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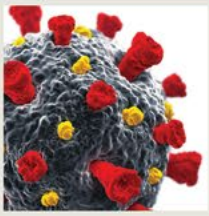
LOWER EXTREMITY REVIEW

October 20 / volume 12 / number 10

FOOT DROP: A PRIMER

COVID-19 UPDATE: 15



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

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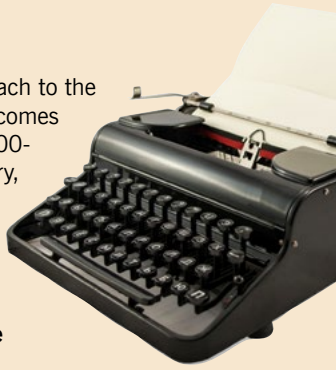

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Secrets of Speed: Seven Smart Steps to Getting Faster

By Phil Maffetone, DC

Athletes in all sports are constantly looking for an edge. Often, the focus is on increasing speed. The importance of high-intensity training cannot be underestimated, but there are prerequisites. These are part of the MAF Method, allowing athletes to develop a lasting individualized plan to improve fitness — including speed — while also maintaining optimum health.

A secret to improving speed is careful preparation. It's as important, or even more so, than the training technique itself (there are many). Unfortunately, there are many prerequisites to building speed that too often go ignored, or are not properly implemented before adding speed workouts. Skipping these key requirements can lead to injury, ill health, and overtraining. We'll outline them here and look for additional readings at the end of this article.

In addition to high intensity interval training (HIIT),[1,2] there are a variety of common training techniques used for increasing speed. They include improving gait, strength training, drills such as leaping and bounding, plyometrics (jumping), and improving flexibility and mobility. While these exercises can complement speed training, they should not replace any of the prerequisites.

Humans already have built-in natural speed just waiting to be called upon. Consider that most people, even those who are out of shape, can sprint fast across the street to avoid a vehicle, catch a child in distress, or just get out of a sudden hard rain. This has more to do with our sympathetic nervous system that's able to turn on the fast-twitch muscles — even if they've not been used much in years.

If it's just the occasional sprint across the street, we already have it. Further developing this natural speed to carry over to athletic events requires a training plan that prepares the body for more consistent and extended efforts. Otherwise, a well-known phrase becomes applicable: Speed kills.

Endurance athletes want to perform faster at relatively low levels of VO2max compared to a 200-meter sprinter. Those who play soccer and other team sports fall somewhere in between. The prerequisites, however, are common to all.

Here are the seven separate steps, although they all overlap:

Brain Power.

When it comes to getting faster, the most important part of the body to consider is the brain. Bill Bowerman, legendary coach (and co-founder of Nike), put it simply: "The idea that the harder you work, the better you're going to be is just garbage. The greatest improvement is made by the man or woman who works most intelligently." It's the brain that triggers muscle contraction and relaxation, regulates the necessary energy, improves economy, and monitors workout recovery. A healthier brain[3] does all this and more, better.

Body Composition.

For increased running speed, including for those participating in team sports, as well as for cycling and most other activities, body composition is a make-or-break factor. A heavier body is simply more difficult to make go fast. Often this is due to excess stored fat.[4] As you develop the exercise and nutritional factors described below, excess body fat should reduce to optimal levels. Excess muscle mass can also add more weight to the body. This may be the result of strength-training methods that add muscle mass. We don't need to add muscle bulk to get stronger[5] or faster (unless we're lacking muscle mass), as mentioned below.

Aerobic Speed.

With aerobic and anaerobic muscles in mind, let's consider that there are two different types of speed. Aerobic function provides submax speed as well as endurance. The ability to run faster at the same submax heart rate, for example, allows a 10K or marathon runner

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to perform faster despite no speed training. Aerobic slow-twitch muscles are more economical and fatigue-resistant than the neighboring fast-twitch speed fibers. The former feeds the latter, and is an integral part of being healthy and preventing injuries.[6] The best way to train for aerobic speeds is by personalizing submax training heart rate using the 180 Formula.[7] Once aerobic base speed is built we can move on to add more high-intensity speed.

Overreaching.

Finding this sweet spot of training where we push enough for optimal benefits but not so much that we risk overtraining[8] or injury is a key to getting faster. This is a delicate balance of two important factors. The first is using the brain to monitor the body. This is best done with the help of a coach or clinician, using the MAF App (available at the App Store), or otherwise self-assessing various signs and symptoms that indicate one may be starting to overtrain. The second is ensuring that we recover from each speed workout. The more and harder we work out, the more recovery is required. Here is my high-performance formula:

Training = Workout + Recovery (rest)

Muscle Function.

Balance and strength are obviously important for speed, with two important factors:

- **Balance.** Working in harmony, muscles move us through the water or over the ground. Even a slight irregularity in gait caused by an imbalance in muscles can reduce movement economy and slow us down. This neuromuscular imbalance between brain and muscles is due to some physical (foot or shoe problems; trauma), biochemical (poor diet or hydration; medication), or accumulation of other stress,[9] with overtraining an end result.
- **Strength.** A separate muscle issue is strength. Traditional weight-lifting routines can often diminish aerobic function, impair gait, add bulk and weight, and reduce endurance, slowing us down. Instead, rely on strength training methods[10] that won't produce significant fatigue or bulking. Being strong enough to tolerate speed work is important.

Foot Force.

The feet are our physical foundation, allowing us to harness the gravitational impact forces from hitting the ground, turning that contact into additional energy for more speed. This unique energy-return system can be a significant contributor to speed. Muscle imbalance, weakness, overstretched tendons, inflexibility, and other problems render many feet unable to work well. One result may be that each foot is on the ground longer, reducing speed. A common cause of foot dysfunction is shoes[11] with over-supported, thick-soled, and outsized heels. Heavier shoes can also slow you down. [For those with diabetes, consult your physician for specific needs.]

Speed Tips

- High-intensity interval training (HIIT) is a very effective approach.
- *Fartlek** is a natural, brain-driven workout that can work well too. (*Swedish for "speed play;" a form of interval/speed training that uses pace variations in running)
- Following aerobic, submax speed development, competition itself also increases one's speed.
- Be relatively rested going into speed training, so little or no training the day before.
- An easy, active aerobic warm up and cool down, which may require 30 minutes or more.
- A tolerable interval distance (how far or long you maintain high intensity) as per your sport. Shorter interval distances are less stressful and can usually provide the same results.
- Recovery is vital; speed training initially causes muscle fatigue and weakness, so reduced or no training the day after is important.
- Two to three days between speed sessions helps ensure proper recovery.

Nutrition.

Eating healthy foods can improve fat-burning (for more aerobic speed), help speed recovery, even from HIIT, spare glycogen, balance muscles, and build a better aerobic body. These and other factors are impaired by eating refined carbohydrates[12] (sugar and processed flour) — avoid them if you want to get faster. This does not mean during hard training or competition, where consuming carbohydrates has value. However, when fat-burning is high, less carbo-

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Continued from page 10

hydrate supplementation is required as fats are used for energy, and glycogen is spared, in all athletes. This reduces the likelihood of indigestion or other GI upset.[13]

While these seven prerequisites are vital, athletes who are not otherwise healthy and fit should not perform speed training. Physical injuries, hormone imbalance, illness and other problems indicate you're not yet ready. In addition, if your life's busy schedule is difficult to manage, finding a non-stress period of time for yet another high-stress activity can be challenging and counterproductive.

With proper preparation, you're now ready to obtain more speed without risking injury and overtraining. There's no magic workout, the simplest easiest high-intensity speed techniques most already know about can work well for most athletes. ler

Philip B. Maffetone, DC, is a clinician, coach, and innovator, whose credo is that "everyone is an athlete." His MAF Method uses exercise, nutrition, and stress awareness to help walkers, runners, cyclists, and elite athletes of all ages and ability. In practice for more than 40 years, he is a pioneer in the field of biofeedback. This article originally appeared on his website, philmaffetone.com, under the same title.

Additional Reading

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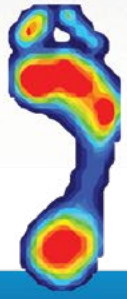

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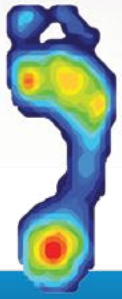

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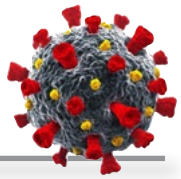

Studies Show Masks, Gaiters Work to Prevent Spread of Coronavirus

Since the spring, it has been demonstrated that masks are a critical deterrent to the spread of SARS-CoV-2, the virus that leads to COVID-19, the worldwide pandemic that has claimed more than 240,000 American lives, and more than 1.25 million lives globally.

Experts are agreed now that transmission of the virus is predominately by respiratory droplets when people sneeze, sing, talk, or breathe. Other transmission routes remain under investigation, but preventing airborne transmission is a key factor in the national fight to stop the spread of this potentially devastating disease.

