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LOWER EXTREMITY REVIEW July 23 / volume 15 / number 7

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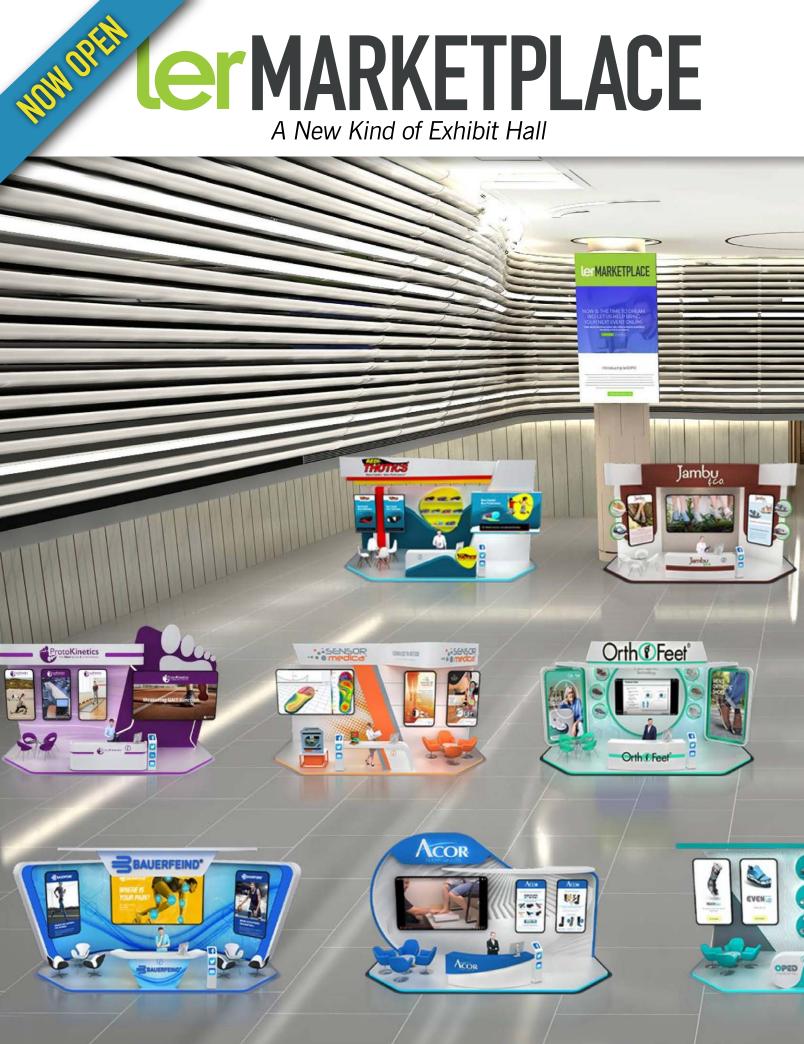
# Johns Hopkins Diabetic Foot and Wound Care Service Asks:

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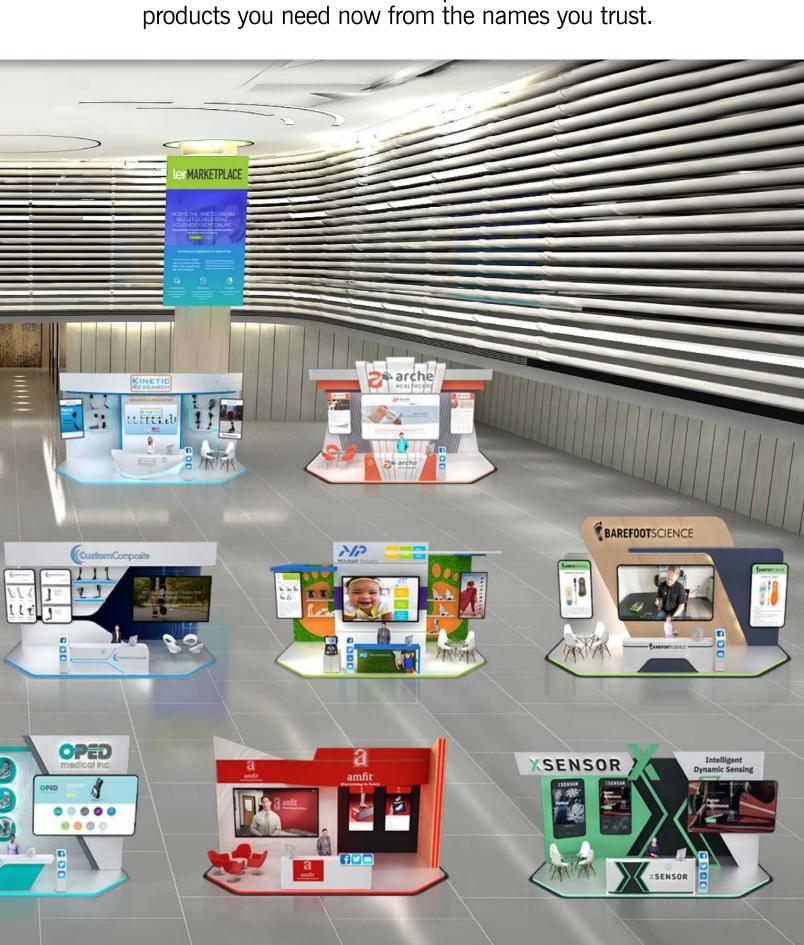


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#### VOLUME 15 NUMBER 7 LERMAGAZINE.COM

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Designed by @YLMSportScience

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> Computer-assisted gait analysis helps identify potential DFU hot spots BEFORE they become a problem.



By Jay Segel, DPM; Sally Crawford, MS; Mark Hopkins, PT, CPO, MBA; Brian Murray, PT; Tracy Winchester; Alexander Lakner, DPM; DeEtta McKnight, RN; Caitlin Hicks, MD, MPH-V, Sanuja Bose, MD, MPH; Alana Keegan, MD; and Ronald Sherman, DPM, MBA

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## Lower Extremity Review

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# **Lower Extremity Review Mission**

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

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

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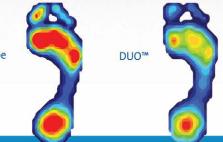
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# Expert **Opinion**



# NATA Offers Vital Tips for Back-to-School Safety

FROM THE NATIONAL ATHLETIC TRAINERS' ASSOCIATION

With temperatures on the rise and student athletes returning to preseason practice fields this summer, the National Athletic Trainers' Association (NATA) has released safety tips to ensure parents ask the right questions of schools to ensure best sports safety practices are in place.

"Participating in sports activities during the height of summer requires careful planning to prevent and reduce the risk of sport-related conditions and illnesses," says NATA President Kathy Dieringer, EdD, LAT, ATC. "Parents should be prepared to ask the right questions of their children's schools. The athletic trainer is often the first person to prevent and manage high school sports injuries – yet only 37% of public US high schools have an athletic trainer on staff. If your school has sports, then you must have an AT," she says.

## **Questions to Ask**

# 1. Who comprises the school's sports medicine team?

Find out who will provide care to your child in case of an injury and ask to review their credentials. NATA recommends that any medical decisions are made by the school's sports medicine professionals, physicians and ATs, and not the coach to avoid conflict of interest. Coaches and even the athletes themselves may unconsciously make decisions that favor winning over safety.

# 2. Does the school have an emergency action plan?

Every team should have a venue-specific written emergency action plan (EAP) for managing serious and or potentially life-threatening injuries. It should be reviewed by the AT and local Emergency Medical Service. Individual assignments, emergency equipment and supplies need to be included. If an AT is not employed by the school, other qualified individuals need to be present to render care.



#### 3. Is the equipment in working order?

Make sure all equipment ranging from field goals, basketball flooring, gymnastics apparatus and field turf are in safe and working order. This also includes emergency medical equipment such as splint devices and automated external defibrillators (AEDs) – which should be checked once per month; batteries and pads need consistent monitoring and replacing. Accidents can occur in every activity, and that is why the AT should be on site after school to help ensure all equipment is safe and in good order.

# 4. Does the school have an AED and someone who knows how to use it?

AEDs can save a life and stave off a catastrophic situation. Ensure that the sports medicine team and other personnel know where they are located and how to use them. They should be readily available within three minutes (preferably one minute) during both practices and games.

# 5. Does the school have lightning protocols?

Summer is a peak time of year for lightning which can appear without warning and is particularly prevalent from afternoon to early evening. Schools should have a lightning-specific emergency action plan in place that ensures lightning and general weather awareness, addresses large venue planning protocols to get athletes and spectators to safe places, and provides for first aid as needed.

## Preparing Kids for Sports Participation

#### 6. Get a pre-participation exam:

All athletes should have a pre-participation exam to determine their readiness to play and uncover any condition that may limit participa-



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#### Continued from page 9

tion. A young athlete's underlying medical condition can be exacerbated with vigorous, sustained physical activity. Parents should also complete an emergency medical authorization form that asks for parent contact information, the athlete's medical history and permission for emergency medical care for that athlete. Check with your school to obtain the forms.

# 7. Physical and mental preparation is paramount:

Parents, with input from coaches and ATs, should determine whether their children are physically and psychologically ready for the sport/activity level they're playing. A young athlete should not be pushed into something he/she does not want to do. If an athlete has been injured and is returning to sport, it's critical for him or her to have the right mindset and confidence to return to play and avoid repeat injury. If an athlete does show signs of mental distress, the AT, coach, and school mental health professional should work together to provide that athlete the best care.

# 8. Get Cardiopulmonary Resuscitation (CPR) Training:

CPR is an emergency lifesaving procedure performed when the heart stops beating. According to the American Heart Association, immediate CPR can double or triple chances of survival after cardiac arrest. In January, the country became vitally aware of CPR when Buffalo Bills' Damar Hamlin was injured on the field and CPR helped to save his life. Student athletes should be well trained on how to do CPR when every second and minute counts.

9. Be educated on reducing risk of injury:

NATA has a public educational website, www. AtYourOwnRisk.org that provides comprehensive information on reducing risk of injury in work, life and sport. The site includes interactive state-by-state maps, an educational blog and resources for parents, coaches and others.

#### 10. Be smart about sickle cell trait:

All newborns are tested at birth for this inherited condition, and those results should be shared during a pre-participation exam. Red blood cells can sickle during intense exertion, blocking blood vessels and posing a grave risk for athletes with the sickle cell trait. Screening and simple precautions may prevent death and help the athlete with sickle cell trait thrive in his or her chosen sport.

# Tips for Athletes and the Sports Medicine Team

#### 11. Beat the heat:

Acclimatize to warm weather activities over a 7 to 14-day period. This includes heat acclimatization, hydration and modifying exercise based on environmental conditions, among other criteria. It is suggested that for the first 2 days in sports requiring protective equipment, only helmets should be permitted (this includes goalies as in the case of field hockey and related sports); during days 3 to 5 only helmets and shoulder pads should be worn; beginning on day 6, all equipment can be worn.

#### 12. Concussion education:

Be certain the medical team is well educated on concussion prevention and management. Some state concussion laws require schools to educate parents, too. The athlete should be encouraged to speak up if he or she is hit in the head and suffering from any related symptoms such as dizziness, headache, loss of memory, light headiness, fatigue or imbalance.

#### 13. Build in recovery time:

Allow time for the body to rest and rejuvenate in between seasons. If the athlete has just finished the basketball season and has his or her sights set on baseball, make sure there is rest time built in to recover from the rigors of grueling months on the court. If athletes don't make time for recovery, injury can occur. Acclimatizing to the next sport, with appropriate strength, flexibility and balance training, and the supervision of an AT, will help ensure a healthy season ahead.

# 14. Pay attention to sport specific injury prevention:

Any repetitive motion can lead to overuse injury. With baseball, it may be the turning of the torso and impact on the hip or the repetitive motion a pitcher goes through each time he or she throws a ball. These motions can put added stress on



the joints, muscles or ligaments with sudden movement or rigorous activity increasing the chance of injury. Following a protocol of flexibility and strength training is integral to a young athlete's participation.

"These recommendations encourage an ongoing dialogue of parents with schools, coaches and others involved in their child's sports participation," adds Dieringer. By following these guidelines, we know that if injury should occur, proper planning is in place with the right health professionals including the athletic trainer, to help prevent manage and treat that injury. That should give everyone peace of mind and confidence that sports safety is paramount." (e)

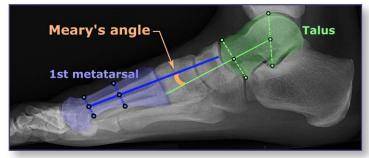
The National Athletic Trainers' Association represents and supports 40,000 members of the athletic training profession. Visit nata.org for more information.

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## PEDIATRIC ARCH PAIN LINKED TO TALUS-1/-2 METATARSAL ANGLES



Case courtesy of Pablo Lorenzzoni, Radiopaedia.org, rlD: 70229

Pain in the flexible flatfoot is a common complaint. When present, it is important to find its exact location and causes. This study aimed to find differences between children with and without medial arch pain and relate them to the reduction of pain following surgical treatment.

Children with idiopathic flexible flatfeet were retrospectively included in the study. All children underwent a clinical, radiographic, and gait examination. The feet were subdivided into 2 groups: asymptomatic and those with medial arch pain. Factors associated with medial arch pain were identified via t test. Significant radiological and gait parameters were correlated to the change in medial arch pain score following surgery.

