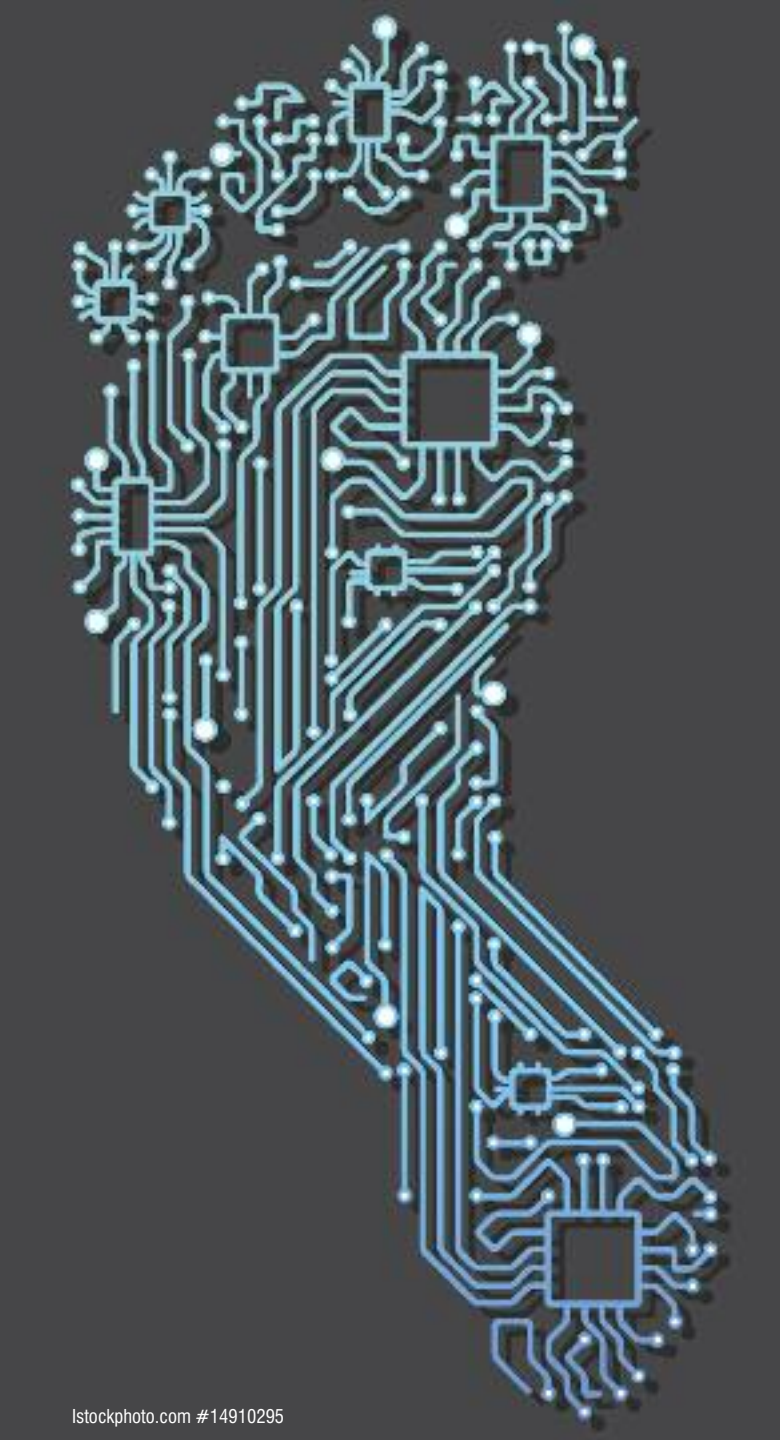
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Smart insoles: Assessing their clinical potential

Athletes have been quick to embrace smart insoles and the biomechanical data generated by the devices' embedded sensors. But experts believe smart insoles may also have potential clinical applications for patients with foot health problems, such as diabetic neuropathy.

By Shalmali Pal

Wearable devices to track exercise and fitness have become ubiquitous in the workout environment, but more often than not, these are basically fancy pedometers. Enter smart insoles, or footwear inserts with embedded sensors, whose developers claim they produce enough legitimate data on the user's biomechanics to fill a medical file.