Some have argued for allowing unchecked spread of the virus to create so-called herd immunity. The consensus of the vast majority of both public health and medical experts, however, is that the spread needs to be contained to prevent not only unnecessary deaths, but the collapse of the overall healthcare system as hospitals are overrun with COVID-19 patients forcing a rationing of care and a disproportionate number of healthcare workers are lost due to ever-increasing viral exposures.

As winter approaches and the population moves indoor, spread has already begun increasing again, with record-breaking numbers of infections, sky-rocketing positivity rates, increasing hospitalizations and ventilator usage, and ultimately, deaths. Returning the focus to basic infectious disease hygiene measures—mask wearing and routine hand-washing—will be critical.

Many have questioned the validity of mask use. Now, 2 different studies using the same protocol for testing have demonstrated that both masks and gaiters provide a level of protection against the spread of the coronavirus 19. The studies, out of Duke University (Durham, NC) and University of Georgia (Athens, GA), used the same protocol, which was developed by Martin C. Fischer, PhD, and Eric Westman, MD, both from Duke.

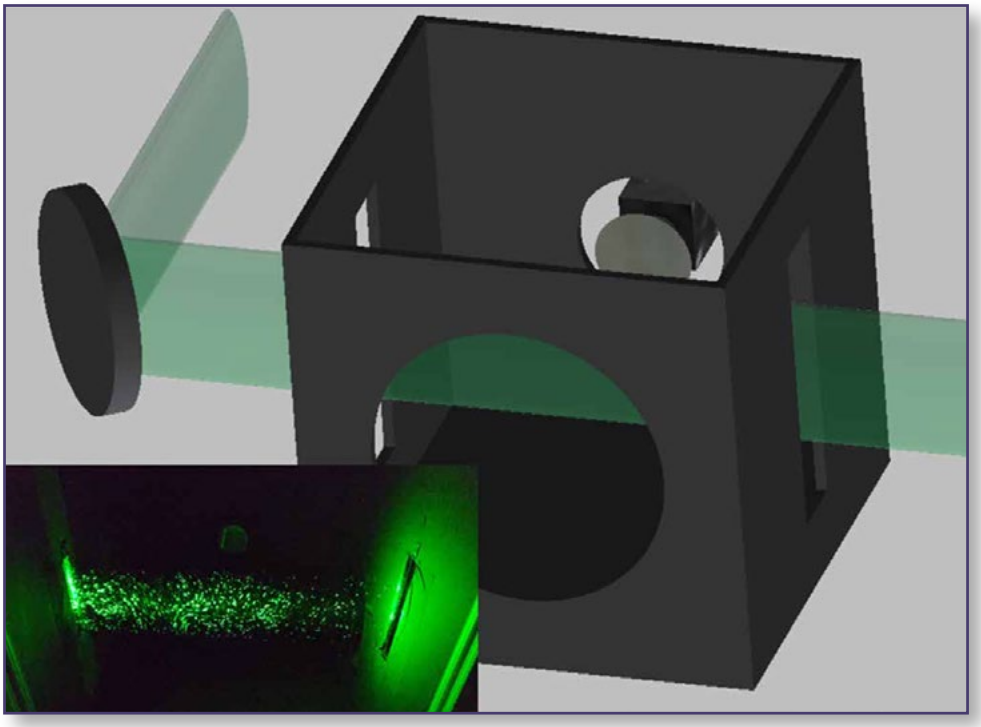

Figure 1. Schematic of the experimental setup. A laser beam is expanded vertically by a cylindrical lens and shined through slits in the enclosure. The camera is located at the back of the box, with a hole for the speaker in the front. The inset shows scattering for water particles from a spray bottle with the front of the box removed. Photo credit: Martin Fischer, Duke University.

Masks Reduce Droplet Transference

The proof-of-concept protocol, which was published in *Science Advances*, reported that a simple, low-cost technique provided visual proof that face masks are effective in reducing droplet emissions during normal wear. The setup, which was designed by Fischer, uses a box, a laser, a lens and a cell phone camera (Figure 1). Then they had a volunteer wear a face mask and speak in the direction of the boxed laser light beam. The droplets that propagate through the laser beam scatter light, which is then recorded with a cell phone camera. A computer algorithm was used to count the droplets in the 40-second videos. Their goal was to create a testing set-up that could be easily built and operated by nonexperts.

They tested 14 commonly available masks/mask alternatives as well as swaths of material and a medical-grade N95 mask (Figure 2). Four volunteers repeated the phrase "Stay healthy, people" 10 times using various masks. Droplet

CDC recommends community use of masks, specifically non-valved multi-layer cloth masks, to prevent transmission of SARS-CoV-2.

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Figure 2. Pictures of face masks under investigation. We tested 14 different face masks or mask alternatives and one mask material. Photo credit: Emma Fischer, Duke University. For photos showing the masks as actually worn, see fig. S8 (Supplementary Materials).

transmission ranged from below 0.1% with the fitted N95 mask to 110% with the neck gaiter (Figure 3).

"In the case of speaking through a mask," they wrote, "there is a physical barrier, which results in a reduction of transmitted droplets and a significant delay between speaking and detecting particles. In effect, the mask acts as a temporal low-pass filter, smoothens the droplet rate over time, and reduces the overall transmission."

In a subsequent news release, Fischer commented, "We confirmed that when people speak, small droplets get expelled, so disease can be spread by talking, without coughing or sneezing. We could also see that some face coverings performed much better than others in blocking expelled particles."

Notably, the researchers report, the best face coverings were N95 masks without valves – the hospital-grade coverings that are used by front-line health care workers. Surgical or polypropylene masks also performed well. And hand-made cotton face coverings provided good coverage, eliminating a substantial amount of the spray from normal speech.

Their findings for gaiters, which are often preferred by those who are physically active, were disappointing: "We noticed that speaking through some masks (particularly the neck gaiter) seemed to disperse the largest droplets into a multitude of smaller droplets, which explains the apparent increase in droplet count relative to no mask in that case. Considering that smaller particles are airborne longer than large droplets (larger droplets sink faster), the use of such a mask might be counterproductive."

Table 1. Face masks under investigation. This table lists the investigated face masks, mask alternatives, and mask material (masks are depicted in Fig. 2). Masks marked with an asterisk (*) were tested by four speakers; all others were tested by one speaker.

Mask, name	Description
1, "Surgical"*	Surgical mask, three layers
2, "Valved N95"	N95 mask with exhalation valve
3, "Knitted"	Knitted mask
4, "PolyProp"	Two-layer polypropylene apron mask
5, "Poly/cotton"	Cotton-polypropylene-cotton mask
6, "MaxAT"	One-layer Maxima AT mask
7, "Cotton2"	Two-layer cotton, pleated style mask
8, "Cotton4"	Two-layer cotton, Olson style mask
9, "Cotton3"	Two-layer cotton, pleated style mask
10, "Cotton1"	One-layer cotton, pleated style mask
11, "Neck Gaiter"	One-layer polyester/spandex, 0.022 g/cm^2
12, "Bandana"*	Double-layer bandana, 0.014 g/cm^2
13, "Cotton5"*	Two-layer cotton, pleated style mask
14, "Fitted N95"	N95 mask, no exhalation valve, fitted
"Swath"	Swath of mask material, polypropylene
"None"*	Control experiment, no mask

Gaiters Reduce Droplet Transference

Enter Suraj Sharma, PhD, and Tho Nguyen, PhD, from University of Georgia. Along with their PhD students, they used the Duke protocol to demonstrate that neck gaiters can provide a level of protection equivalent to masks when used as a face-covering.[2]

Materials tested consisted of the following:

- 4 of the top-selling, 2-layer face masks offered on Amazon.com.
  - To qualify, masks had to receive no less than 2,000 consumer reviews with an average rating in excess of 4
  - Masks were made of various materials (cotton and spandex)
- Five of the top-selling, single-layer gaiters offered on Amazon.com
  - To qualify, gaiters had to receive no less than 4,000 consumer reviews with an average rating in excess of 4.
  - Gaiters were made of various materials (polyester, spandex and nylon)
- 3 multi-layer gaiters offered on Mission.com
  - Gaiters were 2 and 3 layers, made of polyester and spandex

Their study results showed that:

- Single-layer gaiters provided a 77% average reduction in respiratory droplets compared to wearing no face covering at all.