Included were 322 feet belonging to 177 children, with the mean age of 11.8 (SD = 2.2) years. The pain was perceived in 52% of the feet; of these, 74% in the medial arch. In the group with pain, 31 feet received a gait analysis following surgery. The radiological parameters, talus-1 and -2 metatarsal angles and the gait parameter, calcaneal lateral shift during walking showed a significant difference ( $P \le .004$ ) between the no pain and pain groups and were associated (R2  $\ge 0.14$ ,  $P \le .04$ ) with the reduction in pain following surgery. The increased talus-1 and -2 metatarsal angles and the calcaneal lateral shift may cause increased tension on the soft-tissues along the medial side of the foot and may produce pain. Therapies aiming at improving the medial arch pain should be directed to normalize the talus-1 or -2 metatarsal angles and the calcaneal lateral shift.

Source: Böhm H, Dussa CU. Clinical, Radiographic and Gait Parameters Associated with Medial Arch Pain in the Flexible Pediatric Flatfoot. J Foot Ankle Surg. 2023 Jul-Aug;62(4):637-643. Used with permission.

## EFFECTS OF AFO ON STATIC BALANCE IN FOOT DROP PATIENTS

Ankle-foot-orthoses (AFOs) play a significant role in gait biomechanics, but researchers from Italy identified a lack in evidence of the effects of AFOs on static balance. They conducted a study that looked at 24 patients (15 males, age 57±14 yrs, BMI 23.4±4.4kg/m2), with bilateral (3) or unilateral foot drop syndrome (12 right foot). Static balance assessment was performed using ProKin platform (v. 252 Tecnobody, Dalmine (BG) – Italy). The experimental trial consisted of a static acquisition, repeated with open and closed eyes, in which the subject maintains the standing position for 30s, looking straight forward to a reference point with the feet in extra-rotation. Two-way ANOVA was used to analyze 2 main effects (open or closed eyes and the influence of the orthosis) and the interaction factor. Statistical analyses were performed using R version 4.0.3.

Their results appear in Tables 1 and 2. Their findings show that use of the intervention AFO did not produce improvements in the static balance of patients with foot drop. They theorize that AFO impact principally improves gait and dynamic balance rather than static functions. They further note that different AFO designs have different impacts on postural responses, thus being more appropriate for a specific group of patients. One key limitation is their study population was small and the etiology of foot drop varied (ie, not all were stroke patients). They conclude with a call to investigate the impact of long-term use before progressing to general considerations about AFO effectiveness in static balance. (effectiveness in static balance)

	Without AFO		With AFO	
	Eyes Open	Eyes Closed	Eyes Open	Eyes Closed
Sway Area (cm <sup>2</sup> )	4.13±3.58	15.3±21.2	4.69±5.31	17.4±23.8
Sway Path Length (cm)	58.5±29.8	140±114	61.6±34.7	134±96
Standard Deviation AP (mm)	5.97±2.97	$10.0\pm 5.7$	5.66±2.37	11.0±6.5
Standard Deviation ML (mm)	3.84±2.23	6.28±4.91	4.02±3.03	6.79±5.74
COP Velocity AP (mm/s)	15.3±8.1	39.4±32.9	15.9±9.9	37.7±27.5
COP Velocity ML (mm/s)	8.67±4.79	17.5±14.8	9.25±5.68	16.2±13.4
2. ANOVA Statistical Test Results.		1111		
	AFO Condition	Eyes	AFO Condition*Eyes	
Sway Area	0.632	5.37e-5****	0.783	
Sway Path Length	0.887	9.32e-10****	0.670	
Standard Deviation AP	0.632	2.21e-9****	0.354	
Standard Deviation ML	0.579	7.62e-5****	0.794	
COP Velocity AP	0.859	2.37e-10****	0.714	
COP Velocity ML	0.803	2.31c-6****	0.534	

Source: Amitrano F, Coccia A, Pagano G, Biancardi A, Tombolini G, D'Addio G. Effects of Ankle-Foot Orthosis on Balance of Foot Drop Patients. Stud Health Technol Inform. 2023;302:1029-1030. doi: 10.3233/ SHTI230338.

## **INJURIES RELATED TO SAUNA BATHING**

Awareness of well-being and health issues have contributed to increased popularity of sauna bathing. However, little is known about potential risks and injuries. The aim of this study was to identify the causes for injuries, the affected body regions, and to define recommendations for prevention.

Researchers from Austria conducted a retrospective chart analysis Continued on page 14





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looking at patients treated for an injury related to sauna bathing at the local trauma center of the Medical University of Innsbruck between January 1, 2005 and December 31, 2021. Patients' demographics, the cause for the injury, the diagnosis, the body region of the trauma and the treatment methods were collected.



They identified 209 patients with injuries related to sauna bathing (83 female [39.7%] and 126 male [60.3%]). Fifty-one patients showed more than one injuries leading to a total of 274 diagnoses:

- contusions/distorsions (113; 41.2%)
- wounds (79; 28.8%)
- fractures (42; 15.3%)
- ligament injuries (17; 6.2%)
- concussions (15; 5.5%)
- burns (4; 1.5%)
- brain bleeding (3; 1.1%).

The most common cause for an injury was a slip/fall (157; 57.5%) followed by dizziness/syncope (82; 30.0%). Interestingly, head and face injuries were mostly caused by dizziness/syncope, whereas slip/fall was the leading cause for injuries of foot, hand, forearm, and wrist. Nine patients (4.3%) needed surgical treatment mainly due to fractures. Eight patients got injured by wood splinters. One patient sustained grade IIB-III burns lying unconscious with an alcohol intoxication of 3.6% in the sauna.

While the head accounted for 28% of all injuries, the lower extremity accounted for 20%: foot 10%, knee 6%, and ankle 4%.

The authors concluded that key injury prevention would involve improved personal behavior (e.g. drink enough water before and after each sauna bathing), whereas slip/falls might be prevented by the revision of safety regulations, particularly the obligation to wear slip resistant slippers.

Source: Kaiser P, Seeher U, Krasniqi A, Keiler A, Crazzolara R, Meryk A. Injuries related to sauna bathing. Injury. 2023;54(7):110825. doi: 10.1016/j.injury.2023.05.056.

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## **RELATIONSHIP BETWEEN VIT D LEVEL** & OSTEOPOROSIS



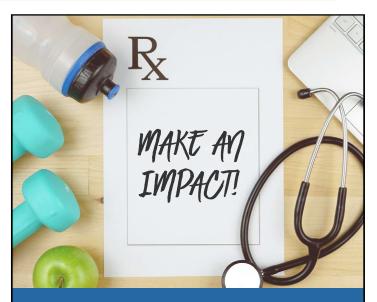
To achieve bone health in general population, the Institute of Medicine (IOM) guidelines and the Endocrine Society guidelines recommend 50 and 75 nmol/L respectively as sufficient levels of serum 25-hydroxyvitamin D (25(OH)D). Researchers from China wanted to understand if there were positive effects with high levels of vitamin D on bone mineral density (BMD).

Using data from the National Health and Nutrition Examination Survey (NHANES), the team used a cross-sectional study design to analyze the relationship between serum 25(OH)D levels and osteoporosis in 2,058 postmenopausal women (age 50+).

Multiple logistic regression was used to explore the relationship between serum 25(OH)D and osteoporosis of total femur, femoral neck and lumbar spine, with stratified analyses for age (<65 and  $\geq$ 65 years), BMI (<25, 25 to <30,  $\geq$ 30 kg/m2) and survey months (winter months and summer months).

In the fully adjusted model, compared with serum 25(OH)D levels <50 nmol/L, the odds ratios (ORs) and 95% confidence intervals (CIs) of serum 25(OH)D 50-<75 nmol/L and  $\geq$ 75 nmol/L were 0.274 (0.138, 0.544) and 0.374 (0.202, 0.693) in osteoporosis of total femur, 0.537 (0.328, 0.879) and 0.583 (0.331, 1.026) in osteoporosis of femoral neck, and 0.614 (0.357, 1.055) and 0.627 (0.368, 1.067) in osteoporosis of lumbar spine, respectively.

The results of this study showed that postmenopausal women with higher serum 25(OH)D levels are less likely to suffer from osteoporosis. Both serum 25(OH)D levels of 50-<75 nmol/L and  $\geq 75$ nmol/L were protective against osteoporosis, compared with serum 25(OH)D levels <50 nmol/L. Specifically, high serum 25(OH)D levels had a significant protective effect on total femur and femoral neck, but not on lumbar spine. After age stratification, the protective effect of high 25(OH)D levels was observed at all 3 skeletal sites in elderly women aged  $\geq 65$  years.



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Medical Footcare

#### Continued from page 15

The authors concluded that adequate vitamin D may reduce the risk of osteoporosis in postmenopausal women in the United States, especially in those aged 65 years and older. More attention should be given to serum 25(OH) D levels to prevent osteoporosis.

Source: Wang D, Yang Y. The Relationship Between Serum 25-Hydroxyvitamin D Levels and Osteoporosis in Postmenopausal Women. Clinical Interventions in Aging. 2023;18:619-627.

EXERCISE MAY DECREASE PARKINSON'S RISK



In a 30-year study of nearly 100,000 females, French researchers found that females who exercised the most had a 25% lower rate of Parkinson's disease compared to those who exercised the least. While the study does not prove that exercise lowers the risk of developing Parkinson's disease, it does show an association.

"Exercise is a low-cost way to improve health overall, so our study sought to determine if it may be linked to a lower risk of developing Parkinson's disease, a debilitating disease that has no cure," study author Alexis Elbaz, MD, PhD, of the Inserm Research Center in Paris, France said in a press release. "Our results provide evidence for planning interventions to prevent Parkinson's disease."

The study included 95,354 female participants (average age 49), mostly teachers who did not have Parkinson's disease at the start of the study. Researchers followed participants for 3 decades during which 1,074 participants developed Parkinson's disease.

Over the course of the study, participants completed up to 6 questionnaires about the types and amounts of physical activity they were getting. They were asked how far they walked and how many flights of stairs they climbed daily, how many hours they spent on household activities as well as how much time they spent doing moderate recreational activities such as gardening and more vigorous activities such as sports.

Researchers assigned each activity a score based on the metabolic equivalent of a task (METs), a way to quantify energy expenditure. For each activity, METs were multiplied by their frequency and duration to obtain a physical activity score of METs-hours per week. For example, a more intense form of exercise like cycling was 6 METs, while less intense forms of exercise such as walking and cleaning were 3 METs. The average physical activity level for participants was 45 METs-hours per week at the start of the study.

Participants were divided into 4 equal groups of just over 24,000 people each. At the start of the study, those in the highest group had an average physical activity score of 71 METs-hours per week. Those in the lowest group had an average score of 27 METs-hours per week.

Among the participants in the highest exercise group, there were 246 cases of Parkinson's disease or 0.55 cases per 1,000 person-years compared to 286 cases or 0.73 per 1,000 person-years among participants in the lowest exercise group. Person-years represent both the number of people in the study and the amount of time each person spends in the study.

After adjusting for factors such as place of residence, age of first period and menopausal status, and smoking, researchers found those in the highest exercise group had a 25% lower rate of developing Parkinson's disease than those in the lowest exercise group when physical activity was assessed up to 10 years before diagnosis; the association remained when physical activity was assessed up to 15 or 20 years before diagnosis. Results were similar after adjusting for diet or medical conditions such as high blood pressure, diabetes, and cardiovascular disease.

Researchers also found that 10 years before diagnosis, physical activity declined at a faster rate in those with Parkinson's disease than in those without, likely due to early symptoms of Parkinson's disease.

"With our large study, not only did we find that female participants who exercise the most have a lower rate of developing Parkinson's disease, we also showed that early symptoms of Parkinson's disease were unlikely to explain these findings, and instead that exercise is beneficial and may help delay or prevent this disease," said Elbaz. "Our results support the creation of exercise programs to help lower the risk of Parkinson's disease."

Source: Portugal B, Artaud F, Degaey I, et al. Association of Physical Activity and Parkinson Disease in Women Long-term Follow-up of the E3N Cohort Study. Neurol. 2023;101(4):e386-398. DOI: 10.1212/ WNL.000000000207424.

## PATELLOFEMORAL JOINT GEOMETRY AND OA

In this cross-sectional study, international researchers compared patellofemoral geometry in individuals with a youth-sport-related intra-articular knee injury to uninjured individuals, and the association between

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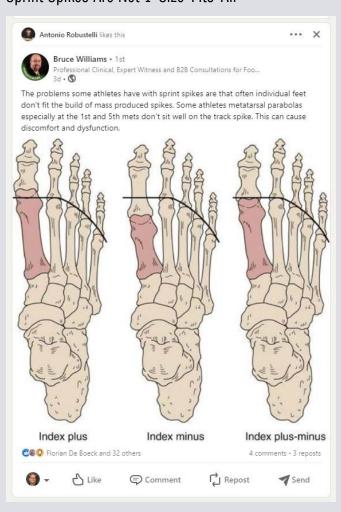
patellofemoral geometry and magnetic resonance imaging (MRI)-defined osteoarthritis (OA) features. In the Youth Prevention of Early OA (PrE-OA) cohort, they assessed 10 patellofemoral geometry measures in individuals 3–10 years following injury compared with uninjured individuals of similar age, sex, and sport, using mixed effects linear regression. They also dichotomized geometry to identify extreme (>1.96 standard deviations) features and assessed likelihood of having extreme values using Poisson regression. Finally, they evaluated the associations between patellofemoral geometry with MRI-defined OA features using restricted cubic spline regression.