Although not as sophisticated (or as expensive) as in-shoe measurement systems used for research, the new generation of smart insoles can measure location, foot pressure, stride length, and more in real time. The data are then sent via wireless technology to a mobile computing platform—tablet, smart phone, smart watch—that allows the user to interact with the information through the software.

"These kinds of tools are going to be a new measure of quality of life, and of how people move through their world," said David Armstrong, DPM, MD, PhD, a professor of surgery at the University of Arizona College of Medicine and director of the Southern Arizona Limb Salvage Alliance (SALSA), both in Tucson.

Many of these devices have been adopted by athletes—runners, in particular—who are keen on self-management and, not surprisingly, interested in the nitty-gritty details of their performance. But do smart insoles have a part to play in helping people with foot health problems, such as diabetic neuropathy? *LER: Foot Health* spoke with an international group of biomechanical experts to get their take on how "smart" these insoles really are.

The personalized feedback smart insoles deliver can help clinicians maintain contact with patients without extra in-person visits or waiting until an emergency arises.

What's out there?

A 2014 white paper on smart textiles, garments, and fabrics, including wearable technology, noted the global market for these products is expected to be worth $1.5 million by 2020.[1] The main growth sector since 2011 has been in the protection and military clothing sector, but sports and fitness applications, following by health and medical, are expected to see major advances.

Just doing a Google search for "smart insoles" yields more than

Continued from page 15

800,000 results. In many cases, these are products that are currently on the market; in others, they are links to crowd-sourcing pages to fund development of experimental products.

One example is Feetme's smart inner insoles, each with 80 pressure sensors, which provide real-time gait analysis via a smart phone, and may prove useful for patients with diabetes to monitor foot pressure and potentially prevent ulcers.[2]

Alexis Mathieu, cofounder and chief executive officer of the Paris, France-based company, said the main target consumers for the insoles are runners and patients with diabetes. Mathieu said the company has conducted one clinical trial with its smart insole, and is in the process of setting up another, but declined to share study details or results.

Made by Orpyx Medical Technologies of Calgary, Canada, Surrosense Rx is a sensor-embedded insert that captures pressure data from feet. The data are sent wirelessly to a smart watch device (which is packaged with the insoles). According to the company, the "smart watch alerts you when dangerous time and pressure levels are detected, so you can modify behavior and avoid damage."[3]

The market for Surrosense Rx is patients with diabetes. Bijan Najafi, PhD, director of clinical research in the Division of Vascular Surgery and Endovascular Therapy at Baylor College of Medicine in Houston, and colleagues recently conducted a pilot study[4] to test the recurrence of diabetic foot ulcers in patients using the device, which is considered a class I medical device and therefore is exempt from FDA 510(k) premarket review.

The study included 21 patients with diabetic neuropathy and recently healed ulcers. The participants received an average of 3.38 daily alerts per day, of which nearly 44% were successfully managed, Najafi said. In addition, the majority of the alerts (45.8%) were related to pressure changes under the metatarsal heads, which is one of the plantar surfaces that is most prone to ulceration.

The preliminary data, presented at the 2015 International Symposium on the Diabetic Foot, showed no serious adverse events with the device, and more importantly, no reulceration or foot

problems during active use of the device or during the three-month follow-up period after discontinuing use of the device. However, when self-reported utilization was compared to sensor-based wear time, results showed patients tended to overestimate their time spent using the device, leading the authors to caution that "patient adherence to [mobile health] technology is highly dependent on user interface, number of false alarms, and level of comfort."

For additional examples of smart insole technology, see the sidebar on page 18.

Real-time feedback and a "user-friendly" interface are two factors that can make a smart insole stand out, said Najafi, who is also director of Interdisciplinary Consortium on Advanced Motion Performance (iCAMP) at the University of Arizona, where the pilot study was conducted. The study was partially funded by Orpyx.

"The big challenge is still how to visualize or feed back key information to patients for assisting them to take care of their own health," Najafi said. "Another key challenge is how to engage patients to continue wearing these insoles."

For Armstrong, a coauthor on the study, smart insoles like Surrosense Rx that rely on sensory substitution technology—or the use of one sensory modality to supply environmental information normally gathered by another sense while still preserving some of the key functions of the original sense—will have the longest staying power in the market.[5]

"There are other kinds of insoles that measure pressure or temperature, but most of them haven't reached the same level of sophistication as the sensory substitution devices," he said.