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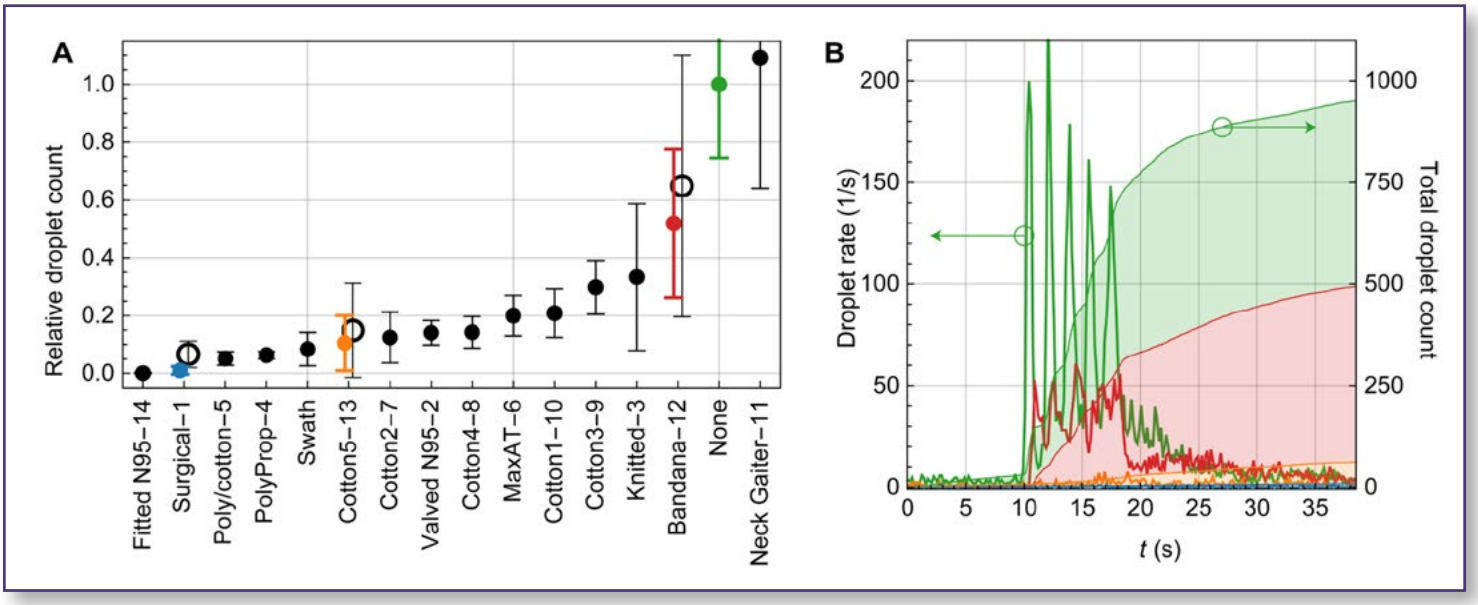

Figure 3. Droplet transmission through face masks. (A) Relative droplet transmission through the corresponding mask. Each solid data point represents the mean and SD over 10 trials for the same mask, normalized to the control trial (no mask), and tested by one speaker. Hollow data points are the mean and SDs of the relative counts over four speakers. A plot with a logarithmic scale is shown in fig. S1. The numbers on the x-axis labels correspond to the mask numbers in Fig. 2 and Table 1. **(B)** The time evolution of the droplet count (left axis) is shown for representative examples, marked with the corresponding color in (A): no mask (green), bandana (red), cotton mask (orange), and surgical (blue, not visible on this scale). The cumulative droplet count for these cases is also shown (right axis). t, time.

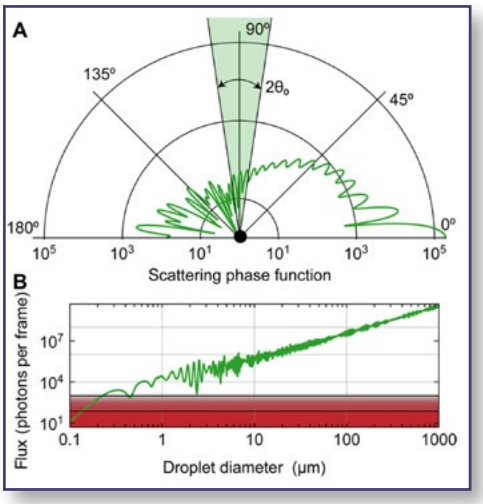

Fig. 4. Light scattering properties. (A) Angle distribution (scattering phase func- tion) for light scattered by a water droplet of 5 μm diameter for illumination with green laser light. Note the logarithmic radial scale. 0° is the forward direction, and 180° is the backward direction. The camera records at around 90°, indicated by the green segment (not to scale). **(B)** Calculated number of photons recorded by the camera in one frame as a function of the droplet diameter. The red shaded area and the two solid lines indicate the detection thresholds of the camera. For ideal conditions (all photons impinge on a single pixel), the camera requires at least about 75 photons per frame corresponding to a droplet diameter of 0.1 μm; for photons distributed over multiple pixels, the threshold is around 960 photons and corresponds to a diameter of 0.5 μm.

- Two-layer masks provided an 81% average reduction in respiratory droplets compared to wearing no face covering at all.
- Multi-layer gaiters provided a 96% average reduction in respiratory droplets compared to wearing no face covering at all.

While the UGA study mirrored the protocol recently developed by Duke University, these researchers added enhancements for more accurate results.

Subjects spoke "Stay Healthy People" 5 times into each of the materials for consistency, and droplets were monitored over a 40-second period. A computer algorithm calculated the number of remaining respiratory droplets over time to determine the efficacy of each material's ability to reduce respiratory droplets from the baseline of "no mask." Each material was tested 3 times to increase accuracy and statistical significance.

Results were calculated using the droplet levels at both the 30-second and 40-second marks. Enhancements to the original study were also put in place. Instead of using a HEPA-filter, UGA scientists used a class 1000 clean room as well as a 3D printed box to dramatically diminish existing particles in the air, thereby reducing the amount of "noise" or unwanted particles from appearing in the results. MISSION, a leading provider of textile accessories, provided the funding necessary to conduct the study.

"Per CDC guidelines, using face covers to prevent the spread of COVID-19 is of the utmost importance," Sharma said. "However, recent media reports have questioned the effectiveness of gaiters as face covers. We hope this study will provide valuable evidence and insight to help answer those questions. In sum, the level of protection provided by a face covering appears to be substantially driven by the number and quality of layers of material and not whether it's in the form of a gaiter or a mask." ler

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Using Shockwave, Foot Core Exercises to Manage Tibialis Posterior Tendinopathy

Figure. Three primary exercises of foot core progression: A) foot doming, B) toe yoga, and C) intrinsic foot abduction. Used with permission; all rights reserved.

Tibialis posterior tendon dysfunction/tendinopathy (PTTP) is a common debilitating condition. The diagnosis is largely clinical with physical examination sufficient to make the determination. Patients will commonly complain of pain in the medial foot and behind the medial malleolus that worsens with prolonged standing and activity.

A recent systematic review found conservative management approaches poorly described and most often ineffective. Typically, they include a plantar cast/removable fracture boot for immobilization and oral anti-inflammatories. Physical therapy traditionally focuses on improving strength and flexibility of the tibialis posterior and ankle and includes use of orthotics. Corticosteriods are then considered for select recalcitrant cases. And finally, surgical options are considered.

These authors present a case series that examines a combination of radial shockwave therapy (R-SWT) and a foot core progression exercise regimen that was used with 10 patients who had failed standard conservative treatment techniques including physical therapy and shoe orthotics.

The shockwave procedure was delivered over 3 weekly sessions, with additional treatments provided if response was positive but not complete. R-SWT was delivered using the Storz extracorporeal pulse activation (EPAT®) technology device (Storz Medical, Tagerwilen, Switzerland). The authors describe treatment specifics in detail, noting that use of shockwave for treatment of PTTD has not been described before.

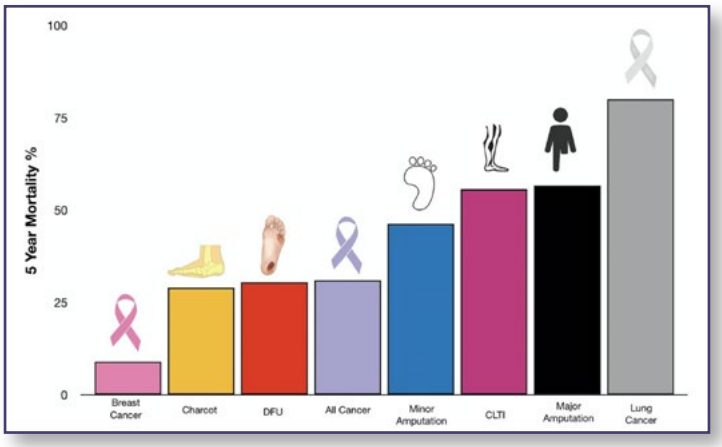
The foot core exercise program consisted of "foot dooming," toe yoga, and toe abduction/adduction (see Figure), practiced 3 times/day with additional balance exercises and hopping and landing exercises added as patient progression allowed. These exercises focused on activation and recruitment of the intrinsic muscles. Exercises to strengthen the extrinsic foot muscles were added as well.

After 4 months, clinically important differences in the Foot and Ankle Ability Measure were met in 9 (90%) and 8 (80%) of patients for activities of daily living and sport sub-scores, respectively, with no adverse effects.

The results suggest R-SWT with a formal physical therapy program using foot core progression may be an effective and noninvasive treatment alternative approach for refractory tibialis posterior tendinopathy.

Source: Robinson D, Mitchkash M, Wasserman L, Tenforde AS. Nonsurgical approach in management of tibialis posterior tendinopathy with combined radial shockwave and foot core exercises: a case series. J Foot Ankle Surg. 2020 Sep-Oct;59(5):1058-1061.