The team found that mean patellofemoral geometry did not differ substantially between groups. However, compared with uninjured individuals, injured individuals were more likely to have extremely large sulcus angle (prevalence ratio [PR] 3.9 [95% confidence interval, CI: 2.3, 6.6]), and shallow lateral trochlear inclination (PR 4.3 (1.1, 17.9)) and trochlear depth (PR 5.3 (1.6, 17.4)). In both groups, high bisect offset (PR 1.7 [1.3, 2.1]) and sulcus angle (PR 4.0 [2.3, 7.0]) were associated with cartilage lesion, and most geometry measures were associated with at least one structural feature, especially cartilage lesions and osteophytes. They observed no interaction between geometry and injury.

Overall, they found that certain patellofemoral geometry features are correlated with higher prevalence of structural lesions compared with injury alone, 3–10 years following knee injury. Hypotheses generated in this study, once further evaluated, could contribute to identifying higher-risk individuals who may benefit from targeted treatment aimed at preventing posttraumatic OA.

Source: Macri, EM, Whittaker, JL, Toomey, CM, et al. Patellofemoral joint geometry and osteoarthritis features 3–10 years after knee injury compared with uninjured knees. J Orthop Res. 2023; 1-12. doi:10.1002/jor.25640

# LINKEDIN COMMENT OF THE MONTH Sprint Spikes Are Not 1-Size-Fits-All





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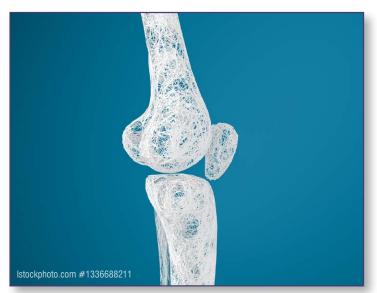
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# Highlights from the Endocrine Society Annual Meeting

## "ROBOTIC PILL" SAFELY DELIVERS INJECTABLE OSTEOPOROSIS DRUG

END**=**202.



A proven and effective medication for osteoporosis, which is currently only available as an injection, can be administered orally using a novel "robotic pill," according to a study presented in June at ENDO 2023, the Endocrine Society's annual meeting in Chicago, Ill.

"We believe this study provides the first clinical evidence of safe and successful delivery of the osteoporosis drug teriparatide through an oral robotic pill," said Arvinder Dhalla, PhD, who leads Clinical Development at Rani Therapeutics, the San Jose, Calif.-based company that developed the technology and funded the study. "Data from this study are very encouraging and should give hope to those suffering from chronic conditions that require painful injections, like osteoporosis, that an oral alternative could be on the way."

When a person swallows the robotic pill, it moves through the stomach intact. In the intestine, the pill releases a self-inflating balloon

with a micro-syringe, which injects a drug-filled microneedle and delivers the medication.

"The intestines do not have pain response to needles, so the injection is painless," Dhalla said. The needle rapidly dissolves, and the medication is absorbed while the delivery mechanism deflates and is safely passed out of the body.

"The robotic pill, which is essentially a swallowable auto-injector in the form of a pill, is designed to deliver the drug safely and efficiently as a painless intestinal injection," she said.

The Phase I study of 39 healthy women evaluated the safety, tolerability and movement through the body of the robotic pill known as RT-102, containing a dose of the drug teriparatide (PTH 1-34). Teriparatide is a synthetic form of the natural human parathyroid hormone. It has been in clinical use for decades as an injectable medication (under the brand name Forteo<sup>®</sup>) for rebuilding brittle bones of osteoporosis patients. It is taken as a daily injection for up to 2 years.

Study participants were divided into 3 groups. Two groups received either a lower or higher dose delivered with the robotic pill, and the third group received a standard injection of teriparatide. Fluoroscopic imaging was used to track the robotic pill through and out the body. Drug concentrations were measured in blood samples collected over 6 hours. The study found the bioavailability of the drug delivered by the robotic pill was comparable to or better than the drug given via the injection.

"This breakthrough technology of converting injections into oral pills is a significant step forward towards ending the burden of painful injections for millions of patients suffering from chronic diseases," Dhalla said. (e)

Source: Myers JT, Dasari A, Battiwala A, et al. An Orally Administered Robotic Pill (RP) Reliably And Safely Delivers the Human Parathyroid Hormone Analog hPTH([1-34) (Teriparatide) With High Bioavailability in Healthy Human Volunteers: A Phase 1 Study. Presented June 17 at Endo 2023. "Excellent as always! As prescribed, as designed, as promised. A real time saver for my clinical hours."

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## BMI ALONE MAY NOT BE A SUFFICIENT INDICATOR OF METABOLIC HEALTH

Evidence shows that a high proportion of U.S. adults with normal body mass index (BMI) still have obesity which highlights the inadequacy of BMI as the gold standard measure of metabolic health.



To better understand drivers

for cardio-metabolic disease, new research highlighted the need to better understand what percentage of the body is fat, muscle, bone, and water, and how much fat is in the abdomen vs. the thighs.

Racial/ethnic differences in body fat, BMI, and body fat distribution may provide evidence for future studies to further determine if these differences are possible drivers of the racial disparities seen in cardio-metabolic diseases, explained Aayush Visaria, MD, MPH, an internal medicine resident at the Rutgers Robert Wood Johnson Medical School in New Brunswick, NJ.

Visaria and colleagues identified non-pregnant US adults aged 20-59 years from the 2011-2018 National Health and Nutrition Examination Survey (NHANES) with whole body DEXA scan data. Their BMI was categorized by ethnicity (non-Asian: underweight <18.5, normal=18.5-24.9, overweight=25-29.9, obese≥30 kg/m2; Asian: <18.5, 18.5-22.9, 23-27.4, 27.5+).

The researchers estimated odds of obesity among adults as normal/ overweight based on BMI or total body fat percentage (BF%) as ≥25% in male and ≥32% in female, by race (non-Hispanic White [NHW], non-Hispanic Black [NHB], Asian, Hispanic, and other). They also estimated mean DEXA adiposity measures by race.

They found that nearly 36% had BMI≥30 (the traditional definition of obesity) but 74% had obesity per BF%. Among normal BMI adults, 44% of NHW, 27% of NHB, 49% of Hispanic, and 49% of Asians had obesity as per BF%. Among normal BMI adults, the mean android-to-gynoid fat ratio (the pattern of body fat distribution associated with increased risk for metabolic syndrome) was 0.84 for NHW, 0.85 for NHB, 0.89 for Hispanics, and 0.91 for Asians.

Nearly 3 in 4 young-to-middle-aged US adults were considered to have obesity according to BF% from DEXA scans. Asian Americans and Hispanics with seemingly normal BMI were more likely to have obesity, and more likely to have a greater proportion of abdominal fat than NHW. Non-Hispanic Blacks had significantly lower chances of obesity at normal/overweight BMI ranges, and a lower proportion of abdominal fat.

"We hope this research will add to the idea of weight-inclusive care

and allow clinicians to 1) routinely use supplementary measures of body fat such as waist circumference or bioimpedance-based body fat measurements (eg, smart scales) in addition to BMI, 2) engage in practices to prevent unconscious biases that may occur when caring for a patient with obese BMI, and 3) engage in clinical decision-making that is not solely dependent on a BMI calculation but rather an overall idea of body composition and body fat distribution," Visaria said. (er)

Source: Visaria A, Sindhu T, Dharamdasani T. Discordance Between Body Mass Index and Dual-energy X-ray Absorptiometry Based Adiposity Measures Among United States Adults. Presented June 16 at Endo 2023.

## FULL RECOVERY MAY BE POSSIBLE AMONG MEN WHO USE STEROIDS FOR MUSCLE GROWTH

Full recovery of testosterone production may be possible for men who wish to stop using anabolic-androgenic steroids for muscle growth.

Anabolic steroids are used as performance-enhancing drugs by professional and amateur athletes, and by other men to improve appearance. Past abuse of anabolic steroids can suppress the body's ability to produce testosterone for months. Bonnie Grant, MD, of Imperial College London in London, UK, and colleagues found that those who used post-cycle therapy have an improved chance at such a recovery. Study participants used post-cycle therapy drugs including human chorionic gonadotrophin (hCG), selective estrogen receptor modulators and aromatase inhibitors to help the body resume producing testosterone.

"It is important to recognize that self-medicating post-cycle therapy is not recommended and may be hazardous if illicitly obtained. However, we were surprised to observe post-cycle therapy use was associated with an improved chance of having fully recovered reproductive hormones in men wishing to stop anabolic steroid use," Grant said.

The research team conducted an audit of 613 men who went to one addiction center for stopping anabolic steroid use in Scotland between 2015-2022. Random blood tests completed within a year of quitting anabolic steroids, with or without post-cycle therapy, were utilized for the study. Grant and colleagues sought to collect the combination of reference range levels of the reproductive hormones serum LH, serum FSH, and total testosterone as surrogate markers of biochemical recovery from hypogonadism.

"Currently, there is no treatment recommended to help men wishing to stop anabolic-androgenic steroid use," said Channa Jayasena MD, PhD, the senior study author. "Our data suggest that self-administered post-cyRemovable Pegs Unload Targeted Areas

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#### Continued from page 23

cle therapy drugs may be associated with improved reproductive hormone levels in men stopping anabolic steroid use. We also showed other factors which are associated with improved recovery. This information may help improve therapeutic options in the future treatment of men wishing to stop using anabolic steroids."

Seventy-six percent of the men reported post-cycle therapy use. Among them, the researchers noted significantly higher serum total testosterone following anabolic steroid cessation compared to men who did not report post-cycle therapy use.

Post-cycle therapy use was linked to a greater chance of normalized reproductive hormones and a shorter time span between stopping anabolic steroid use and the normalized hormone levels. The chances improved significantly when post-cycle therapy was used, fewer anabolic steroids were used, there was a shorter duration of anabolic steroid use, and when anabolic steroids were stopped for a longer amount of time. These improvements were statistically significant, according to the researchers.

"We need further studies to help doctors and other healthcare professionals advise men about the risks of anabolic steroid use and support those who are motivated to stop," Jayasena said. (e)

Source: Grant B, Campbell J, Pradeep A, et al. Self-administration of Post-cycle Therapy Is Associated With Increased Probability of Subsequent Normalisation of Reproductive Hormones Following Anabolic-androgenic Steroid Cessation in Men. Presented June 17 at Endo 2023.

# REDUCED BONE QUALITY LINKED TO SOCIAL ISOLATION IN MICE STUDY



Social isolation may negatively impact bone health according to a new study conducted in mice.

"Social isolation is a potent form of psychosocial stress and is a

growing public health concern, particularly among older adults," said lead researcher Rebecca Mountain, PhD, of Maine Health Institute for Research in Scarborough, Maine. "Even prior to the onset of the COVID-19 pandemic, which has significantly increased the prevalence of isolation and loneliness, researchers have been concerned about a rising 'epidemic of loneliness."

EN

Mountain noted that social isolation is associated with increased risk for many health conditions in people, including mental health disorders, as well as higher overall rates of illness and death.

"Previous clinical research has demonstrated that psychosocial stressors, and subsequent mental health disorders, are major risk factors for osteoporosis and fracture, which disproportionally affect older adults," Mountain said. "The effects of social isolation on bone, however, have not been thoroughly investigated."

In the new study, researchers exposed adult mice to either social isolation (one mouse per cage) or grouped housing (4 mice per cage) for 4 weeks. They found that social isolation caused significant reductions in bone quality, including reduced bone mineral density, in male, but not female mice.

"Overall, our data suggest that social isolation has a dramatic negative effect on bone in male mice, but it may operate through different mechanisms or in a different time frame in female mice," Mountain said. "Future research is needed to understand how these findings translate to human populations."

In addition to exploring the effects of social isolation in human datasets, her research team will also investigate the mechanisms of how social isolation contributes to bone loss using mouse models.

"Our work provides critical insight into the effects of isolation on bone and has key clinical implications as we grapple with the long-term health impacts of the rise in social isolation related to the COVID-19 pandemic," Mountain said. (er)

Source: Mountain R, Langlais A, Hu D, Baron RE, Lary C, Motyl KJ. Social Isolation Stress Leads to Bone Loss in Adult Male, but Not Female, C57BL/6J Mice. Presented June 18 at Endo 2023.

## T1DM SURVEY SHOWS STRUGGLE TO MANAGE DISEASE & EXERCISE

For people with type 1 diabetes (T1DM), managing blood glucose levels before, during and after aerobic exercise is a major struggle. Several major professional organizations have published guidelines and recommendations to address various aspects of the struggle. But how those guidelines are understood and implemented by patients has not been

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widely studied...until now.

Researchers at the University of Arkansas in Little Rock put together an online survey which was posted to social media groups limited to adults with T1DM who run, jog, or walk for exercise. The survey was completed by 102 adults with T1DM and found that:

- 68% reported exercising 4+ days per week
  - o They averaged 23 miles per week
- 98% reported using continuous glucose monitors
- 75% used insulin pumps
- Self-reported average HbA1c was 7.1%

Despite being under a physician's care, most respondents felt they had learned about diabetes and exercise on their own:

- 80% learned mostly from "trial and error"
- 46% from social media
- 32% from their medical team
- 28% from online searches
- Some used multiple methods

As for hypoglycemia and exercise, the survey found that:

- 27% reported ongoing fear of hypoglycemia as a significant barrier to exercise
- 36% reported noticing increased glucose variability because of exercise
- 19% reported having hypoglycemia unawareness, which occurs when a person with diabetes does not experience the usual early warning symptoms of low blood sugar (eg, sweating, trembling, butterflies in the stomach, tingling, numbress and rapid pulse)
- 73% reported that they exercised even if they had severe hypoglycemia in the last 24 hours
- 74% did not perform testing for diabetic ketoacidosis even when they had very high and unexplained blood sugar prior to exercise
- 49% reported not wearing diabetes identification during exercise

"This survey demonstrated that many people who live with T1DM, despite being tech-savvy and engaged, passionate about exercise, and seemingly well-controlled based on hemoglobin A1c, are still struggling to exercise safely without high and low blood sugar," said lead researcher Joseph Henske, MD, of the University of Arkansas for Medical Sciences in Little Rock. "We hope to increase awareness of published guidelines regarding exercising with diabetes and help create better practical educational tools."