And, even the devices that are driven by more sophisticated software still contend with the challenge of being user-friendly and comfortable.

"Right now, the form factor of smart insoles is like the early days of the cell phones, when the phones were large and clunky," Armstrong explained. "That form factor was good, but it was uncomfortable. Eventually, we evolved to the smart phone, which is much smaller in comparison. There are some insoles right now that are good products, but they are unwieldy and not necessarily practical."

Rob Conenello, DPM, immediate past president of the American Academy of Podiatric Sports Medicine, and a podiatrist with Orangetown Podiatry in New York, said he does not currently use smart insoles in his practice, though he is interested in doing so.

"I'll go to a show, see a smart insole that interests me, and then six months later at another show, the device is that much better," Conenello said. "My biggest concern is that...I don't want to invest in a product that is basically going to become obsolete before I've really had a chance to use it."

In addition, he said, many smart insoles offer quantitative data (eg, step counts), which isn't necessarily what he's looking for.

"I'd like more qualitative analysis from these devices, and I think that's where they are headed," he said.

Clinical value

Experts say the personalized feedback smart insoles can deliver to users and clinicians makes them a worthwhile consideration for practitioners looking to maintain contact with patients without extra in-person visits or waiting until an emergent situation arises.

Smart insoles can also help patients with self-management,

Continued on page 18

Continued from page 17

A sampling of smart insoles

• **Lechal** (Hyderabad, India) manufactures smart insoles that feature haptic, or kinesthetic, feedback to provide the wearer with navigation via their smart phone in addition to tracking steps and calories. http://lechal.com/insoles.html

• **Digitsole** (Nancy, France) has developed a smart insole with customizable temperature available via a smart phone interface that tracks steps and warms the feet.

http://www. digitsole.com/

• **The FootLogger insole** (Seoul, South Korea) features a three-axis accelerometer along with eight pressure sensors that collect, transmit, and store data related to the weight distribution of each step.

http://footlogger.com:8080/hp_new/ footlogger/

• **Wiiv Wearables** (Vancouver, Canada) makes biomechanically optimized custom insoles that are 3D-printed based on scans taken with a user's smart phone. The insoles aren't smart yet, but the company hopes to incorporate into the orthoses electronic sensors that collect and record dynamic data. https://wiivv.com/

• **HCi Viocare Technologies** (Glasgow, UK) has a smart insole that can measure pressure exerted and shear across the sole, as well as determining weight, balance, calories burned, and distance traveled. http://www.hciviocare.com/

• **Moticon** (Munich, Germany) manufactures OpenGo smart insoles that come with 13 pressure sensors and 3D acceleration sensors to determine the direction and speed of movement. Data are communicated to a Bluetooth-enabled smart phone or tablet. http://moticon.com/

• **ReTiSense** (Bengaluru, India) has developed the Stridalyzer for runners. Sensors embedded in the insoles measure impact and pressure experienced in the foot and knees and sends real-time data on running form and style and foot and knee stress points to the user's smart phone.

http://www.retisense.com/

• **Kinematix** (Porto, Portugal) is in the process of bringing its Tune device to market. The 2-mm sensors fit underneath an insole and track running activity information. These data are combined with GPS-based assessments of the runner's speed, pace, distance, and time. http://www.kinematix.pt/

• **Feetme** (Paris, France) has smart inner insoles that provide real-time gait analysis via a smart phone, and may prove useful for patients with diabetes to monitor foot pressure and potentially prevent ulcers. http://www.feetme.fr

• **Surrosense Rx insoles from Orpyx** (Calgary, Canada) collect pressure data and send it to a smart watch, which alerts the user when dangerous time and pressure levels are detected. http://orpyx.com/

Armstrong said. For instance, the smart insoles may alert a user with a healed diabetic foot ulcer that her activity level is outside the norm for her on a given day, and that this has led to pressure and temperature changes in the feet.

"This may make the patient realize that she's been on her feet, running errands or something similar, for longer than she realized," Armstrong said. "That perhaps it's time to take a break."

But, in terms of clinical applications, two major questions remain: What to do with all the data these insoles have the potential to generate, and how to get users to pay attention to it?

One drawback of these devices is the potential for "analysis paralysis," Armstrong noted.