5-year Mortality, Costs of Diabetic Foot Complications Comparable to Cancer



Five Year Mortality of Diabetic Foot Complications and Cancer. Diabetic foot complications compared to cancer. DFU = diabetic foot ulcers = 30.5%. Charcot = Charcot neuroarthropathy of the foot. All Cancer = pooled 5-year survival of all cancers. CLTI = chronic limb threatening ischemia. Major Amputation = above foot amputation. Minor Amputation = foot level amputation. Use is per the Creative Commons License 4.0.

The purpose of this brief report was to refresh a 2007 data summary comparing diabetic foot complications to cancer with the best available data as they currently exist. Since that time, more reports have emerged both on cancer mortality and mortality associated with diabetic foot ulcer (DFU), Charcot arthropathy, and diabetes-associated lower extremity amputation.

These investigators collected data reporting 5-year mortality from studies published following 2007 and calculated a pooled mean. They evaluated data from DFU, Charcot arthropathy, and lower extremity amputation, and then dichotomized high and low amputation as proximal and distal to the ankle, respectively. This was compared with cancer

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mortality as reported by the American Cancer Society and the National Cancer Institute.

Five-year mortality for Charcot, DFU, minor and major amputations were 29.0, 30.5, 46.2 and 56.6%, respectively. This is compared to 9.0% for breast cancer and 80.0% for lung cancer. 5 year pooled mortality for all reported cancer was 31.0%. Direct costs of care for diabetes in general was $237 billion in 2017. This is compared to $80 billion for cancer in 2015. As up to one-third of the direct costs of care for diabetes may be attributed to the lower extremity, these are also readily comparable.

Diabetic lower extremity complications remain enormously burdensome. Most notably, DFU and LEA appear to be more than just a marker of poor health. They are independent risk factors associated with premature death. While advances continue to improve outcomes of care for people with DFU and amputation, efforts should be directed at primary prevention as well as those for patients in diabetic foot ulcer remission to maximize ulcer-free, hospital-free and activity-rich days. ler

Source: Armstrong DG, Swerdlow MA, Armstrong AA, et al. Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer. J Foot Ankle Res. 2020;13:16.

Gait Speed as Risk Tool for Falls

Keeping older adults physically active is critical to health maintenance and walking is a key form of exercise for this population. However, foot pain represents a leading cause of mobility limitations and lower quality of life in older individuals. Nearly 25% of adults report foot pain, and those with frequent foot pain are at double the risk of falling.

Walking speed tends to steadily decrease with age and foot pain can add to that decline. Researchers in Croatia and the Czech Republic sought to establish a clinically significant gait speed cut-off value that would predict foot pain and the risk of falls among community dwelling older adults.

They recruited 120 women from Zagreb, Croatia who were living independently, able to ambulate with or without aid for at least 10 minutes, passed a short mental status exam, were free from neurological diseases, and were able to arrange their own means of transportation to the testing site. Mean age of the group was 71.02 years and mean body mass index was 26.79 ± 4.42 kg/m^2.

Prevalence of foot pain was assessed by a single question: "On most days do you have pain, aching or stiffness in either of your feet?" Respondents had 6 possible responses broken down by yes/no and by left/right or both. Risk of falls was assessed using the Downtown Fall Risk Index which includes 5 questions about previous falls, medication use, sensory deficits, mental status, and gait characteristics.

For the study, participants walked barefoot back and forth on a 10.5-meter pressure platform at their preferred speed for 4 trials.

More than 50% of participants reported foot pain and one third were at higher risk of falls. Mean gait speed was 0.95 m/s. Gait speed cut-off for foot pain was 0.88 m/s and 0.85 m/s for risk of falls. Participants who walked ≤0.88 m/s and ≤0.85 m/s were nearly 11 times more likely to report foot pain (OR = 10.92, 95% CI 4.28 to 27.89, $P < 0.001$) and were nearly 13.5 times more likely to have higher risk of falls, and higher risk of falls (OR = 13.59, 95% CI 5.45 to 33.87, $P < 0.001$). According to the authors, the gait speed cut-off values can predict 20.25% and 24.01% of foot pain and the risk of falls.

While noting that theirs is the first study to define specific gait speed cut-off values for use in predicting foot pain and the risk of falls in older women simultaneously, the authors write that this new gait speed cut-off value of ≤0.88 m/s can be used by health-related professionals as a diagnostic tool in detecting a "risky" group of older women, who may be more vulnerable because they have foot pain.

In their conclusion, they note that by using the proposed cut-off values, individuals who walk slower should be a target population for special interventions that improve foot biomechanics and reducing both foot pain and future risk of falls. ler

Source: Stefan L, Kasovic M, Zvonar M. Gait speed as a screening tool for foot pain and the risk of falls in community-dwelling older women: a cross-sectional study. Clin Interven Aging. 2020:15 1569–1574.

Improved Patient-Provider Relationship Boosts Outcomes

While a good patient-provider relationship has been the bedrock of today's much-needed patient satisfaction scores, such relationships are also proving to boost functional outcomes.

In a recent study published in the *Annals of Family Medicine*[1], physician researchers from Case Western Reserve University used data from the Medical Expenditure Panel Survey (MEPS) from 2015 and 2016 to measure both improvements in patient-provider relationships and functional health status over the course of the year.

The researchers assessed relationship quality by asking adult patients (average age 52.7 years [SD = 17.7 years], 59.4% female) whether they believed their provider listened to them and whether their provider explained concepts in an understandable way. In total, the researchers

used 14 questions to assess relationship quality, and then looked at whether relationship quality and functional health status improved at the start and end of the study.

As might be expected, good patient-provider relationships were positively associated with functional status. But when looking at the trajectory, when those relationships improved over the course of the year, the patients' functional health status improved by a correlation coefficient of between 0.05 and 0.08. The inverse was true as well: when relationships did not improve, or deteriorated, functional status followed in that downward manner.

Patients with 5 or more comorbidities were likely to experience a poor relationship with their provider than healthier counterparts. This discrepancy, the authors wrote, could signal an opportunity for intervention.

Their work builds on that of others about the benefits of good, ongoing patient-provider relationships. Indeed, researchers from Stanford University identified 5 best practices for patient-provider relationships and communication strategies. These include:[2]

- Prepare with intention (take a moment to prepare and focus before greeting a patient)
- Listen intently and completely (sit down, lean forward, avoid interruptions)
- Agree on what matters most (find out what the patient cares about and incorporate these priorities into the visit agenda)
- Connect with the patient's story (consider life circumstances that influence the patient's health; acknowledge positive efforts; celebrate successes)
- Explore emotional cues (notice, name, and validate the patient's emotions)

Sources

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"Renal Foot" – Angiographic Patterns in Chronic Limb Threatening Ischemia + Renal Disease

Patients with chronic limb threatening ischemia (CLTI) and end-stage renal disease (ESRD) have greater risk of limb loss compared to those with CLTI alone. These researchers investigated angiographic patterns in patients with CLTI and evaluated for differences based on ESRD status.

They reviewed lower extremity angiograms of 152 CLTI patients at a single academic medical center from 2011 to 2017 and analyzed them based on the Graziani and Bollinger classification systems. The researcher evaluated for angiographic patterns and arterial disease severity categorized by the presence or absence of ESRD.

The analysis included 152 CLTI patients (161 angiograms). Patients' mean age was 63.4 ± 11.3 years and 20 (12.4%) patients had ESRD. In they study population, infrapopliteal arterial disease was more severe than femoropopliteal disease. Disease of the arteries providing direct flow to the plantar arch was more severe in ESRD patients compared to non-ESRD patients, evident by higher Graziani Class VII disease (20% vs. 4.9%, $P = .03$). ESRD patients also had higher rates of concurrent significant stenosis of the posterior tibial and lateral plantar arteries (70% vs. 23%, $P < .0001$).

The authors concluded that in people with CLTI, infrapopliteal arteries are more severely affected than proximal femoropopliteal arteries. ESRD patients exhibit a pattern of arterial disease, which they termed the "renal foot," that frequently involves arteries providing direct flow to the plantar arch.

Source: Baghdasaryan PA, Bae JH, Yu W, et al. "The Renal Foot" – angiographic pattern of patients with chronic limb threatening ischemia and End-Stage Renal Disease. Cardiovasc Revasc Med. 2020;21(1):118–121.