Source: Henske JA, Beach G, Albashaireh A. Real-World Survey of Adherence to Guidelines Regarding Type 1 Diabetes and Aerobic Exercise. Presented June 15 at Endo 2023.

## AROMATASE INHIBITORS MAY LIMIT EFFECTS OF WEIGHT LOSS MEDS

Aromatase inhibitors, some of the most common breast cancer medications, may lessen the effect of weight loss drugs, according to a new study from the Mayo Clinic.

The study found that weight loss medications are less effective in breast cancer survivors who are treated with aromatase inhibitors, compared with women without a history of breast cancer who are not taking aromatase inhibitors.

Aromatase inhibitors are used to treat some types of breast cancer as well as to help prevent breast cancer in some women who are at a high risk of developing it. By blocking aromatase, an enzyme required to make estrogen, these drugs lower the amount of estrogen made by the body, which may stop the growth of cancer cells that need estrogen to grow.

"Weight gain is a common concern in breast cancer survivors," said lead researcher Sima Fansa, MD, of the Mayo Clinic in Rochester, Minn. She said studies have shown that aromatase inhibitors may be a risk factor for weight gain. Weight gain and obesity, in addition to being associated with breast cancer recurrence and breast cancer-related death, can lead to heart disease and heart-related death.

"This is the first study assessing response to weight loss medications in a subgroup of breast cancer survivors taking aromatase inhibitors," Fansa said. "Our results highlight the need to develop better approaches to manage weight gain in patients with a history of breast cancer taking aromatase inhibitors. Preventing weight gain in this group or treating obesity effectively will improve breast cancer outcomes, prevent further health complications, and improve quality of life for these people."

The study included 99 patients—63 women with a history of breast cancer taking aromatase inhibitors and weight loss medications (liraglutide, semaglutide or phentermine); and 36 women without a history of breast cancer who were not taking aromatase inhibitors but were taking weight loss medications.

The women in the breast cancer group lost less weight at 3, 6 and 12 months compared with the women without a history of breast cancer (3.7% vs. 5.6% at 3 months; 3.9 vs. 9.5% at 6 months; and 5.2% vs. 10.5% at 12 months).

"We believe that this difference may be explained, at least partially, by the anti-estrogen effect of aromatase inhibitors," Fansa said. "Aromatase inhibitors can lead to decreased muscle mass, increased fat mass, and changes in energy expenditure. This may affect the body's response to weight loss interventions, including weight loss medications."

Source: Fansa S, Ghusn W, Tama E, et al. Efficacy of Anti-obesity Medications Among Breast Cancer Survivors Taking Aromatase Inhibitors. Presented June 16 at Endo 2023.

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# Motor Point Heatmap of the Calf

By Elias Schriwer, Robin Juthberg, Johanna Flodin, and Paul W. Ackermann

# Mapping muscle motor points in the calf could improve electrode placement for neuromuscular electrical stimulation and thereby enhance outcomes.

Muscle contractions in the calf induced by neuromuscular electrical stimulation (NMES) may prevent venous thromboembolism, help rehabilitation, and optimize strength training, among other uses. However, compliance to NMES treatment is limited by the use of suboptimal stimulation points which may cause discomfort and less effectivity. Knowledge of where it is most likely to find muscle motor points (MP)defined as the point on the skin that resulted in a small but clearly visible contraction of a muscle in the calf at the lowest possible level of stimulation by an NMES device-could improve NMES comfort and compliance. Toward that end, the aim of this study is to anatomically map the MPs of the calf as well as calculate the probability of finding an MP in different areas of the calf.

# Methods

Anatomical landmarks on the lower limbs were defined on 30 healthy participants (mean age 37 years). The test protocol included measurements of the calf and MP scans. The midline of the calf (MC) was defined as the line connecting the center of the fossa poplitea to the calcaneal insertion of the Achilles tendon (Figure 1). The



location of the 4 most responsive MPs on the medial and lateral head of the gastrocnemius were determined in relation to these anatomical landmarks using an MP search pen and a pre-set MP search program. The anatomy of the calves was normalized and subdivided into a matrix of 48 ( $6 \times 8$ ) smaller areas ( $3 \times 3$ cm), from upper medial to lower lateral, in order to calculate the probability of finding an MP in 1 of these areas. The probability of finding an MP was then calculated for each area and presented with a 95% confidence interval.

## Results

The MP heatmap displayed a higher concentration of MPs proximally and centrally on the calf. However, there were wide inter-individual differences in the location of the MPs (Figure 2). The highest probability of finding an MP was in area 4, located centrally and medially, and in area 29, located centrolaterally and around the maximum circumference, both with 50% probability (95% CI: 0.31–0.69). The second highest probability of finding MPs was in areas 9, 10, and 16, proximally and medially, all with 47% probability (95% CI: 0.28–0.66). Areas 4, 9, 10, 16, and 29 exhibited a significantly higher probability of finding MPs than all areas with a mean probability of 27% and lower (P < 0.05). The lateral and distal outskirts exhibited almost zero probability of finding MPs.

## Discussion

This study demonstrated a pronounced inter-individual variation in the localization of calf muscle MPs. The 2 areas with the highest concentrations of MPs were localized in the midline close to the fossa poplitea and in the proximity of the transverse plane at the maximum circumference of the calf. A computed MP heatmap displayed the probabilities of finding MPs on an anatomical chart, which may guide and help the clinician in daily NMES application.

The prominent inter-individual variability in the anatomical localization of MPs on the calf muscle was the main finding of this study, which suggests that each patient, when possible, should undergo an MP scan before NMES elec-

This article has been excerpted from "Motor Point Heatmap of the Calf," published in the Journal of NeuroEngineering and Rehabilitation. 2023;20:28. https://doi.org/10.1186/ s12984-023-01152-5. Editing has occurred, including the renumbering or removal of tables, and references have been removed for brevity. Use is per CC 4.0 International License.



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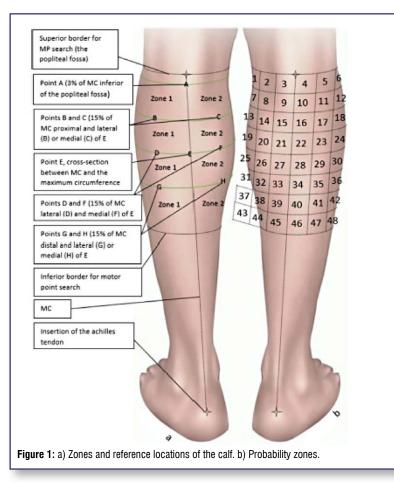
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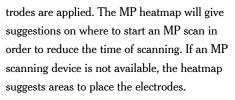




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The observation of the most distal MP being localized at around 50% length of the calf suggests that clinicians do not have to scan for MPs below the mid of the calf when applying calf NMES. The study authors' identification of the most medial and lateral MPs both being localized at around 6cm (18%) from the MC implies a further restriction of the search area for the clinician performing the MP scan.

The second main finding of this study was the localization of the 2 areas on the calf that exhibited the highest concentrations of MPs.

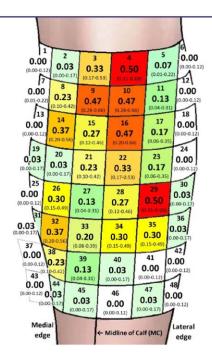
Based on the study authors' main findings, they established a novel MP heatmap displaying the probabilities of finding MPs in 48 predefined,  $3 \times 3$ cm areas of the calf. The heatmap displayed that central and proximal areas of the calf showed a much greater probability of

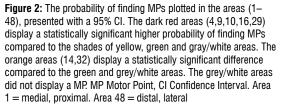
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containing an MP than the most medial, lateral, and distal areas. The graphical display of the heatmap suggests an anatomical chart, which can be used to search for MPs in a subsequent, logical order.

The observation of areas 4 and 29 demonstrating the highest probability of containing an MP, at 50%, suggests that these areas may be good starting points for the clinician to locate MPs. Area 4, located 0–3cm below the fossa poplitea and just lateral of the midline, and area 29, located 12–15cm below the fossa poplitea at the largest circumference of the calf and 3–6cm lateral of the midline, may be easily identified by the clinician. The finding that areas 4 and 29 exhibited a significantly higher probability of identifying an MP than in 39 of the 48 areas examined on the calf strengthen the observation that these areas are good starting points to look for MPs.

The discovery that areas 9, 10, and 16, which demonstrated the second highest probability of finding an MP (47%), share borders





with each other and with area 4 implies how a manual search with MP pens on the calf could be performed. After the search in area 4, the study authors suggest that the search of MPs should continue in a distal and medial direction to area 9, followed by searching laterally toward area 10, subsequently in a distal direction to area 16, then continuing the search distally toward area 29, passing areas 22 and 28 on the way.

## Conclusions

This study demonstrated a distinct inter-individual variation in the localization of MPs on the calf muscle. However, certain anatomical patterns of likelihood of where to find MPs seem to repeat among subjects. This MP heatmap of the calf could be used to expedite electrode placement and to improve compliance in order to receive consistent and enhanced results of NMES treatments.

# Welcome To The Reality Of Diabetic Foot Ulceration: A Multidisciplinary Approach To Evaluation and Management Through Computer-Aided Gait Analysis & Custom Diabetic Orthoses

BY JAY SEGEL, DPM; SALLY CRAWFORD, MS; MARK HOPKINS, PT, CPO, MBA; BRIAN MURRAY, PT; TRACY WINCHESTER; ALEXANDER LAKNER, DPM; DEETTA MCKNIGHT, RN; CAITLIN HICKS, MD, MPH-V; CHRISTOPHER ABULARRAGE, MD; SANUJA BOSE, MD, MPH; ALANA KEEGAN, MD; AND RONALD SHERMAN, DPM, MBA

Diabetes mellitus has exploded in its prevalence worldwide, affecting millions with grave consequences, crippling both the patient and the medical system alike. The diabetic foot is a significant contributor to the global burden of disability.

#### "Diabetes is an epidemic."

Three years ago, at a round table discussion, these words inspired an evocative and profound study centered at the Johns Hopkins Hospital. This discussion would be the commencement of an Institutional Review Board approved study to determine the efficacy of diabetic re-ulceration prevention through Computer Aided Gait Analysis (CAGA), custom prescription orthoses, and defined footwear.

The majority of diabetic ulcers develop as a result of everyday stresses, or repetitive micro-trauma at the foot's plantar surface. These can occur during routine ambulation as patients go about their normal routine, or occurrence can be heightened with specialized activities.

The underlying contributory factors for this are biomechanical and structural deformities of the foot that directly impact areas of identifiable risks on the diabetic plantar foot. This is secondary to multifactorial diabetic co-morbidities including both sensory and motor neuropathy. Hence, as a sequela of the neuropathy and deformities, this patient population will demonstrate an abnormal

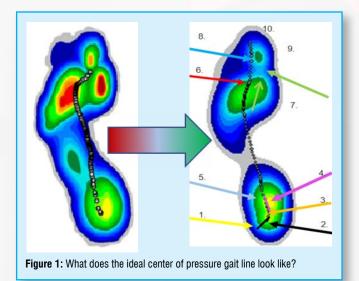
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walking pattern, including a less stable gait and truncated center of pressure, as well as the development of multiple abnormal temporospatial parameters in the multiple phases of gait. These, in turn, create altered gait kinematics and increased peak plantar pressures which overall impair the ability to heal (Figure 1). Herein, a three-dimensional foot of limited mass is colliding with a two-dimensional, relatively unyielding surface of relatively unlimited mass (the ground or support surface). This is a battle the foot encounters 4 million times per year, as this is the average number of steps an individual takes.

These repetitive deforming, shock-producing, and energy-dissipating events will opportunistically wreak havoc on areas at risk on the plantar surface of the foot. Calluses/ulcerations form with the repetitive trauma, and peripheral neuropathy desensitizes the patient to these problems. Furthermore, the presence of arterial disease, common in the diabetic population, makes it difficult to heal these areas. Unfortunately, it is a battle the foot faces repetitively, making it a battle it cannot win. Because of the additional musculoskeletal, neurological, integumentary, and circulatory complications, it is particularly devastating to the compromised diabetic foot which will eventually lose the war to deformity, tissue quality as well as circulatory, neurological complications, and the driving biomechanical forces of basic collision dynamics.

At Johns Hopkins, a multidisciplinary team approach was leveraged to provide the best care possible for these patients. Each contributor brings their own unique viewpoint and expertise of this devastating disease, including predominant specialties: Surgical Podiatry, Vascular Surgery, and Endocrinology. A further contribution is seen by physician assistants, certified prosthetists, physical therapists, occupational therapists, wound care nurses, biomechanist, and a data management team. Consultations from other specialists, including plastic surgery, orthopedic foot and ankle, and infectious disease specialists, are utilized as needed. Efforts by the team in the past were able to repetitively achieve high limb preservation rates for complex diabetic wounds, but the recurrence rates seen were similar to the nationwide rate: 40% ulcer recurrence within

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12 months, 60% in 3 years, and 65% recurrence in 5 years. There had to be a better mousetrap, perhaps one that wasn't in existence or utilized to its full potential. It is into this reality that CAGA was introduced into the treatment paradigm (Figure 2).