"When you start hitting people with reams of data, then that becomes something they will ultimately ignore," he said. "How many apps do we have on our phone right now that are constantly sending us alerts or updates? And how many times do we actually access that information, or simply ignore it, over the course of a day?"

In fact, feedback received when patients are not experiencing symptoms can lead them to simply stop using the device.

"People don't necessarily change their behavior unless something 'breaks,'" he said. "They tend to distance themselves from their issues unless there's a problem."

Conenello said he likes the idea of getting complete information on how a person's gait changes over time, in a real-world setting.

"When I work with a patient or an athlete in the lab or office, I can't replicate what they go through in their life or game play," he explained. "There's an advantage to obtaining that data in real-time. However, I also want good information from that device. I want that Aha! moment where the patient can see how and why they need to make changes, whether that's in their movement patterns or in their footwear choices."

Along with patients with diabetes, Conenello said he'd consider using smart insoles in patients with Parkinson disease, to show them changes in their gait and balance over time. For instance, performing the single-leg stance with the smart insole could give the patient visual feedback about weight distribution and how to make corrections for greater stability.[6]

He'd also consider using it for children with lower extremity movement disorders, such as lower limb spasticity related to cerebral palsy, to collect qualitative data on the gait cycle.[7]

The clinical usefulness of smart insoles will also involve the extent to which they are compatible with therapeutic footwear and functional orthotic devices, Conenello noted.

Experts agree that smart insoles don't give clinicians a license to cut back on patient interaction.

"I think it's the responsibility of the [healthcare provider] to fine-tune the use of the insoles," Armstrong said. "You have to become what I call 'an activity doctor,' helping high-risk patients and their caregivers understand what information from the device is important and what's less important."

While that will require a higher level of upfront engagement by healthcare personnel, Armstrong said, it fits well with the current trend in medicine to offer value-based, rather than volume-based, care.

"If a diabetic patient has a foot disorder that is in remission, the device can warn us if he is nearing the point of potential reulceration. That's where the value is," he said.

The athlete's foot

Athletes clearly have different needs and goals than patients with diabetes or other serious health issues with foot-related comorbidities, but some of the same questions about the value of feedback from smart insoles apply.

The technology's benefits include device portability, the ability to do in-field measurements, and the potential to assist with shoe prescription for runners with a recent history or metatarsal stress fractures or hallux rigidus, said Richard Willy, PhD, PT, assistant professor in the Department of Physical Therapy at the College of Allied Health Sciences at East Carolina University in Greenville, NC.

Thor Besier, PhD, an associate professor at the Auckland Bioengineering Institute in New Zealand, noted that there are many examples of sensors and new sensing technology that are making in vivo force and pressure measurement possible.

"However, on their own, the data are less interesting and difficult sometimes to interpret," said Besier, a codeveloper of I Measure U Run (IMU-Run) a wearable device that monitors tibial shock in runners.[8] "Having these data inform a biomechanical model that can predict joint moments is really where they will add value to a runner."

Drawbacks to the technology, according to Willy, are possibly low data sampling rates and sensor resolution, likely high cost and unknown durability, and variable calibration procedures.

Data overload is another potential pitfall, Besier said.

"An athlete can only focus on a few key pieces of information at a time, so being able to obtain such a huge amount of data over the course of a run is overwhelming," he said.

Ideally, feedback should be simple and intuitive, allowing the user to adjust technique to modify the input signal. With the IMU-Run, "we are still exploring what key metrics might be useful to runners and learning how runners respond to receiving this feedback," Besier said.

It's also important to remember that any gait modifications—including those inspired by smart insole technology—come with both benefits and risks, Willy said.

"Any time a gait modification is undertaken, load is shifted elsewhere," he said. "Thus, injury risk or metabolic demand may increase, particularly if the feedback does not include limits on a modification."

For example, in runners with high impact forces, increasing running cadence by 5% to 10% over the runner's preferred cadence can help reduce those impact forces by up to 20%.[9] But increasing running cadence more than 10% over a runner's preferred cadence also may increase metabolic demand—which, in turn, is likely to affect runner adherence.[9]

"Gait modifications should not be undertaken unless there is a specific need and a specific parameter of gait that should be changed," Willy said.

Besier said he believes the best use of such devices will be for each user to understand his or her own body and its response to loading.