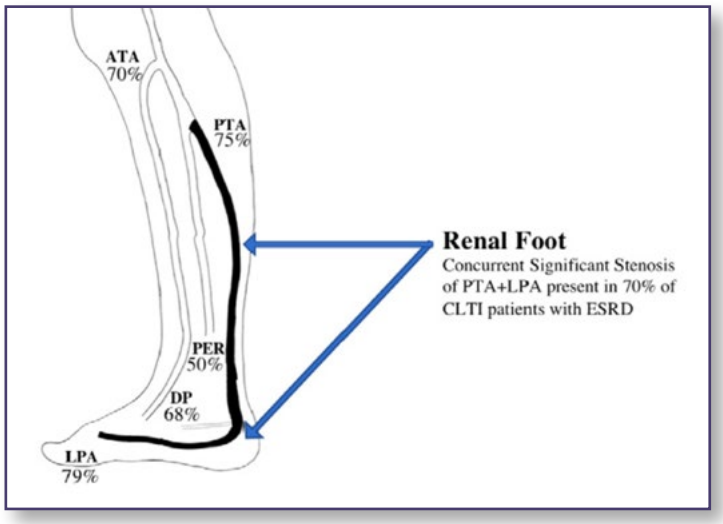

Figure. The "renal foot." The diagram displays the percentage of individuals with significant stenosis in the posterior tibial artery (PTA) (75%), peroneal artery (50%), anterior tibial artery (ATA) (70%), lateral plantar artery (LPA) (79%), and dorsalis pedis (DP) (68%) arteries in end-stage renal disease (ESRD) patients with chronic limb threatening ischemia (CLTI). The accompanying table compares the rates of significant stenosis of the lumen of the PTA and LPA arteries in ESRD and non-ESRD patients. It then further compares the rates of individuals with concurrent significant stenosis in both the PTA and LPA. Use is per the Creative Commons License 4.0.

WOUND CARE UPDATE

Can Bioabsorbable Borate-based Glass Fibers Support Wound Healing?

By Windy Cole, DPM, CWSP

With increasing demand for biomaterials that have the ability to support wound healing, tissue engineers have been challenged to develop innovative bioactive scaffold materials. In general, bioactive materials have the mechanical properties of the tissue to be replaced while supporting biological activities such as cellular adhesion, proliferation, differentiation, and angiogenesis. Ideally, tissue scaffolds should be biocompatible, non-toxic, have similar porosity to the tissue to be replaced, be degradable, resorb at the same rate as new tissue is produced, be excretable, and be sterilized for clinical use.[1]

Borate bioactive glass (BBG) is one such material gaining favor in the wound care space. Research has shown that BBG has demonstrated the ability to assist in cellular chemotaxis, proliferation, and differentiation in vivo.[2] BBG has distinctive properties that can support repair and regeneration of soft tissue defects. When implanted, BBG forms a direct bond to living tissues.[3] The specific architecture of the BBG scaffold contributes to the material degradation rate while the pore structure provides the support for cellular ingrowth and new tissue formation.[1]

Herein the author details 3 patient case reports in which BBG in the form of MIRRAGEN® Advanced Wound Matrix was used to treat chronic hard-to-heal wounds of varying etiology. In all cases, wounds were treated with standard of care which included cleansing wounds with normal sterile saline, debridement to appropriate level to remove devitalized tissues, application of MIRRAGEN wound matrix, and application of a secondary dressing to ensure a moist healing environment. Patients were monitored weekly. Wound assessments including wound measurements were obtained. Normal saline solution irrigation was used to flush away any loose MIRRAGEN still present in the wound base. Reapplication of MIRRAGEN was performed weekly until evidence of wound closure was noted.

Case 1

Case 1

Case 1 (see image, above) is a 78-year-old male who presents to the wound care center with a long-standing history of chronic ulcers of the right lower leg. Patient relates that he has suffered from various areas of ulceration on the leg for several years. He states that the wounds crust over and then breakdown again. These particular open wounds have been present for 6 months. He has tried and failed numerous wound care therapies including collagen, alginates, and hydrogels. His past medical history includes hypertension, degenerative join disease (DJD), psoriasis, atrial fibrillation (A-fib), anxiety, restless leg syndrome, and sleep apnea. Upon physical exam it is noted that the proximal wound measures 0.7cm x 0.5cm x 0.1cm and the distal wound measures 1.2cm x 1.1cm x 0.1cm. The wounds are granular and clean without clinical evidence of infection. Moderate serous exudate was noted on the previous bandage, but no active drainage is noted at the time of examination. No erythema or malodor is present. Ankle Brachial Index (ABI) is 1.02. At the initial visit, MIRRAGEN

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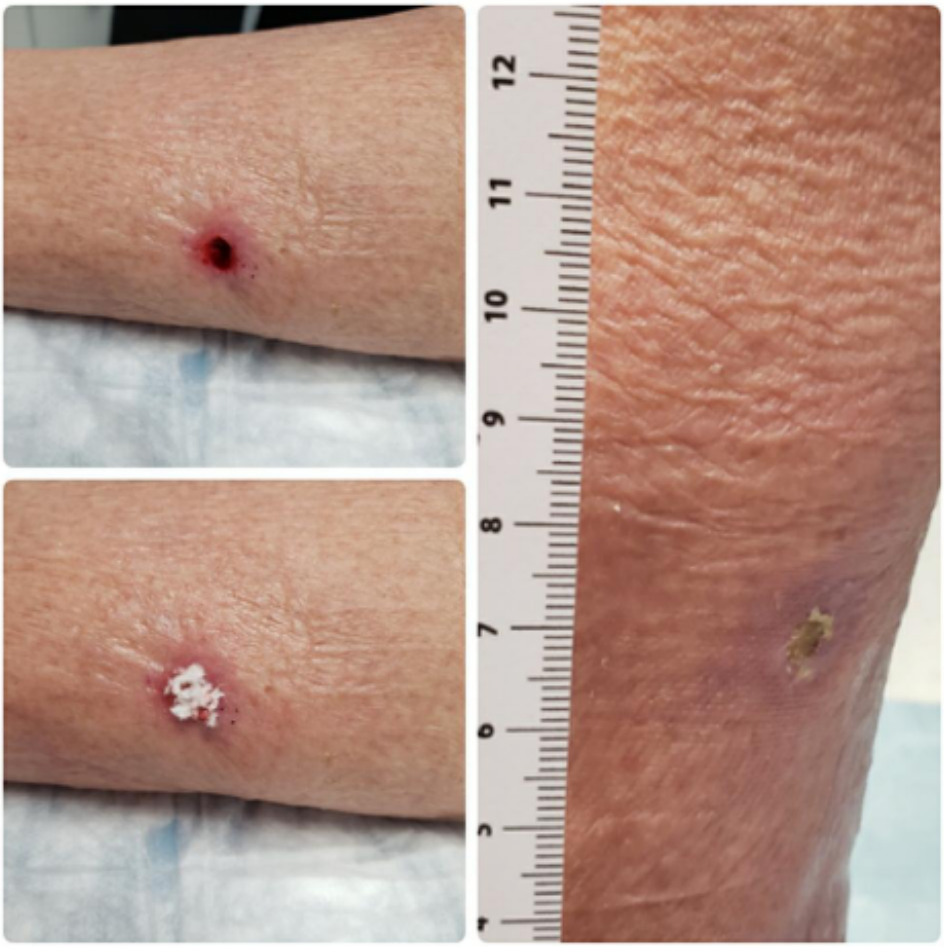
was placed in the base of both wounds and covered with foam and a multilayer compression bandage. The patient was directed to keep the bandage dry and intact and reappoint for weekly wound assessment visits. Patient complied with the treatment regimen without any issues or complaints. Both wounds went on to complete healing with 3 weekly MIRRAGEN applications.

Case 2

Case 2 (see image, right) is a 68-year-old female who presented to the wound center with a 6-week history of a right lower leg wound. It originally began as a small blister that opened and drained a bloody discharge. The area has continued to enlarge, and the patient made an appointment at the wound care center for this issue. Past medical history is positive for varicose veins, peripheral vascular disease, DJD, COPD, pulmonary hypertension, aortic stenosis, and obesity. Upon initial presentation, the wound measured 0.5cm x 0.7cm x 0.6cm. ABI was 1.14 on the right leg. At her first wound care visit, the wound was packed with alginate ribbon and a multi-layer compression wrap was applied to the leg. Patient presented for follow up the next week. Wound measurements had not progressed. It was then decided that we would discontinue the alginate and begin treatment with MIRRAGEN. After debridement, the wound base was packed with MIRRAGEN, covered with foam and a multi-layer compression bandage. She was compliant with the wound care regimen without issues or complaints. Weekly wound assessments were performed. The wound completely healed with 2 weekly MIRRAGEN applications.

Case 3

Case 3 (see image, page 29) is a 62-year-old female who presented to the wound center with a 4-week history of a right lower leg ulcer. She relates that she has been applying Neosporin to the area daily. She relates that the wound is heavily draining and painful. Past medical history includes type 2 diabetes and Rheumatoid arthritis. Upon intake the wound measures 8.1cm x 2.2cm x 0.1cm. The wound base is clean and granular. Moderate serous exudate present. No clinical signs and symptoms of wound infection noted. We began weekly MIRRAGEN application under multi-layer compression bandaging. Patient was compliant with the wound care regimen. No adverse events were reported. The wound completely resolved after 4 weekly applications.