Modern-day technology has evolved; the applications and possibilities of today's advancements are endless and constantly being developed. The progressing technology, CAGA, allows for the objective collection of data for this at-risk patient population. With CAGA technology, the understanding of diabetic gait and the identification of occult high plantar-foot pressures is possible, even prior to any apparent clinical signs or symptoms identified by patient and physician. These metrics are then able to be communicated to specialists, who interpret and apply the data to try to prevent future ulceration through footwear and gait modification.

The prevalence and consequence of a diabetic foot ulcer (DFU) remains a devastating life altering event which continues to be a major contributor to our medical and public health challenges. These chronic wounds encompass complexities which have a longterm impact on patients' morbidity, mortality, and quality of life. Globally, more than 425 million people are living with diabetes, and its prevalence is expected to increase at least 50% by 2045.<sup>1,2</sup> Diabetes is, worldwide, the leading cause of blindness, non-traumatic lower extremity amputations, peripheral neuropathy, and end-stage kidney disease, which accounts for 43% of all diabetes-related deaths in people younger than 70 years of age.<sup>3-7</sup> The American Diabetes Association estimates 10.5% of the US population is diagnosed with diabetes (32 million people) and is expected to be 36 million people affected by 2045.8 Diabetes is the 7th leading cause of death in the US as of 2017. More than 200,000 non-traumatic amputations linked to diabetes occur yearly. In the United

States, 230 amputations per day occur in patients with diabetes. Worldwide it is estimated that every 30 seconds a leg is amputated from the manifestations of diabetes.<sup>9-10</sup> Eighty-five percent of diabetes-associated amputations are preceded by the development of foot ulcers. It is estimated that 19–34% of patients with diabetes are likely to be affected with a diabetic foot ulcer in their lifetime, and the International Diabetes Federation reports that 9.1–26.1 million people will develop DFUs annually.<sup>11</sup> Adding to the burden, even when a diabetic ulcer is finally healed, the risk of recurrence is rather commonplace with reported rates between 30% and 40% within the first 12 months.<sup>12-13</sup> Lastly, the medical expenditure for the management of diabetic foot disease in the United States ranges from US \$9.1 to \$13.2 billion annually.<sup>14</sup>

Initially, the diabetic ulcer recurrence rate of the Johns Hopkins multidisciplinary team was similar to that of the nationwide data, as stated above. Our understanding of the literature found that preliminary protocols utilizing CAGA were creditable at improving outcomes. Therefore, CAGA had the potential to help us direct individuals into remission, thereby avoiding the development of recurrent foot ulceration and its associated morbidity, hospital admission, and subsequent amputation.

## Methodology

Through the philanthropy of one patient, who personally realized our limb preservation success, initial resources were obtained to further comprehend the etiology and development of the diabetic foot ulceration. It was this initial impetus to construct the CAGA Diabetic Ulcer Reduction Study (CAGA DURS study). After approval



Figure 2: Johns Hopkins takes a multidisciplinary team approach using Computerized Gait Analysis (CAGA) to revolutionize care and recommendations.

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Continued on page 35

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#### Continued from page 33

by the Johns Hopkins Institutional Review Board (IRB), a nationwide, multidisciplinary committee was assembled and anchored at Johns Hopkins Hospital, utilizing the Noraxon MR3 software paired with a companion outfitted treadmill/video capture system, to perform computer-aided gait analysis.

The team continues work today and is comprised of notable and seasoned experts who are leaders in their fields. These specialists hold credentials and positions in podiatric and vascular surgery, podiatric biomechanics/orthotic prescription writing, biomedical engineering, pedorthics, physical therapy, orthotic lab management, medical writing, and statistical analysis.

Patients are seen by principal providers of the service (vascular surgery, surgical podiatry, and endocrinology) at each inpatient admission and a weekly outpatient clinic visit. They are examined in an integrated fashion within a single location and followed up at frequent intervals for ongoing wound assessment and intervention (Figure 3). The service is designed to optimize wound healing in patients with DFUs. Patients undergo both conservative and surgical modalities to heal the ulcerations according to standard practice. Once healed, an explanation of the CAGA DURS study, its goals, parameters, and limitations/risks are presented to the patient. Each patient is informed and consented for participation within the study.

Inclusion criteria include a diagnosis of diabetes and a foot ulceration where the wound had remained healed for at least 4 weeks. Excluded were those candidates with Charcot neuroarthropathy and compliance issues.

Consented patients are simultaneously referred to the study's physical therapist (PT) and orthotist/prosthetist (Certified Prosthetist/ Orthotist, CPO) for independent initial evaluations. Johns Hopkins has multiple academic locations and laboratories which were all made available to accommodate this patient population's needs.

The initial evaluation is done by PT and includes measurements on limb length, muscle tone, flexibility, and other parameters affecting gait. Before the PT facilitates the patient walking on the specialized treadmill for their initial formal computerized gait analysis, a baseline scan of the patient's bilateral feet is performed by the CPO with iPad scanning software.

CAGA testing is then performed. All testing for this study was completed on a medical grade treadmill where spatial, temporal, center of pressure, and variability parameters are obtained. This is done using the research grade Zebris FDM-T Treadmill (Zebris1 Medical GmbH, Germany) fitted with an under-belt platform consisting of 10,240 force sensors, each approximately 1 cm × 1 cm. Patients are initially walked at a comfortable gait speed (traditionally 0.7mph-1.2mph), while barefoot, to create a baseline gait assessment. During walking (dynamic) and standing (static) modalities, as well as reactive-normal forces are captured in the X, Y, Z directions by the sensors at a sampling rate of 120 Hz. Due to the high density of the sensors, the foot is mapped at a high resolution to facilitate even subtle changes in force distribution. Timing can also be monitored and standardized in a fashion allowing adequate repeat testing. Dedicated Noraxon MyoResearch Software 3.18 running dynamic hardware configurations in 10 zone Myopressure expert mode is integrated with the force signals and provides 2D/3D graphic representation. Additionally, synchronized to the pressure outfitted treadmill

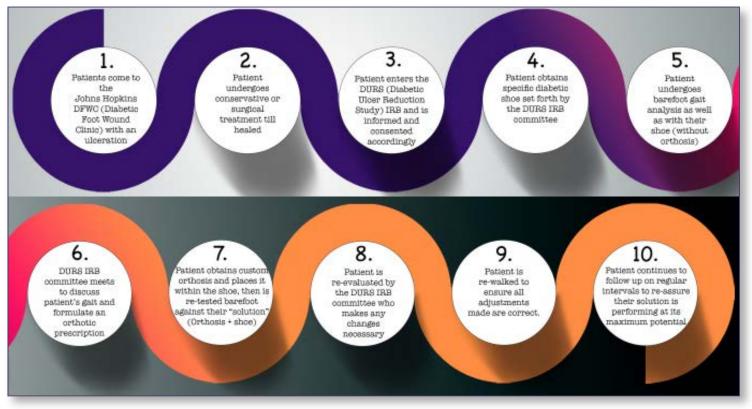


Figure 3: Participant timeline.

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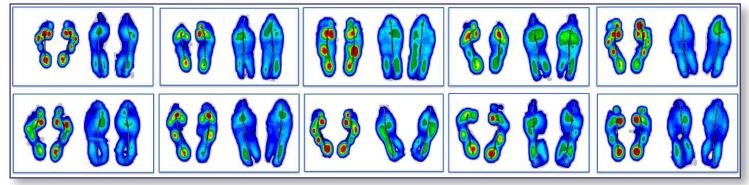


Figure 4: Sample of typical integrated round data comparisons characterizing baseline, test, re-test outcome tracking to monitor solution and care progress.

are 2 slow-motion high-definition cameras (Logitech C 920) to capture video for analysis.

Once the patient is tested by PT, the findings are reviewed by the CAGA DURS committee which meets weekly. The committee assesses the patient's past medical and surgical history, as well as the PT physical exam findings (limb length, muscle tone, etc.). The committee scrutinizes the analytical components of the CAGA data, focusing on quantifying characteristics of the gait pattern and formulates a prescription for a custom orthotic and/or prosthetic based on the patient's areas of risk and their unique biomechanics (Figure 4). The majority of DFUs arise from everyday wear-and-tear, the result of repetitive micro-trauma. In analyzing the pressure print generated by the CAGA, one can identify the areas experiencing a high N/cm2 (usually in excess of 40 N/cm2) which denote an area at heightened risk for future ulceration. This may be the area of former ulceration or an area of current stresses which may become a future ulceration without proper intervention. Furthermore, morphological assessment of the center of pressure (COP) line, indicative of the foot moving throughout stance phase of gait cycle, can denote progressive and/or regressive pronatory and supinatory events of the foot/ ankle complex as well as initial contact point, propulsion throughout the gait cycle, and many other parameters. By observing the manner in which the patient walks and identifying overburdened areas based on pressure and timing abnormalities, the podiatric biomechanical gait specialist can devise a device to effectively offload areas of risk for ulceration and improve problematic gait characteristics. The initial committee session examining the CAGA findings

ends with a coordination of care plan which starts by communicating our custom orthotic to the director of manufacturing of said device.

Orthotic prescription writing is both an art and a science, and for this research study, a choice is made between 3 shell types and a multitude of additions and modifications for further customization. The type of orthotic prescribed will determine the materials used. There are 3 types of devices employed:

- **Type 1** is a soft tri-laminate foam foot bed that is used mainly for cushioning and offloading of the insensate foot.
- **Type 2** is a functional orthotic device with a thermoplastic shell and Poron (a polyurethane) arch reinforcement. The rigidity of the shell is determined by patient weight or the amount of control that is needed. These devices are covered

full length with a layer of Poron padding and a high rebound ethylene vinyl acetate (EVA) as a top cover.

• **Type 3** is an Ankle Foot Orthosis (AFO) brace.

The most prescribed device is the Type 2. The casts are digitally corrected and milled on a Computerized Numerical Control (CNC) router. Materials are pressed into to the cast forms and then postings are added according to the prescription. The final step is finishing the devices, adding pads or accommodations that have been specified by the providers. They are quality checked and sent back to the CPO to dispense.

Patients are then instructed to obtain a designated diabetic shoe from a specifically recognized diabetic shoe manufacturer. The shoes are fitted and provided by 2 local medical pharmacies. Once the prescription is generated

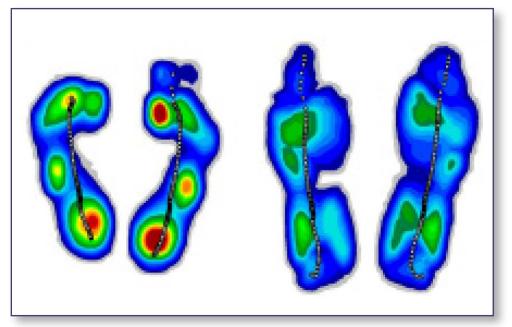


Figure 5: Understanding the magnitude of off-loading captured through all subsequent visits.

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Indy 2 Stage

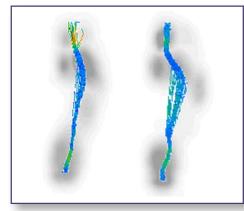


Figure 6: Center of Pressure Gait Line morphologies.

and the devices are authorized by the patient/ funding source, the order is sent to the orthotic manufacturer for fabrication. The fabricated devices are then sent to the CPO who checks them for quality against the prescription and if accurate, then schedules the patient for dispensing and fitting of the device. At this appointment, the patient is expected to have acquired their specified diabetic shoes as it may be coordinated with re-testing of the patient's gait with PT if that is possible and convenient for all parties.

The dispensing and fitting appointment involves a brief screening for any new issues, an assessment of the shoes for fit/size, fitting of the device to the shoes, and an education on use/ care. This is followed by a full second gait analysis or Re-Test of the patient's gait on the specialized treadmill with the custom orthotic plus shoe which is herein described as the "Solution." The patient is re-tested barefoot against their solution (orthotic+shoe), and the results are reviewed by the CAGA DURS committee.

The CPO participates in the re-testing review meetings process and initiates any required follow-up visits for adjustments, repairs, re-fabrication, or replacement based on the outcome of the review process. These subsequent visits, at regular intervals with the CPO, are based on traditional wear patterns observed as well as any needs identified during the subsequent CAGA review meetings (Figure 5).

This process continues for the duration of the study at 1 month, 3 months, 6 months, 1-year, and 2 years per the rigors of the study guidelines.

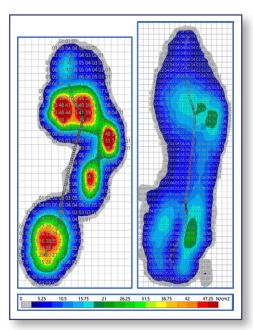


Figure 7: Pressure cell mapping for average contact phase of gait with and without solution.

The plan is to maintain this process and support the patient ongoing—even beyond the study period, through regular and typical clinical activities and incorporating lessons learned from the larger

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#### **Biomechanical Analysis**

Our primary goal, and consistent with our larger goal, is returning our patient population to their activities of daily living (ADLs). The decision-making around shell material is made considering the weight, foot length, and structural integrity of the wearer. For instance, there is an adage to be considered: the more flexible the foot, the more control it needs. Where length is concerned, the longer the foot, the longer the device, which makes the shell less rigid. When it comes to areas on the plantar surface deemed "at risk" for ulceration, the best techniques for offloading those regions are employed in accordance with the evidence base. Examples would include: arch height alteration, wells/cut-outs under the areas of high pressure, and/or domes underneath the adjacent metatarsal heads to reduce and divert forces away from the over-pressured forefoot

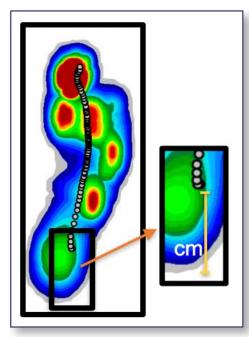


Figure 8: Average pressure plot with center of pressure initiation point quantified.