"The more our sensors become integrated into the standard ritual of your daily run, the more likely they will have a chance to make a true impact on your performance," he said. "Ultimately you should not even be aware that the sensors are there. You just get dressed and get on with your run." ler

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The importance of obesity in foot pain management

Increasing numbers of studies suggest that a high body mass index can significantly affect foot structure and function, increasing the risk of painful conditions. But questions remain as to how foot health specialists can best address foot pain in their obese and overweight patients.

By Barbara Boughton

Many scientific studies have documented the link between body mass index (BMI) and foot pain, and research has now shown conclusively that being overweight also increases the risk of abnormal plantar pressures, foot function, and foot structure. Obese individuals (defined by the World Health Organization as having a BMI of 30 kg/m^2 or higher) and overweight individuals (BMI between 25 and 29 kg/m^2) also are more likely than their normal-weight counterparts to develop foot complications such as osteoarthritis, tendinitis, and plantar fasciitis, which can be disabling enough to compromise quality of life.

Yet, how these findings translate to the clinical management of overweight and obese patients with foot pain is still not entirely clear. Although some studies have documented that losing weight by calorie restriction or bariatric surgery may reduce plantar pressures on the foot, no research has shown conclusively that either of these solutions significantly reduces foot pain or the risk of abnormal foot conditions.

Still, foot specialists and researchers interviewed by *LER* said they make adaptations in clinical practice for overweight and obese individuals to maximize treatment efficacy and safeguard patient health.

The increased plantar pressures seen in overweight and obese patients, as well as their decreased tolerance for high-impact exercise, may change a clinician's prescription for foot orthoses, exercise, and even recovery after surgery, for instance. Foot specialists may be more likely to prescribe nonaerobic exercise and stiffer and thicker orthotic devices for a patient with a high BMI. After foot surgery, specialists are also less likely to utilize early weightbearing during recovery in heavier patients.

"There's only so much weight a foot can take before overuse sets in—affecting the muscles, ligaments, and bones," said Alex Kor, DPM, clinical associate at Johns Hopkins Bayview Medical Center in Baltimore, MD. "Yet, it's not the only factor to consider in treating a foot condition. The structure of the foot, the shoes worn by the

Obesity is strongly associated with low-arched foot posture, dynamic pronation, and increased plantar pressures during gait; all of these can contribute to foot pain.

patients, and activity level are all important contributors to foot pain."

Kor prescribes exercise and proper shoe wear for all his patients with foot pain and foot disorders, no matter their weight, and sometimes orthotic devices, as well.

"While I'll prescribe exercise for all my patients with foot conditions, there are some patients—including those with high BMI and diabetes—for whom running, jumping, or even walking long distances is inappropriate," he added.

Experts say it's crucial for all clinicians—not just foot specialists—to be aware of the increased potential for foot pain and foot damage in overweight and obese individuals of all ages. Clinicians should also use strategies to prevent the development or progression of foot pain in overweight and obese patients, since foot pain and damage in these patients tends to increase over time, said Catherine Bowen, PhD, a researcher, podiatrist, and associate professor in the faculty of Health Sciences at the University of Southampton in the UK.

"Treating foot joint pain early in high BMI patients could possibly prevent longer-term loss of mobility," she said.

The evidence

Recent systematic reviews have found that obesity is strongly associated with low-arched foot posture, pronated dynamic foot function, and increased plantar pressures when walking—all of which can contribute to foot pain.[1-2] High BMI causes increased loading on the foot during standing and walking, which in turn puts additional stresses on the soft tissues that support the joints within the foot, Bowen said.

"Over time these stresses cause the joints of the feet to collapse when the soft tissues are no longer able to support the foot joints. As the joints collapse, the joint capsules swell—causing pain and eventual remodeling of pain and cartilage," she said.

In a study published in *Arthritis Care & Research* in December 2014, Bowen and colleagues reviewed data regarding foot joint pain over a five-year period in 639 middle-aged women, who were part of a community cohort for the Chingford Women's Study.[3] Both BMI and foot joint pain increased significantly from year 10 to year 15 of the 20-year study, and BMI at year 10 was significantly associated with incidence of foot joint pain five years later (odds of foot pain increased by 5% for each BMI unit). This association was independent of age, diabetes mellitus, and rheumatoid arthritis.

"The fact that foot joint pain was independent of age was a surprising finding to us," Bowen said. "We did expect that women would have more foot joint pain as they aged, but our findings imply that foot health should be considered and monitored in patients with high BMI at any age."