Case 2

Discussion

MIRRAGEN Advanced Wound Matrix is a resorbable and biocompatible borate-based bioactive glass specifically designed for wound healing.[4] The BBG material slowly dissolves upon exposure to body fluid. As the borate glass dissolves, it releases regenerative ions at the wound site.[4] The fibrous structure of MIRRAGEN Advanced Wound Matrix was specifically engineered to absorb fluid from the wound bed.[4] The product can absorb 400% of its weight in exudate, making it ideal for use in heavily exudating venous leg ulcers. In this case series, application was performed weekly without evidence of secondary dressing saturation or peri-wound tissue maceration. The spacing of the fibers within the matrix creates a pore network similar to dermal tissue, facilitating accelerated cellular ingrowth and angiogenesis. Additionally, room temperature storage and long shelf life allowed the product to be easily stocked in the wound clinic. MIRRAGEN Advanced Wound Matrix proved to be an effective treatment in this case series of hard-to-heal chronic wounds.

Windy Cole, DPM, CWSP, serves as Adjunct Professor and Director of Wound Care Research at Kent State University College of Podiatric Medicine and Student Rotation Coordinator, UH Richmond Medical Wound Center both in Cleveland, Ohio. She is a dedicated healthcare advocate with interests focused on medical education,

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diabetic foot care, wound care, limb salvage, clinical research and humanitarian efforts. Dr. Cole has published extensively on these topics and is a sought-after speaker both nationally and internationally. Dr. Cole also serves as a member of the Editorial Advisory Board for LER.

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Case 3

Peripheral Artery Disease

Peripheral Artery Disease (PAD) is a deadly chronic condition that can lead to heart attack, stroke, or amputation.

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Foot Drop: A Primer

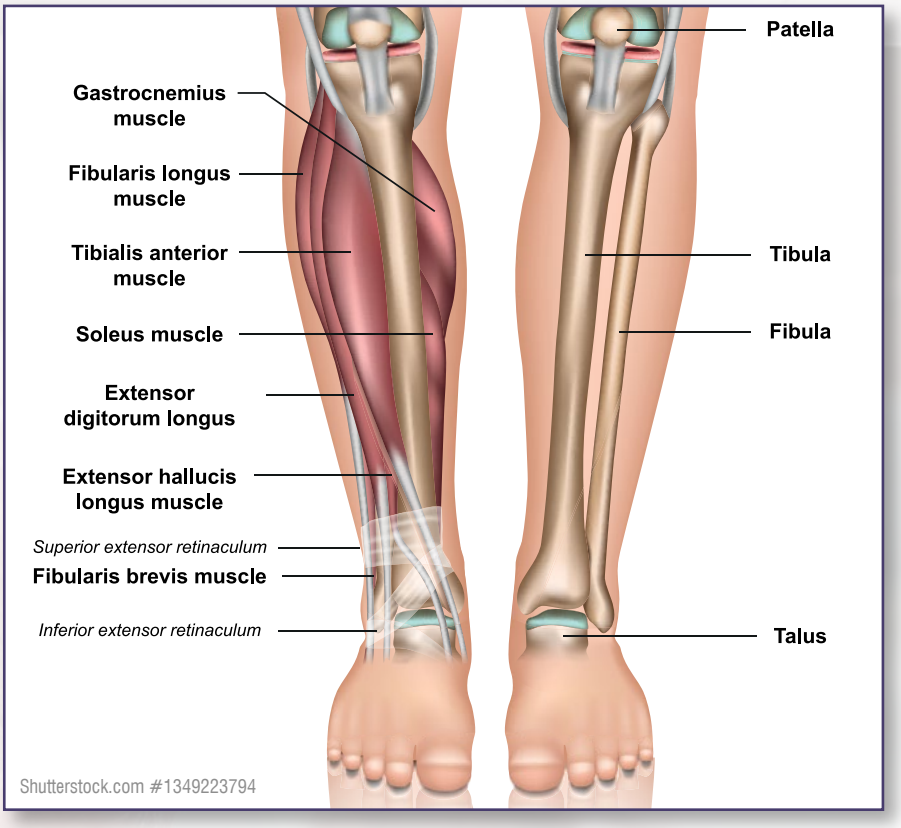
Foot drop, a complex condition that can have a significant impact on independent ambulation, can have many causes. Treatment options vary by cause. These authors provide a review of the condition from etiology through treatment.

By Subhadra L. Nori, MD, and Michael F. Stretanski, DO

Foot drop (also known as steppage gait) is an inability to lift the forefoot due to the weakness of dorsiflexors of the foot. This, in turn, can lead to an unsafe antalgic gait, potentially resulting in falls.

The etiologies behind this presentation are varied and include muscular, neurologic, spinal, autoimmune and musculoskeletal disorders. Depending on the etiology, treatment options differ.

A thorough understanding of the underlying pathophysiology is necessary before designing a treatment plan. This article will review the etiology, clinical features, diagnosis, and treatment.



Anatomy

Lumbar nerve roots

There are 5 lumbar vertebrae. The lumbar nerve roots emerge from the lateral spinal recess formed by the inferior facet of the rostral vertebrae and the superior facet of the caudal vertebra. The L5 nerve root exits between the L5 and S1 vertebrae.

Lumbar plexus

The lumbar plexus is composed of the anterior rami of spinal nerves L1-L4. Multiple nerves emerge from this plexus. The iliohypogastric and ilioinguinal nerves supply the transverse abdominis and internal oblique muscles. The obturator nerve supplies the adductors of the thigh. The femoral nerve is a large nerve that supplies the quadriceps femoris group and continues as the saphenous nerve which is the sensory nerve to the medial leg.

Sciatic nerve

The sciatic nerve is the largest branch of the lumbosacral plexus and consists of nerve roots L4 to S4. It travels in the posterior thigh to the popliteal fossa. Here it divides into 2 branches: the tibial and the common fibular (historically peroneal) nerves. The tibial innervates hamstrings, plantar flexors, and invertors of the foot.

Common fibular nerve

The common fibular nerve is the lateral terminal branch of the sciactic and runs laterally across the lateral head of the gas-

Continued on page 34

This article is excerpted from "StatPearls: Foot Drop," by the same authors which appears in the Bookshelf of the National Center for Biotechnology Information available at https://www.ncbi.nlm.nih.gov/books/NBK554393/. Its use is per the Creative Commons License 4.0; editing has occurred, and references have been deleted for length considerations.

Continued from page 33

trocnemius muscle. It then continues around the fibular head where it is subcutaneous and so is vulnerable to compression. As it passes between the fibula and fibularis longus muscle it divides into the deep and superficial fibular nerves. The deep fibular nerve innervates ankle and toe-extensors and supplies sensation to a small area at the first web space between the first and second toes. The superficial fibular nerve supplies the main evertors of the foot, the fibularis longus, and brevis muscles. The superficial fibular sensory branch supplies sensation to the dorsum of the foot and lateral calf.

Etiology

Compressive Disorders

Entrapment syndromes of the fibular nerve at various locations along its anatomical pathway can lead to compressive neuropathy. Of these, common fibular neuropathy at the fibular head is the most common mononeuropathy affecting the leg. The fibular nerve is quite superficial near the head of the fibula, making it vulnerable to pressure palsies. Anatomic variations of the biceps femoris muscle, between the gastrocnemius and distal biceps, can contribute to the formation of a tunnel that can predispose to compression of the nerve. Other contributing factors include weight loss, prolonged bedridden status, tight casts, space-occupying lesions, and bone metastasis involving the fibular head.

Sciatic nerve compression between the two heads of the piriformis muscle leading to foot drop has been reported.

Compression palsies in the ICUs due to protracted bed rest, have been known to occur. Approximately 10% of patients that stay in the ICU for a period longer than 4 weeks are expected to develop paresis of the fibular nerve. Critical illness polyneuropathy involving multiple motor and sensory nerves can also present with foot drop. Depending on the extent of involvement, weakness can be bilateral. Patients with diabetes are more vulnerable to these compression neuropathies.

Lumbar radiculopathy is also a common cause of foot drop. L5 radiculopathy is the most common lumbar radiculopathy and typically results from lumbar disc herniation or spondylitis in the spine.

Extraforaminal compression of the L5 nerve from disc herniations and bony (osteophytes or sacral ala) or ligamentous (sacroiliac ligament and lumbosacral band) compression is known to occur. Bone metastasis at the fibular head, although uncommon, can cause foot drop.

Traumatic Injuries

Traumatic injuries often occur in association with orthopedic injuries as knee dislocations, fractures, blunt trauma, and musculoskeletal injuries. Sciatic neuropathy most commonly results from a traumatic injury of the hip or secondary to surgery. Sciatic neuropathy is the second most common mononeuropathy of the lower extremity and typically presents with foot drop.

A less common cause is lumbosacral plexopathies, which can result from traumatic injury, a complication of abdominal or pelvic surgery, or a complication of neoplasm or radiation therapy.

Neurologic Disorders

ALS (Amyotrophic lateral sclerosis), also known as motor neuron disease (MND) or Lou Gehrig disease, is a neurodegenerative disease manifested by the death of motor neurons in the anterior horn cells leading to muscle weakness, difficulty speaking and swallowing. Initial presentation can be a painless foot drop.

Cerebrovascular disease (CVA) can present as hemiplegia. Foot drop is a part of this presentation. Other signs of upper motor neuron involvement as increased muscle tone, hyperreflexia, and circumduction of the lower extremity during ambulation are also seen. Depending on the location of ischemia, aphasia can be present.