#### regions.

Another well-utilized addition is that of a metatarsal pad to control forefoot frontal plane

motion, also known as "the forefoot pronatory event." This is particularly helpful for DFUs occurring under the first metatarsal head of a forefoot with a moderate- to high-varus component and calluses at the first interphalangeal joint. Indicators of the biomechanical deformity can be seen in the CAGA, with identification of regions of the foot and noting the segmental loading patterns and times of these various regions. CAGA also identifies pressure changes across each of the metatarsal bones as well as specific regions of the foot.

As an example, if the COP follows a "hockey stick" shaped morphology with a radical turn in the COP line in the vicinity of the metatarsal head region, a metatarsal pad is usually a good inclusion to most orthotic prescriptions (Figure 6). Each CAGA screen, with its graphs and temporospatial parameters, contribute to the discipline of writing a custom prescription orthotic and the above examples were but a few solutions employed in an ulcer

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prevention functional diabetic orthotic.

#### **Preliminary Study Data**

Through preliminary data assessment of those who have completed the study thus far, CAGA was instrumental in identifying peak plantar pressures representing areas at risk for diabetic foot ulceration, and analysis of those modifications implemented.

Analysis of the observed data was performed in the following manner:

Utilizing the Noroxon MyoResearch technology, the area in which a foot contacts the weight-bearing surface was mapped out indicating the maximum pressure values obtained throughout the gait cycle. These pressures, measured in N/cm2, were identified in a 1cm2 grid overlying each foot's plantar pressure print.

To obtain a baseline data point, the highest single pressure measurement value on each foot's average contact, while barefoot, was then recorded (Figure 7). The corresponding osseous structure was also recorded, identifying these areas of highest risk: Submetatarsal 1: 33%; calcaneus: 24%; sub-metatarsal 3,4: 20%; cuboid 13%. The patient was then placed within their Solution (custom orthotic and specific diabetic shoe), and re-examined to identify the effective reduction in plantar foot pressures at the same identified zones. To decrease the chance incident of a single 1cm2 area measuring an abnormally high pressure, the identified 1cm2 highest single maximum value pressure reading was averaged along with the surrounding 8cm2 zones for a 9cm2 average.

A direct comparison and percent reduction between the barefoot and Solution values were then calculated and analyzed for both 1cm2 and 9cm2 metrics on the bilateral foot.

Furthermore, the center line of pressure was identified as a useful tool for analyzing the subject's gait. This identifies the initial contact point of the foot within the stance phase of the gait cycle as well as various pronatory, supinatory, transitional, and propulsion changes throughout the gait cycle. The initial contact point of the foot was compared between the initial barefoot gait and initial contact point once

	Table 1		
	Test Variable	Baseline	With Solution*
	Length of gait line left [mm]	240.42	266.08
	Length of gait line left Variation [mm]	17.91	12.61
Center Of Pressure	Length of gait line right [mm]	242.47	261.74
	Length of gait line right Variation [mm]	14.02	13.57
Stride	Stride length [cm]	60.49	67.00
	Stride length Variation [cm]	4.55	3.58
Lateral symmetry	Lateral symmetry [mm]	16.63	23.64
	Lateral symmetry Variation [mm]	30.68	35.47
Step Width	Step width [cm]	13.85	13.59
	Step width Variation [cm]	1.69	1.81
	Foot rotation left [deg]	8.68	8.39
Foot	Foot rotation left Variation [deg]	2.32	2.12
Rotation	Foot rotation right [deg]	10.27	10.25
	Foot rotation right Variation [deg]	2.38	2.02
Temporal Phases	Stance phase left [%]	72.61	72.20
	Swing phase left [%]	27.39	27.80
	Stance phase right [%]	72.32	72.22
	Swing phase right [%]	27.68	27.78

solution was employed (Figure 8).

This yielded an average 66.18% decrease in pressure (Left: 47.79nm2 vs. 12.36nm2 and Right: 47.79nm2 vs. 13.46nm2, P<0.001) [Table 1]. It was also noted that the initial contact point of gait (Figure 8) was decreased (moved more proximally/posteriorly by an average of a 28.69% (Left: 2.67cm and Right: 2.42cm, p<0.001) [Table 1], elongating the gait line, and subsequently better dispersing the forces acting upon the foot. The most consequential parameters which are contributory to this success are being statistically analyzed and include: length and deviation of gait line, stride length, lateral symmetry, step width, foot abduction, and stance vs. swing ratio. The preliminary data utilizing CAGA shows that the length of gait line was elongated on average by 22.96mm (Left:26.66mm, Right: 19.26mm) and stride length increased by 6.5cm. Lateral symmetry

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(COP intersecting/ a balance measurement/ center of mass) increased by 7.01cm, step width (heel to heel width) decreased by 0.25cm, and rotation/abduction of the foot decreased by 0.33 degrees (Left: 0.29 degrees, Right:0.37 degrees). Lastly, swing vs/stance phase was modified by 0.255% (Left: 0.41% more time spent in stance, Right: 0.1% more time spent in stance phase). These pressure and gait modifications are encouraging as they demonstrate overall changes in a positive direction. All parameters and data will be fully analyzed and published once full cohort (n=90) is completed.

#### Conclusion

Utilizing a disciplined, multidisciplinary approach that begins with a healed diabetic foot, we are able to use CAGA to analyze the temporospatial gait parameters of a patient with diabetes. Computer-assisted gait analysis allows practitioners to perform a detailed comparison between a patient's gait while barefoot and with their unique solution (orthotic and specific shoe) to obtain the best quantitative data. This objective data allows users to analyze both the biomechanical deformity and structural deformity (eg, limb length, metadductus, cavus foot type, diminished fat pad), as well as the effectiveness of footwear modification. As a highly accurate, objective diagnostic tool, CAGA yields the ability to capture temporospatial parameters, both statically and dynamically, pinpointing plantar regions that are at risk. These areas can be identified even before they show signs of pre-ulceration. It allows a detailed evaluation of a patient's gait, identifying areas of concern, success in the management of problematic areas, and areas that need further attention. Our preliminary data has validated our ability to provide increasing gait stability and off-loading, leading to a potential decrease in risk of ulceration. It is hopeful this is the impetus for dramatic change that yields a new and brighter future for this highly "at-risk" patient population.

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### Thick Shells, Medially Wedged Posts Increase Foot Orthoses Medial Longitudinal Arch Stiffness

BY ANA SOFIA TAVERA PELAEZ, NADER Farahpour, Ian B. Griffiths, and Gabriel Moisan

#### A better understanding of how the medial arch stiffness of foot orthoses can be modulated by changing structural factors is necessary to better customize them for patients.

It is postulated that foot orthoses (FOs) provide their effects through the production of reaction forces at the foot-FOs interface. An important parameter to provide these reaction forces is medial arch stiffness, as greater stiffness is correlated with greater pronatory control of the foot and ankle during locomotion. Rearfoot and forefoot extrinsic posts are among the most commonly used extrinsic additions to increase FOs medial arch stiffness and consequently enhance their ability to change lower limb biomechanics through greater resistance to deformation. FOs with posts decrease ankle eversion angles/ moments and tibialis posterior muscle activity during locomotion. However, even though these FOs extrinsic additions have been used for a few decades, their utilization to modify medial arch stiffness remains an emerging rather than a proven concept.

A better understanding of how the medial arch stiffness of FOs can be modulated by changing structural factors is necessary to better customize FOs for patients. The objectives of this study were to compare FOs stiffness and force required to lower the FOs medial arch in



3 thicknesses and 2 models (with and without medially wedged forefoot-rearfoot posts).

#### Methods

Two models of FOs, 3D printed in Polynylon-11, were used: (1) without extrinsic additions (mFO), and (2) with forefoot-rearfoot posts and a 6-degree medial wedge (FO6MW). For each model, 3 thicknesses (2.6mm, 3mm, and 3.4mm) were manufactured. FOs were fixed to a compression plate and vertically loaded over the medial arch at a rate of 10mm/minute. Twoway ANOVAs and Tukey post-hoc tests with Bonferroni corrections were used to compare medial arch stiffness and force required to lower the arch across conditions.

#### Results

Regardless of the differing shell thicknesses, the overall stiffness was 3.4 times greater for FO-

6MW compared to mFO (P < 0.001). FOs with 3.4mm and 3mm thicknesses displayed 1.3- and 1.1-times greater stiffness than FOs with a thickness of 2.6mm. FOs with a thickness of 3.4mm also exhibited 1.1-times greater stiffness than FOs with a thickness of 3mm. Overall, the force to lower the medial arch was up to 3.3 times greater for FO6MW than mFO and thicker FOs required greater force (P < 0.001).

#### Discussion

The most important findings of this study were that, according to the authors' hypothesis, 3D-printed FOs in Polynylon-11 with greater thickness presented greater medial arch stiffness, and that FO6MW were significantly stiffer than mFO.

FOs thickness in the 2 models (mFO and FO6MW) was increased by 0.4mm (15% relative increase) between the first and the second

This article has been excerpted from "Thick Shells and Medially Wedged Posts Increase Foot Orthoses Medial Longitudinal Arch Stiffness: An Experimental Study," Journal of Foot and Ankle Research. 2023;16:11. https://doi.org/10.1186/s13047-023-00609-z. Editing has occurred, including the renumbering or removal of tables and figures, and references have been removed for brevity. Use is per CC 4.0 International License.

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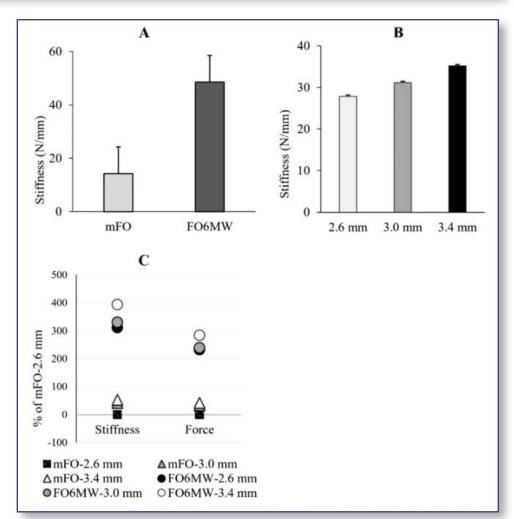
#### Table 1 Stiffneess and Force Data Expressed as Mean ± Standard Deviation

Model	Thickness (mm)	Stiffness (N/mm)	Force (N)
	2.6	10.90 ± 0.35	82.15 ± 1.41
mFO	3.0	15.39 ± 0.71	109.01 ± 5.00
	3.4	16.63 ± 0.14	116.91 ± 0.57
	2.6	44.85 ± 0.96	273.43 ± 3.51
FO6MW	3.0	46.97 ± 0.43	278.30 ± 2.78
	3.4	53.85 ± 1.04	315.68 ± 7.36

thickness and by 0.4mm (13% relative increase) between the second and third thickness. For mFO, the first increase in thickness, from 2.6mm to 3.0mm, increased arch stiffness by 41%. The additional increase in thickness, from 3mm to 3.4mm, reflected an additional 11% increase of stiffness, for a total 52% increase between the 2.6mm and 3.4mm shells. For FO6MW, the first increase in thickness, from 2.6mm to 3mm, only increased arch stiffness by 5%, and the additional increase in thickness, from 3mm to 3.4mm, resulted in an additional increase of 15%, for a total increase in arch stiffness of 20% between the 2.6mm and 3.4mm shells (See Table 1 and Figure 1C). These results reveal that the importance of FOs thickness to increase stiffness is highly dependent on the presence or absence of forefoot-rearfoot posts with a 6-degree medial wedge. As forefoot-rearfoot posts provide additional support underneath the proximal and distal part of the FOs arch, the proportional importance of shell thickness is lower than for mFO.

The study authors also found that to increase FOs medial longitudinal arch stiffness and peak force required to lower the arch, adding medially wedged forefoot-rearfoot posts was significantly more efficient than increasing shell thickness. For example, by increasing the thickness of mFOs from 2.6mm to 3.4mm, the force required to lower the arch and the arch stiffness were only 1.4 times (117 vs 82N) and 1.5 times (16.6 vs 10.9 N/mm) greater, respectively. However, by adding medially wedged forefoot-rearfoot posts on the 2.6mm mFO, the force required to lower the arch and the arch stiffness were 3.3 times (273 vs 82 N) and 4.1 times (44.8 vs 10.9 N/mm) greater, respectively. These results suggest that to significantly

ler



**Figure 1.** A) Stiffness in mFO and FO6MW models regardless of the thickness effects. B) FOs stiffness in different thicknesses, regardless of models. C) The ratio (%) of increased stiffness and force as a result of adding medially wedged forefoot-rearfoot posts, and increasing the thickness.

increase FOs medial arch stiffness, medially wedged forefoot-rearfoot posts should be used rather than only changing shell thickness.