Another large epidemiological study also found that foot pain was significantly increased in overweight (BMI 25-30 kg/m^2) and obese (BMI greater than 30 kg/m^2) patients older than 60 years, and these patients were also more likely than normal-weight individuals to exhibit diminished foot strength, stride length, and walking speed.[4] High BMI was associated with disabling foot pain and alterations in foot function that negatively affected patients' quality of life, according to Karen Mickle, PhD, research fellow at the College of Sport and Exercise Science at Victoria University in Footscray, Australia.

In the study, 312 Australian men and women aged between 60 and 90 years completed a questionnaire that assessed foot pain, as well the 36-item Short Form Health Survey (SF-36). The researchers assessed musculoskeletal foot structure using a 3D foot scanner, and soft tissue thickness at the heel, midfoot, and first and fifth metatarsal heads using ultrasound. They recorded maximum isometric dorsiflexion strength, hallux strength, and lesser toe flexor strength using pressure platforms. They also assessed ankle dorsiflexion flexibility with a modified lunge test, and gait while the patients walked at a comfortable pace.

Obese participants had a significantly higher prevalence of disabling foot pain (40%) than overweight patients (23.4%) or normal-weight participants (11.4%). Obese and overweight patients also had greater disability as measured by the SF-36. Compared with normal-weight subjects, obese participants had greater tissue thickness at all sites except the first metatarsal head, and overweight patients had thicker soft tissue and fat pads at the fifth metatarsal head and at the heels. Obese patients also had significantly reduced flexor strength of the hallux and lesser toes compared with overweight and normal-weight participants. As well as having shorter stride length and reduced walking speed, the obese patients spent more time in stance and double support phases and less time in swing phase than their leaner counterparts. They also generated greater plantar pressures across the foot when walking.

> Foot muscle strengthening exercises may reduce foot pain in overweight and obese patients, and may decrease the risk of falling in individuals who are also elderly.

Foot strength as a factor

"High plantar pressures in overweight and obese people have been reported in both children and younger adults, so this study confirmed that altered foot loading patterns are also seen in obese older adults," Mickle told *LER Foot Health*. "The foot muscle weakness we reported was a novel finding—and may contribute to altered loading patterns during walking."

The observed gait alterations also suggest that the participants' ability to perform activities of daily living was inhibited by their excess mass and confounded by the presence of foot pain, Mickle and colleagues wrote in the paper.

The high prevalence of disabling foot pain in obese patients most likely contributed to reduced function and quality of life, Mickle noted. The decreased muscle strength combined with the increased plantar pressures in obese patients were probably the most important contributors to excess foot strain and foot pain, the researchers concluded.

Foot muscle strengthening exercises may reduce foot pain in overweight and obese patients, and may decrease fall risk in those who are also elderly, according to Mickle and other researchers.

Focused exercises that build strength in the forefoot benefit both overweight and obese patients, but walking and other weight-bearing exercises have even more advantages—helping to strengthen the muscle groups that affect ankle and hindfoot motion and function, according to Bowen.

For overweight and obese patients with decreased foot muscle strength, Kor advises specific exercises that target the foot's intrinsic muscles, including the abductor hallucis, flexor hallucis brevis, and

flexor digitorum, he said. Physical and aquatic therapy can also be effective for strengthening the muscles of the feet in overweight and obese patients, he added.

What about weight loss?

Large epidemiological and review studies contribute to our understanding of the increased prevalence of foot pain, and suggest the benefits of muscle strengthening exercise for obese and overweight patients. Yet, these studies have other clinical implications.

"From many biomechanical studies, we know that three to six times body weight is transmitted though the foot with normal cadence and gait," said Zachary Vaupel, MD, assistant professor of orthopedic surgery at Oakland University William Beaumont School of Medicine in Royal Oak, MI. "So I tell my patients that just by losing five pounds, they will potentially be transmitting thirty pounds less through the foot and ankle."

Researchers and clinicians like Vaupel acknowledge that the medical literature has yet to prove the benefits of weight loss for obese patients with foot pain.

"In the peer-reviewed literature, weight loss has not been consistently linked with a reduction in foot pain, although research studies do show that it reduces back and knee pain," said Todd Davenport, PT, DPT, MPH, OCS, an associate professor in the Department of Physical Therapy at the University of the Pacific in Stockton, CA.