Mononeuritis multiplex is defined as the involvement of one or more sensory and peripheral motor nerves. It is usually painful and asymmetrical. It can be associated with AIDS, leprosy, hepatitis, granulomatis with polyangiitis (Wegener granulomatosis), and rheumatoid arthritis. Loss of sensation and movement may be associated with dysfunction of specific nerves. The sciatic nerve is one of the commonly affected nerves in this condition. Vasculitis of small epineuria arteries leads to damage to the axons causing disruption in nerve conduction and eventually leading to muscle weakness.

Acute inflammatory demyelinating polyneuropathy (AIDP), also called Guillain-Barré syndrome, is an autoimmune process in which progressive motor weakness, sensory loss, and areflexia is a characteristic presentation. Sensory symptoms often precede motor weakness. Autonomic dysfunction is a common accompaniment to this condition. Damage to the myelin sheath leads to segmental demyelination.

Continued on page 37

Cerebrovascular disease (CVA) can present as hemiplegia. Foot drop is a part of this presentation.

Pearls and Other Issues

- Foot drop is an inability to lift the forefoot due to the weakness of the dorsiflexors.
- This may be a result of muscular-skeletal or nervous system pathology.
- A thorough evaluation should include medical history, physical examination and necessary imaging, and or electrodiagnostic studies.
- Depending upon the etiology, either surgical or non-surgical options are exercised.
- Prognosis depends upon the extent of nerve damage and the viability of the remaining muscles.
- A comprehensive approach, including referrals to appropriate services, will result in a better outcome.
- Careful analysis of the presenting history and physical examination is essential to arrive at the proper diagnosis.
- Management is contingent upon diagnosis and severity.

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A hallmark of AIDP is the slowing of nerve conduction velocities and conduction block. Foot drop can be part of the clinical presentation.

Charcot–Marie Tooth (CMT) is a primary congenital demyelinating peripheral neuropathy and is one of the most common inherited neuropathies. It affects both motor and sensory nerves. The incidence is 1 in 25,000. One of the main symptoms is foot drop along with wasting of the lower leg muscles, giving a typical "stork leg" appearance.

Somatization disorder and conversion reaction are not uncommon etiologies to foot drop. In the event of an otherwise unremarkable workup, psychiatric evaluation should be considered. It should be noted that both the needle EMG and nerve conduction portions of the electrodiagnostic medicine study will appear normal in cases of poor or no effort for ankle dorsiflexion or other motor groups.

History and Physical

A careful history and physical exam can help identify the likely cause of foot drop.

Standard musculoskeletal testing asking the patient to toe stand, heel stand, and do a deep knee bend should be observed. MRC scale rating 0-5 for the major muscle groups to the lower extremities, including ankle plantarflexion, ankle dorsiflexion, ankle inversion, ankle eversion, knee extension, knee flexion, and hip flexion should be performed and graded. Neurosensory exam for pinprick should be performed in the distribution looking for both peripheral nerves, as well as lumbar dermatomes. Muscle mass with the side to side comparison observing the major muscle group bulk areas can be done well doing manual motor testing, and side-to-side circumference measurements can be made and documented to note progression, or recovery of mass further down the road. The ASIA (American Spinal Cord Injury Association) point and motor groups are a standardization convenient for communication between professionals; however, it does not include evaluation of specific peripheral sensory nerves.

A formal electrodiagnostic medicine consult, including EMG and nerve conduction studies, is considered to be an extension of the physical examination and may need to be obtained from the subspecialist who is not commonly the first clinician to be involved in the care of the patient.

Any damage affecting the neuraxis from the roots to the peripheral nerve can lead to weakness of the muscles supplied by that nerve.

A lesion of the L5 root, lumbar plexus, sciatic nerve, common peroneal, or the deep peroneal nerve can potentially lead to foot drop due to the weakness of the anterior compartment musculature. The presenting symptom is the inability to ambulate as before. More specifically, weakness of the muscles in the foot that assist in dorsiflexion. There may or may not be a pain. The person will be unable to dorsiflex during the heel strike. The foot remains flat on the ground. Sometimes can also cause toe drag and inability to clear the foot. This can potentially lead to falls.

Radiculopathy affecting the fifth lumbar nerve root typically results in neuropathic pain starting in the lumbar region and radiating down the posterior thigh, anterolateral leg to the foot down to the big toe. Sensory symptoms include the medial aspect of the foot, including the first webspace. Motor symptoms include weakness of dorsiflexors and evertors of the foot.

Lumbosacral plexopathies can present with similar sensory and motor deficits that are similar to sciatic neuropathy. Weakness may also affect hip girdle muscles, including hip abduction (gluteus medius) and hip extension (gluteus maximus).

Sciatic neuropathy classically presents with sensory loss of the whole foot and weakness of ankle plantar flexors (gastrocnemius, soleus) as well as ankle inversion, and can result in a 'flail foot.' Hamstring muscles may also be involved resulting in knee flexion weakness. It is not uncommon for an incomplete sciatic neuropathy to present as a common peroneal neuropathy, as many times the peroneal fascicles in the sciatic nerve are more susceptible to injury than are the tibial fascicles.

In common fibular neuropathy, the patient presents with sensory and motor deficits. History may include leg crossing, prolonged kneeling, immobility, or trauma. Sensory loss or paresthesias affect the lateral leg below the knee and the anterolateral foot. Muscle weakness affects both ankle dorsiflexion (tibialis anterior), toe extension (eg, extensor hallucis longus), and ankle evertors (peroneus longus and brevis).

If only the deep fibular portion is affected, only minimal sensory deficits (limited to the web space between the first two digits) and isolated weakness of toe and ankle extensors are seen. Ankle eversion and inversion are normal.

Isolated superficial fibular neuropathy is rare and presents as the sensory deficit of the foot except for the first webspace. Only ankle eversion/inversion may be affected.

60% of the normal gait cycle consists of

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60% of the normal gait cycle consists of the stance phase and 40% of the swing phase.

The Following is an Example of the Care Coordination Plan

1. A thorough history and physical examination
2. Assessment of risk factors
3. Consultation with neurology and PMR
4. Order diagnostic imaging, EMG
5. Provision of pain management
6. Provision of the brace as needed with orthotist
7. Referrals to PT and OT
8. Potential surgical consultation and or intervention
9. Review of skincare, fall prevention
10. Follow up appointments as needed

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the stance phase and 40% of the swing phase. When one foot is in the swing phase, the other is in the stance phase. The gait cycle starts with a heel strike and ends with a heel strike on the same side. During the stance phase, the foot remains flat on the ground. In the heel strike, the foot is in dorsiflexion, preparing for gradual lowering before the stance phase. In the absence of dorsiflexors, the foot remains in plantar flexion during the stance phase. This prevents the ability to clear the ground and prepare for the next phase of the gait cycle. The patient either drags their toes or lifts the foot high to clear the ground.

Evaluation

After a careful physical exam, diagnostic testing should include plain radiographs of the pelvis and tibia and fibula to rule out fracture or dislocation. MRI may be indicated in suspected plexopathies, due to masses, or tumors. MRI of the lumbar spine, knee, and or ankle may be indicated for potential soft tissue masses in cases of compressive neuropathies. MSK ultrasound is also utilized for evidence of swelling at or proximal to the site of compression.

In many cases, an electrodiagnostic study is an important test to confirm the clinical diagnosis or provide an alternate localization and diagnosis. This study can also define the injury severity and provide information regarding prognosis. This study contains two parts: nerve conduction studies and needle electromyography. (EMG).

Treatment / Management

The approach to a patient depends upon the etiology of foot drop and the nature of the compressive lesion. Based on the evaluation and diagnostic findings, many options exist.

Surgical Options

In trauma cases, for nerve transection, nerve reconstruction should take place within 72 hours of injury. Primary nerve repair techniques, autologous nerve graft are usually performed.

For complete nerve compression, necrolysis and nerve decompression should be performed. Return to function has been reported in about 97%. A surgical release may be necessary for patients with equinus deformity.

In cases of significant nerve dysfunction, nerve or tendon transfers may be required. A detailed discussion of surgical options is beyond the scope of this article.

For the other etiologies, treatment is initially conservative because there may be a chance of partial or complete resolution of symptoms spontaneously overtime.

Conservative Management

This includes physical therapy and or splinting and pharmacological therapy to manage pain. The goals of conservative management are to stabilize the gait, and to prevent falls and contractures. Physical therapy focuses on stretching and strengthening muscles. Electrical stimulation techniques of the weakened dorsiflexors have shown promise. A home

exercise program should be an integral part of therapy – specifically to maintain strength and range of motion of muscle groups that are working in the prevention of flexion contracture.

Splinting is utilized to minimize contractures. For complete nerve palsies with insufficient recovery, an ankle-foot orthosis (AFO) to prevent further plantarflexion should be ordered. Sufficient education and training should be included to assist in proper usage and maintenance of the brace.

For patients with numbness, instructions for skincare to prevent abrasions and ulcerations are a significant part of management and are often coordinated with the orthotist fabricating the AFO.