#### Conclusions

An increased medial longitudinal arch stiffness is seen in FOs following the addition of 6-degree medially inclined forefoot-rearfoot posts, and when the shell is thicker. Overall, adding forefoot-rearfoot posts to FOs is significantly more efficient than increasing shell thickness to enhance these variables should that be the therapeutic aim.

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### Plantar Pressure and Fall Risk in Older Individuals

BY YIFENG YAN, JIANLIN OU, HANXUE SHI, Chenming Sun, Longbin Shen, Zhen Song, Lin Shu, and Zhuoming Chen

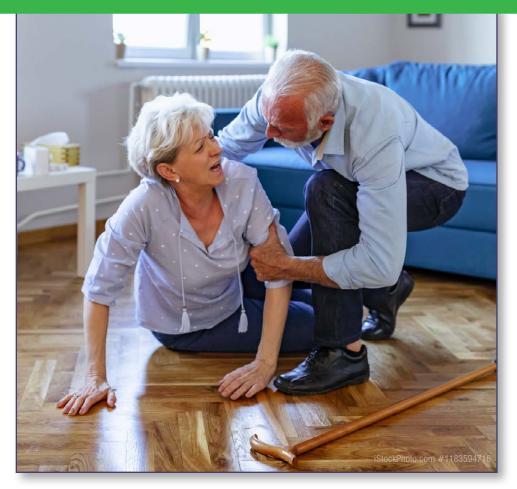
Previous studies have confirmed that there is a difference in plantar pressure between falls and non-falls in elderly people, but the relationship between fall risk and foot pressure has not been studied.

Studies show approximately 28% of elderly people age 65 and above fall every year. The increased risk of falls is associated with an increment of gait variability. These gait changes are caused by diminished balance control, degeneration of the musculoskeletal system, and diminished sensorimotor function. As gait changes, plantar pressure will change correspondingly. Therefore, the plantar pressure in walking is often used to study normal and abnormal gait characteristics.

Previous studies have confirmed that there is a difference in plantar pressure between falls and non-falls in elderly people, but the relationship between fall risk and foot pressure has not been studied. The 2 aims of this study were to investigate whether there are differences in dynamic plantar pressure among elderly people at high and low risk of falls. And if there are differences, the study authors tried to search for the plantar pressure characteristic parameters.

#### Methods

For this cross-sectional study, 24 high-fall-risk elderly individuals (HR) and 24 low-fall-risk el-



derly individuals (LR) were selected using the Berg Balance Scale 40 score. Inclusion criteria: (a) age 65 or older; (b) capable of independent walking for 3 minutes without assistance; (c) clear consciousness, able to cooperate with the assessment, Mini-mental State Examination score > 24; and (d) with available informed consent. The baseline data, including sex, age, height, body weight and body mass index of the 2 groups were compared, and the differences were not statistically significant (P > 0.05).

#### **Results & Discussion**

This paper prospectively investigates the relationship between fall risk and plantar pressure. The results showed that the differences in between-group comparisons were mainly focused on midfoot and heel, so the study authors assumed that HR may have been more cautious when landing. As for the comparison within the group, the differences between the left and right foot in LR occurred mainly when the heel contacted the ground, while in HR they occurred mainly when the foot stroked the ground. In the within-group comparisons between the 2 groups, the differences in foot pressure were in different areas.

During the formal experiment, participants needed to walk for more than 2 minutes along a 20-meter corridor at their normal gait and usual walking speed. Based on previous studies combined with plantar mechanics,

This article has been excerpted from "Plantar Pressure and Falling Risk in Older Individuals: A Cross-sectional Study." Journal of Foot and Ankle Research. 2023;16:14. https://doi.org/10.1186/s13047-023-00612-4. Editing has occurred, including the renumbering of tables, and references have been removed for brevity. Use is per CC BY.

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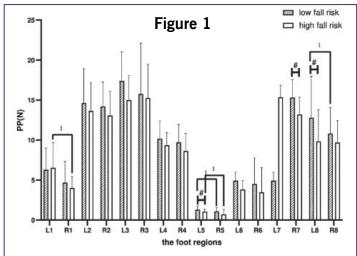
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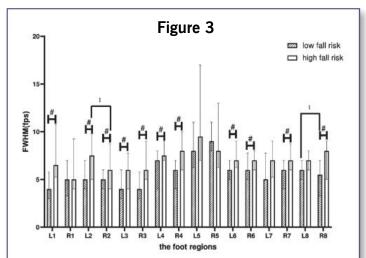
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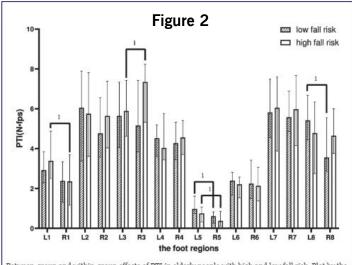
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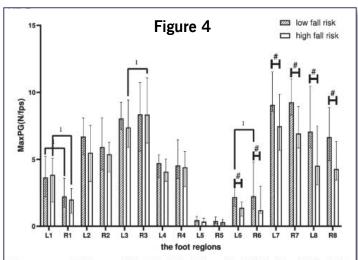
Between-group and within-group effects of PP in elderly people with high and low fall risk. Plot by the median  $(Q_{4},Q_{3})$ . Where significant at p < .05 for pared-samples T-test or Wilcoxon paired test. #where significant at p < .05 for independent-samples T-test or Mann-Whitney U test



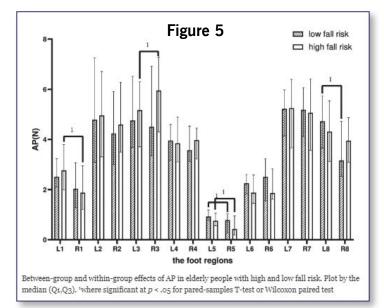
Between-group and within-group effects of FWHM in elderly people with high and low fall risk. Plot by the median (Q4,Q3). 'where significant at p < .05 for pared-samples T-test or Wilcoxon paired test. "where significant at p < .05 for independent-samples T-test or Mann-Whitney U test



Between-group and within-group effects of PTI in elderly people with high and low fall risk. Plot by the median (Q1,Q3). 'where significant at p < .05 for pared-samples T-test or Wilcoxon paired test

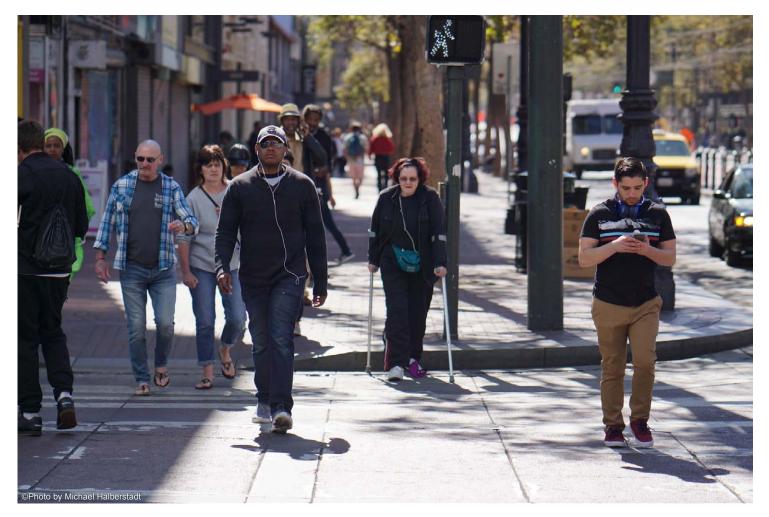


Between-group and within-group effects of MaxPG in elderly people with high and low fall risk. Plot by the median (Q<sub>1</sub>,Q<sub>3</sub>). <sup>1</sup>where significant at p < .05 for pared-samples T-test or Wilcoxon paired test. <sup>\*</sup>where significant at p < .05 for independent-samples T-test or Mann-Whitney U test



Continued on page 53





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#### Continued from page 51

the plantar area was divided into 8 regions for analysis: 1st toe (T1), 1st metatarsal head (M1), 2nd-3rd metatarsal head (M2-3), 4th-5th metatarsal head (M4-5), medial midfoot (MMF), lateral midfoot (LMF), medial heel (MH), and lateral heel (LH) (See Figure A).

After weight normalization and identification of valid gait cycles, for each foot region, the study authors calculated the following parameters: peak pressure (PP), pressure-time integral (PTI), pressure gradient (maximum pressure gradient (MaxPG), minimum pressure gradient (MinPG), full width at half maximum (FWHM)), and average pressure (AP).

#### Peak pressure

Between-group comparison: Compared with the LR, the PP was reduced in the left-MMF, left-LH and right-MH in the HR (P < 0.05). Within-group comparison: In the LR, differences comparing the left foot with the right foot were shown in the LH and MMF (P < 0.05). In the HR, it was shown in the

Previous studies have confirmed that there is a difference in plantar pressure between falls and non-falls in elderly people, but the relationship between fall risk and foot pressure has not been studied.

MMF and the T1 (P < 0.05), as shown in Figure 1.

#### Pressure-time integral

Within-group comparison: In the LR, differences comparing the left foot with the right foot were shown in the LH and MMF (P < 0.05). In the HR, it was shown in the T1, the M2-3 and the MMF (P < 0.05) (Figure 2). Comparison between groups: There was no statistical difference.

#### Full width at half maximum

Comparison between groups: Compared with the LR, the FWHM increased in elderly people in the HR in the following regions (P < 0.05): the left-T1, the left-M1, the left-M2-3, the left-M4-5, the left-LMF, the right-M1, the right-M2-3, the right-M4-5, the right-LMF, the right-MH, the right-LH. Within-group comparison: In the LR, the difference comparing the left foot with the right foot was shown on the LH (P < 0.05). In the HR, it was shown at the M1 (P < 0.05), as shown in Figure 3.

#### Maximum pressure gradient

Between-group comparison: Compared with the LR, the MaxPG in elderly people in the HR decreased in the following regions (P < 0.05): left-LMF, left-MH, left-LH, right-LMF, right-MH, and right-LH. Within-group comparison: In the LR, differences comparing the left foot with the right foot were shown in the T1 and LMF (P < 0.05). In the HR, it was shown in the T1 and the M2-3 (P < 0.05), as shown in Figure 4.

Continued on page 55



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#### Minimum pressure gradient

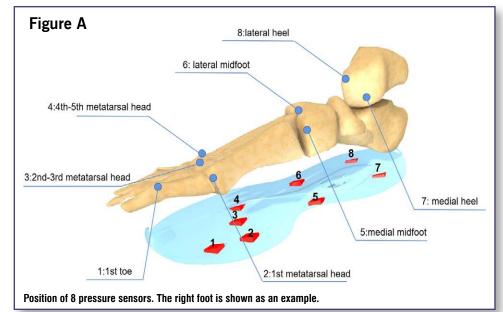
Within-group comparison: only in the LR, the left and right feet of the M4-5 showed differences (P < 0.05). Comparison between groups: There was no statistical difference.

#### Average pressure

Within-group comparison: in the LR, differences comparing the left foot with the right foot were shown in the LH and MMF (P < 0.05). As shown in Figure 5, in the HR, it was shown in the T1, M2-3 and MMF (P < 0.05). Comparison between groups: There was no statistical difference.

#### Conclusion

These preliminary results suggest that there were indeed differences in plantar pressure between high- and low-fall risk in older adults and that plantar pressure may be used to determine fall risk, especially pressure gradient. The differences comparing the high-fall risk with low-fall risk groups were mostly reflected in the midfoot and heel. The HR may have



been more cautious when landing. In the intra-group comparison, the difference between the right and left foot of the LR was mainly reflected during heel striking, while it was mainly reflected during pedaling in the HR. The sensitivity of PP, PTI, and AP was lower, and the newly introduced pressure gradient could better reflect the difference in foot pressure between the 2 groups. The pressure gradient can be used as a new foot pressure parameter in scientific research. (er)

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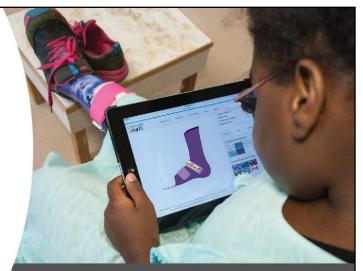
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The PETAL (Paper-like Battery-free In situ AI-enabled Multiplexed) sensor patch comprises 5 colorimetric sensors that can determine the patient's wound healing status within 15 minutes by measuring a combination of biomarkers—temperature, pH, trimethylamine, uric acid, and moisture of the wound. These biomarkers were carefully selected to effectively assess wound inflammation, infection, as well as the condition of the wound environment. More biomarkers can be added if required.



The sensor patch can be integrated easily with wound dressing and can also be customized for different types and sizes of wounds. Image courtesy of NUS.

The sensor patch is able to operate without an energy source—sensor images are captured by a mobile phone and analyzed by artificial intelligence (AI) algorithms to determine the patient's healing status. In lab experiments, the PETAL sensor patch demonstrated 97% accuracy in differentiating healing and non-healing chronic and burn wounds.

There were no apparent signs of adverse reactions observed on the skin surface in contact with the PETAL sensor patch over 4 days, demonstrating the biocompatibility of the PETAL sensor patch for ambulatory wound monitoring.

This technology can be adapted and customized for other wound types by incorporating different colorimetric sensors, such as glucose, lactate, or Interleukin-6 for diabetic ulcers. The number of detection zones can also be reconfigured to detect different biomarkers concurrently, so its application can be broadened for different wound types.