A systematic review published in *Obesity Reviews* in 2012,[2] for instance, concluded that greater BMI was strongly associated with increased risk of chronic plantar heel pain. Yet there was only limited and weak evidence showing that weight loss resulted in any improvements or changes in plantar heel pain.

Still, Davenport and other physical therapy experts felt strongly enough about the benefits of weight loss for obese patients to include it as a treatment recommendation for heel pain in the 2014 American Physical Therapy Association guidelines.[5]

The guidelines suggest clinicians should educate and counsel obese patients with heel pain to use low-impact exercise strategies that can maintain optimal lean body mass. The guidelines also note that obese individuals with heel pain should be referred for nutritional counseling. Davenport, however, noted that weight loss and exercise recommendations also need to take into account individual patients' body structure, foot diagnoses, and goals.

When prescribing exercise for his patients, Kor often advises very obese patients or those with diabetes to start out with low-impact or nonweightbearing exercise. Walking 30 minutes each day may be too much for these patients, so swimming or using a seated stationary bicycle may be better choices. But, once the patient's foot-related symptoms or overall fitness improve, weightbearing exercise such as walking or running can play a part in their continued treatment, he said.

Tailoring treatment

Whether an obese or overweight patient should receive different treatments than normal-weight individuals for foot-related symptoms is also a question that has not been resolved—nor has it received much attention in the scientific literature. Yet, in small studies, researchers have begun to consider the efficacy of different treatment modalities for obese patients with foot pain and other symptoms.

In a small study on 10 normal-weight individuals, for instance, published in the *Journal of Foot and Ankle Surgery* in 2014, researchers studied the effect of adding weights with anterior and posterior body packs to mimic the BMI of overweight and obese individuals.[6] As more weight was added, the mean peak plantar pressures in the heel, midfoot, and forefoot also increased in a linear fashion. The researchers also tested the effects of using three different off-loading devices—a surgical shoe, a controlled ankle motion walker, and a total contact cast.

"The walking boot and the total contact cast were the best at reducing plantar pressures in the foot," said lead researcher Andrew Meyr, DPM, associate professor in the Department of Surgery at Temple University in Philadelphia. "The surgical shoe provided some improvement—but the plantar pressures with these shoes were not dramatically different than those seen with sneakers."

Although some obese patients, such as those with diabetes, would benefit from these types of off-loading devices, many overweight patients need less-intensive interventions. Most patients with foot-related symptoms—whether or not they are obese—benefit from sturdy shoes with stiff soles to provide support and symptom relief, Kor said.

"My shoe recommendations really don't vary based on a patient's weight," he added.

Overweight and obese patients, however, are more likely to benefit from thicker and more rigid orthoses, such as those made of polypropylene, than from softer or less durable devices.

"These types of orthotics will be more durable and last longer, because they can withstand the heavier weight of an overweight and obese individual," Kor said.

By contrast, a graphite orthosis would be a poor choice for an overweight or obese patient, because it is less able to withstand excess weight, he said.

Although some studies have suggested obese patients have higher risks of complications than normal-weight patients after ankle surgery,[7,8] other studies have not,[9,10] and there is limited evidence that such risks also extend to foot surgery. In 2007, Pinzur et al reported that obesity was one of five variables associated with a high risk of complications following midfoot arthrodesis in patients with Charcot arthropathy.[11] And researchers from Singapore found that obese (BMI of 30 or higher) patients undergoing hallux valgus surgery were significantly more likely than nonobese patients to need repeat surgery for complications.[12]

A patient's weight, however, is likely to make little difference in the type of physical therapy or surgery they receive for foot disorders and ailments, clinicians said.

"Whether or not a patient is overweight or obese does not change my surgical plan," Vaupel said. "But I would be more cautious in recommending early weightbearing after surgery for a patient who is obese. In heavier patients, early weightbearing has greater potential to jeopardize surgical results."

Yet, no matter what the surgery or treatment plan is for an obese or overweight patient, Vaupel always recommends weight loss and makes a referral for nutrition and exercise counseling.

"Even if we don't have scientific proof that there are worse outcomes with obesity, we also have to consider that weight loss can have a beneficial impact on the whole patient—on the patient's overall health and well-being," he said. ler

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

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