#### COMPACT IN-SHOE FOOT FUNCTION, GAIT ANALYSIS SYSTEM



F-Scan<sup>™</sup> GO, a light weight, compact, new generation technology, allows clinicians and researchers to conduct quick and natural in-shoe gait analysis while the user has complete freedom of movement. Information obtained from the device is used in real-world applications, like designing and testing orthotics, offloading diabetic feet, and evaluating footwear and techniques in elite athletes. The Wi-Fi enabled system works with cordless ankle units, combining the high scanning speed and spatial resolution of the current F-Scan system with fully wireless electronics and data logging. It provides gait analysis parameters like pressure and force data, timing parameters, and center of force. F-Scan GO is powered by FootVIEW software, which identifies and quantifies peak pressure areas; isolates the heel, metatarsal, and whole foot for analysis; and generates a report for before-and-after comparison. Key parameters are automatically calculated to assess foot function and gait.

#### Tekscan

800/248-3669 tekscan.com

#### COMPRESSION KNEE BRACE WITH SIDE STRAPS



Fuelmefoot's Compression Knee Brace with Side Straps is intended for people who have meniscus tears, arthritis, and ACL injuries, or who are in need of joint pain relief or sports injury recovery. The brace is widely used in many sports such as weightlifting, basketball, running, jogging, volleyball, CrossFit, gym, tennis, hiking, and more. Features and benefits include: ultra-light weight (3.5 oz.), breathable, fast drying, sweat absorbing, ergonomic fabrication, enhanced elastic strap support, supportive without bulk, dual anti-slip straps, and improved kneecap control. Universal fit for men and women, and available in sizes medium, large, X-large, and XX-large. Material: 85% nylon and 15% spandex and silicone.

#### Fuelmefoot

fuelmefoot.com

#### 3D-PRINTED INSOLES MEASURE SOLE PRESSURE

To optimize their performance, athletes may use custom-made insoles. People with musculoskeletal pain also turn to insoles to combat their discomfort. However, before specialists can accurately fit such insoles, they must first create a pressure profile of the feet. To this end, athletes or patients have to walk barefoot over pressure-sensitive mats, where they leave their individual footprints. Based on this pressure profile, foot care professionals then create customized insoles by hand. However, with this approach, optimizations and adjustments take time. Another disadvantage is that the pressure-sensitive mats allow measurements only in a confined space, but not during workouts or outdoor activities.

Now an invention by a research team from ETH Zurich, Empa (Swiss Federal Laboratories for Materials Science and Technology), and École Polytechnique Fédérale de Lausanne could greatly improve things. The researchers used 3D printing to produce a customized insole with integrated pressure sensors that can measure the pressure on the sole of the foot directly in the shoe during various activities. In addition to being easy to use, the insoles are also easy to make.



The insoles, together with the integrated sensors and conductive tracks, are produced in just 1 step on a 3D printer. Image courtesy of Marco Binelli / ETH Zurich.

Tests showed that the additively manufactured insole works well. With data analysis of the pressure patterns detected, the researchers can determine whether someone is walking, running, climbing stairs, or even carrying a heavy load on their back.

At the moment, a cable connection is required to read out the data. However, 1 of the next development steps will be to create a wireless connection.

#### HYDRATING ANTI-EMBOLISM STOCKINGS, SOCKS, SLEEVES

Skineez has launched Hydrating T.E.D. (thrombo-embolic deterrent) Anti-Embolism stockings and compression socks and sleeves. These US Food & Drug Administration–approved compression products are clinically proven to



help to prevent deep vein thrombosis, edema, and leg discomfort for pre- and post-operative patients while hydrating the skin at the same time. As consumers wear Skineez wearable skincare and wellness wear, the microcapsules embedded in each garment break open naturally and slowly deliver the patented cosmetic ingredients to the skin. After 10 washings, simply spray on the skincare with the Skineez cosmetic spray back into the garments for another 10 wearings. Other key features of these stockings and socks include: 24-hour skin hydration, which moisturizes, rejuvenates, soothes, and nourishes the skin; relief for foot arch, heel, ankle, and nerve pain; 100% latex free; moisture wicking; and antimicrobacterial. Available in knee-high and thigh-high lengths.

#### Skineez 978/261-5326 myskineez.com

#### ADVANCED CONTROL SYSTEM MAY ADVANCE LOWER LIMB EXOSKELETON EXPERIENCE

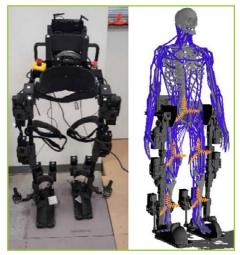
A team of researchers from the New Jersey Institute of Technology (NJIT), North Carolina State University, and University of North Carolina at Chapel Hill have developed a new method for controlling lower limb exoskeletons. The

#### **NEW & NOTEWORTHY**

novel method developed by the research team uses deep reinforcement learning to improve exoskeleton control. Reinforcement learning is a type of artificial intelligence (AI) that enables machines to learn from their own experiences through trial and error. The method enables more robust and natural walking control for users of lower limb exoskeletons.

"Using a musculoskeletal model coupled with an exoskeleton, we simulated the movements of the lower limb and trained the exoskeleton control system to achieve natural walking patterns using reinforcement learning," explained research team member Xianlian Zhou, PhD, associate professor and director of the BioDynamics Lab in the Department of Biomedical Engineering at NJIT. "We are testing the system in real-world conditions with a lower limb exoskeleton being developed by our team and the results show the potential for improved walking stability and reduced user fatigue."

The team determined that their proposed model generated a universal robust walking controller capable of handling various levels of human-exoskeleton interactions without



(Left) The developed prototype of the lower extremity robotic exoskeleton (LE-RE). (Right) The integrated musculoskeletal and exoskeleton model. The yellow coordination frames show the bushing frames coincidentally fixed on the LE-RE and the human.

the need for tuning parameters. The new system has the potential to benefit a wide range of users, including those with spinal cord injuries, multiple sclerosis, stroke, and other neurological conditions. The researchers plan to continue testing the system with users and further refine the control algorithms to improve walking performance.

#### FINDING THE PERFECT FIT FOR A PROSTHETIC LEG



University of Washington (UW) Professor Joan Sanders, PhD, and her team are creating a new type of transtibial prosthetic leg that automatically adjusts its fit throughout the day. Their latest prototype alters its fit without the need for adjustments to padding or user action. It detects in real time how well the prosthetic socket and amputation site are fitting and responds by automatically changing the size of the socket. Test results with volunteers are so promising that the researchers hope to eliminate the need to add or remove padding throughout the day.

It contains several key features to make auto adjustment possible:

- A gel interface material—shaped like a sock that users typically wear over the amputation site—that contains a small amount of iron.
- Three ultrathin sensors embedded within the wall of the prosthetic limb's socket detect the distance to the iron in the gel and send that data to the socket's microcontroller.
- The microcontroller calculates whether adjustments are needed. If so, it transmits instructions to 3 motorized "panels" within the socket wall—2 in the front, 1 in the back. The panels can move in to

make the socket smaller, or out to make it bigger.

The adjustments that the panels make, which can also be controlled manually via an app on the user's smartphone, are usually tiny—less than a millimeter. Through trials with volunteers, the team has found that these automatic adjustments take the place of switching out padded socks that prosthesis users normally wear and change throughout the day. Through user trials with volunteers, Sanders' team is collecting more detailed data on the device's performance and is working to make the prototype's motors smaller and lighter.

#### REHABILITATION, ATHLETIC TRAINING, PERFORMANCE– ENHANCING PLATFORM



TRAZER XP is a multi-patented technology designed for rehabilitation, athletic training, and enhancing human performance. With applications across healthcare, senior care, rehabilitation, sports medicine, and sports performance, TRAZER empowers professionals with actionable data. The system, which includes specialized hardware with a high-powered depth sensing camera, a cloudbased software application with proprietary algorithms, and a HIPAA-compliant portal for secure data storage and analytics, features over 150 reaction-based activities and injury-specific protocols. The system immerses users into reaction-based activities that track physical and cognitive reactions to generate data related to dynamic movement, kinematics, balance, and neuromechanics. The camera tracks 32 key movement points on the body, processing

millions of data points in real-time to provide immediate post-activity, on-screen feedback. From the online portal, customers manage information, and use advanced analytics to produce comprehensive and easily understood graphs and reports.

Trazer trazer.com

#### MASSAGE GUN



The Compex<sup>®</sup> Fixx<sup>™</sup> 2.0 Massager helps warm up muscles before a workout and relieve stiffness after a hard session. Five powerful intensity settings, paired with a high-stall force, impacts the muscle groups with targeted percussive massage therapy that will give the intense pressure needed to help relieve the toughest spots safely and comfortably. Interchangeable tips (included) and a rotating head help tailor the massage to the specific needs of different muscle groups. Deep muscle treatment helps to increase blood flow, relieve sore or tight muscles, enhance performance, improve range of motion, prevent injury, and release knots or tension. Aiding in the relief of targeted muscle areas feeling sore or aching from exercise or recreational activities helps the user to avoid injury and increase performance. Removeable and rechargeable batteries, a compact design, and a quiet motor help provide relief anywhere and everywhere.

#### Compex

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#### LIGAMENT REINFORCEMENT



Artelon's US Food & Drug Administration 510(k)-cleared FlexBand®, FlexPatch®, and FlexBand Plus® are designed for ligament repair surgery in addition to tendon repairs, with new clearance that has expanded the indications for these products to now include reinforcement of medial, lateral, and ulnar collateral ligaments, spring ligaments, deltoid ligaments, and extra-articular ligaments in the ankle, knee, and other joints around the body. Artelon's Dynamic Matrix® technology used in FlexBand products is a proprietary polymeric bio-textile for musculoskeletal soft tissue reinforcement. Dynamic Matrix is designed to mimic the natural mechanical and biological properties of healing tendon and ligament tissue. It has been proven in clinical studies to protect the surgical repair during early healing, quickly restore the mechanics of motion, and support development of regenerating tissue before dissolving over several years.

Artelon

800/610-3446 artelon.com

#### BIODEGRADABLE GEL PROMISING FOR CARTILAGE REGENERATION

A gel that combines both stiffness and toughness is a step forward in the bid to create biodegradable implants for joint injuries, according to new research from the University of British Columbia (UBC).

Hongbin Li, PhD, a professor in the UBC department of chemistry, and his team developed a new approach to stiffen a protein gel without sacrificing toughness, by physically tangling together the chains of a particular protein that made up the gel's network. "These entangled chains can move, which allows energy, for instance, the impact from jumping, to be dissipated, just like shock absorbers in bikes," said Linglan Fu, PhD, who conducted the research as a doctoral student at UBC's department of chemistry. "In addition, we combined this with an existing method of folding and unfolding proteins, which also allows for energy dissipation."



Fu holding the gel. Image courtesy of Alex Walls.

The resulting gel was super tough, able to resist slicing with a scalpel, and was more stiff than other protein hydrogels. Its ability to resist compression was among the highest achieved by any such gels and compared favorably with actual articular cartilage. And the gel was able to rapidly recover its original shape after compression, as real cartilage does after jumping.

Rabbits implanted with the gel showed notable signs of repair of articular cartilage 12 weeks after implantation, with no hydrogel remaining and no rejection of the implant by the animals' immune system. The researchers observed bone tissue growth similar to the existing tissue, and regenerated tissue close to existing cartilage for the gel implant group much better results than they saw with a control group.

## DO YOU HAVE A NEW PRODUCT OR NEWS?

We want to hear about your new product, news, or innovation! We want to hear from you! Please send information to Laura@LERmagazine.com

## The LAST WORD

### TRAINING METHODS TO IMPROVE THE ABILITY TO CHANGE OF DIRECTION



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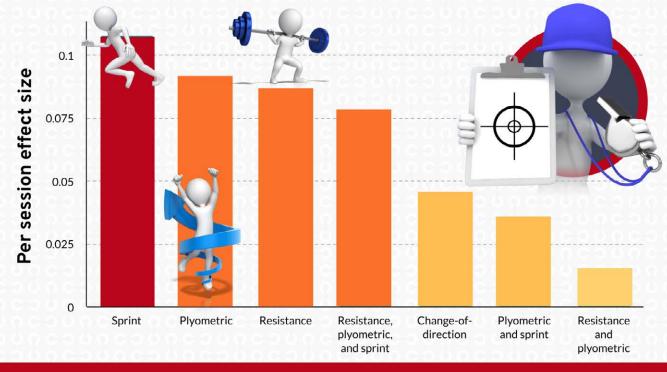


#### 20 studies were analyzed to examine the effect of specific and non-specific training methods on pro-agility performance

1. Sprint training, specifically inclined sprint training, was found to have the largest per session training effect: inclined or resisted sprint training methods are particularly effective for enhancing accelerative capability

2. Plyometric training was found to be the second most effective method, which underlies the importance of the stretch-shortening cycle and leg power in change-of-direction given the accelerative and decelerative nature of this motor task

3. Resisted strength training, particularly unilateral strength training, appears to transfer well to pro-agility performance given the high force demands associated with 180° change-of-direction and because sprinting and changing direction are unilateral in nature



Training all three training types concurrently, with the same emphasis, may not provide ample stimulus compared to focusing on developing one neuromuscular quality to a greater extent compared to another

Programming a resistance training cycle focusing on maximum strength prior to a plyometric or sprinting-focused cycle may help improve contractile tissues capabilities which will then enable greater elastic tissue development, thereby stretch-shortening cycle performance, in subsequent cycles

**Source:** Forster JWD, Uthoff AM, Rumpf MC, Cronin JB. Training to Improve Pro-Agility Performance: A Systematic Review. J Hum Kinet. 2023;85:35-51. doi: 10.2478/hukin-2022-0108.

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