For pain management, topical analgesics, serotonin reuptake inhibitors, membrane stabilizers, and opioids can be used. But are not likely to result in clinical recovery.

Follow up electrodiagnostic studies to reassess the situation, looking for reinnervation should also be part of the treatment planning.

Treatment Planning

Early range of motion and potential strengthening should be planned. The electrodiagnostic study may assist in helping plan as to whether or not the patient will be needed for long-term bracing and or whether or not the weakness is likely to get worse or spread to other motor groups. Early placement into the ankle dorsiflexor brace improves gait mechanics, decreases falls, and helps to minimize other secondary musculoskeletal complaints from the altered gait cycle.

Preparation for long-term care, as to bracing, and adaptive equipment should be considered. Rehabilitation medicine services and other therapy should be directed toward the underlying etiology in addition to the foot drop itself. Staging will depend upon the underlying diagnosis such as multiple sclerosis or Lou Gehrig disease being treated differently in terms of staging compared to lumbar spinal pathology.

Complications can be a result of nerve damage itself or a consequence of gait aids and braces.

Nerve damage leading to foot drop impairs the ability to clear the ground resulting in a fall. Gait aids as walkers and canes can also be an impediment, especially on uneven surfaces. Anesthetic skin can be a source of ulceration. Abrasions can be a result of poor fitting braces. Bracing may need to be variable depending upon bulk change. In cases such as renal failure and congestive heart failure, different braces for different phases of edema and swelling may need to be provided.

As outlined above, physical therapy, occupational therapy can play a major role in whether the patient had conservative or surgical management. ler

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A New Ankle–Foot Orthosis Using Wire for Stroke Patients with Foot Drop

Researchers from Korea have developed a new type of AFO that uses neoprene and a novel wire configuration for use with foot drop after stroke.

BY JUNG-HOON LEE, IM-RAK CHOI, AND HYUN-SU CHOI

Foot drop can be a sequela of stroke. An ankle–foot orthosis (AFO) is the most widely used method to prevent foot drop in patients with stroke, and is used during weight-bearing training of the limb on the affected side or when there is ankle spasticity or deformity. AFO use has been reported to improve abnormal gait caused by mediolateral instability of the ankle in patients with stroke and enhance balance in these patients. However, AFOs passively fix the ankle to restrict ankle joint movement, thus limiting mobility of the joint; and they have been reported to cause contracture of the ankle joint and reduce muscle activity of the lower extremity. They also limit ankle range of motion (ROM), which makes standing from a seated posture difficult; thus, the neuromuscular system cannot be stimulated. However, despite these shortcomings, plastic AFOs are widely used for foot drop in patients with stroke.

Thus, the aim of this cross-over study was to investigate the immediate static balance effects of bare foot, plastic UD-Flex AFO, and a newly developed AFO using wire (AOW) in stroke patients with foot drop.

The AOW Orthosis

The AOW (Okmeditech Co., Ltd, Changwon, Korea) is a newly developed AFO designed by the first author. It is made of a flexible material consisting of neoprene and spandex and has a polyvinyl chloride (PVC) wire to induce passive ankle dorsiflexion (Figure 1). The device was designed such that turning the wire adjustor above the lateral and medial malleoli (A in Figures 1 and 2) triggers the wire crossed above the dorsum of the foot (B in Figure 1), inducing passive ankle dorsiflexion and preventing plantarflexion (B in Figure 2). Further, to assist ankle dorsiflexion, a talus strap made of polyester with rubber is stretched and attached from the front of the ankle joint toward the inferior posterior direction on both sides (C in Figure 1) to induce talus posterior gliding (Arrow of Figure 1). A Velcro strap on the top of the ankle secures the AOW from sliding down the ankle (D in Figure 1). Another Velcro strap is used to fix the front part of the orthosis above the intermetatarsal joints (E in Figure 1).

Figure 1. Lateral view of the ankle–foot orthosis using wire. A: wire adjustor; B: wire; C: talus posterior gliding Velcro; D: Velcro for ankle fixation; E: metatarsal joint stabilization strap.

Figure 2. Lateral view of induction of passive ankle dorsiflexion. A: wire adjustor; B: passive ankle dorsiflexion.

The UD-Flex AFO

The UD-Flex AFO used in this study was a type of plastic AFO that compensates for the shortcomings of the posterior AFO, which is widely used in hospitals to prevent foot drop in patients with stroke (Figure 3).

Figure 3. Lateral view of the UD-Flex ankle–foot orthosis.

Results

Seventeen patients with foot drop resulting from stroke (8 men and 9 women) were randomized to three conditions (bare foot, UD-Flex AFO, or AOW made with a flexible material). Static balance was assessed using the Zebris (Zebris GmbH, Isny, Germany) and BioRescue (RM Ingenierie, Rodez, France) pressure platform by a single examiner, following a random order.

The center of pressure path length (mm) measured using

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The AOW used in this study seemed to improve static balance, with the polyvinyl chloride (PVC) wire attached to the mediolateral side of the ankle potentially inducing passive ankle dorsiflexion and preventing plantarflexion, as well as promoting even distribution of pressure while decreasing COP displacement.

Zebris showed significant differences among the three conditions (bare foot, 484.47 ± 208.42; UD-Flex AFO, 414.59 ± 144.43; AOW, 318.29 ± 157.60) ($P < 0.05$). The bare-foot condition was not significantly different from the UD-Flex AFO condition ($P > 0.05$), but was significantly different from the AOW condition ($P < 0.05$). The surface area ellipse (mm^2) measured using BioRescue showed significant differences among the three conditions (bare foot, 241.35 ± 153.76; UD-Flex AFO, 277.41 ± 381.83; AOW, 68.06 ± 48.98) ($P < 0.05$). The bare-foot condition was not significantly different from the UD-Flex AFO condition ($P > 0.05$), but the AOW condition was significantly different from the bare-foot ($P < 0.05$) and from the UD-Flex AFO conditions ($P < 0.05$).

Discussion

The static balance of the UD-Flex AFO condition was not significantly increased in the BioRescue and Zebris measurements compared to the bare-foot condition. The BioRescue measurements showed significantly improved static balance when using AOW compared with the bare-foot and UD-Flex AFO conditions and the Zebris measurements showed significantly increased static balance when using the AOW compared with the bare-foot condition. AFO made with plastic limits the ROM of the ankle and decreases its control, therefore, AFO aggravates mobility and balance. Although the study of Kim et al. [2015] did not focus specifically on the use of AOW, their use of an elastic band-type AFO led to improved balance compared to when a plastic AFO or bare foot was used. The reason for this was suggested to be the ability of the elastic band-type AFO to promote even weight distribution between the affected and nonaffected limbs. The AOW used in this study seemed to improve static balance, with the polyvinyl chloride (PVC) wire attached to the mediolateral side of the ankle potentially inducing passive ankle dorsiflexion and preventing plantarflexion, as well as promoting even distribution of pressure while decreasing COP displacement. Furthermore, the flexible material consisting of neoprene and spandex permitted minimal movement required to control the position of the ankle joint, possibly helping to improve static balance.

Patients with stroke have trouble controlling their ankles due to the weakening of tibialis anterior, spasticity of gastrocnemius, and asymmetry of the anterior talofibular ligament, with further difficulty regarding posterior gliding of the talus below the tibia during dorsiflexion. The lack of posterior gliding of the talus limits ankle dorsiflexion, which alters the alignment of the foot in turn, thereby leading to abnormal ankle movement and increased risk of ankle injury. In a previous study, patients with chronic stroke who wore a flexible AFO made of elastic bands demonstrated increased balance due to the elastic band providing lesser limitation of dorsiflexion than the plastic AFO. Lee et al. [2017] reported that talus posterior gliding in a weight-bearing posture improved static balance in patients with stroke by increasing afferent stimulation of the ankle joint. Talus posterior gliding stimulates the afferent pathway of the mechanical receptors around the ankle joint, which enhances talocrural articulation and afferent information in the surrounding tissues. Applying taping in the inferior posterior direction for talus posterior gliding increased ankle dorsiflexion in patients with limited dorsiflexion and improved static balance in patients with chronic stroke. The talus-stabilizing strap attached to the dorsal part of the AOW developed in this study probably functioned similarly to the taping used in previous studies, as inferior posterior gliding of the talus in a weight-bearing posture may assist ankle dorsiflexion.

Conclusions

Our results showed that the use of AOW led to immediate effects on static balance in patients with stroke compared to those with bare feet. The use of UD-Flex AFO did not show any immediate effects on static balance in comparison with the bare-foot condition. However, further studies on the effects of dynamic balance and gait should be conducted to clinically suggest the use of AOW for stroke patients with foot drop.

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Pain Reduction Methods for Peripheral Neuropathy

As obesity and type 2 diabetes continue to be growing public health burdens, clinicians will be faced with increasing numbers of patients who suffer from their complications, in particular, peripheral neuropathy. These authors review the multiple medications available to help.

By Shana Shetty, DPM PGY3, and Marshall G. Solomon, DPM FACPM, FACFAS

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A 2015 report published in the *Journal of Pain*, found that 23.4 million adults (10.3%) in the United Stated experience a lot of pain. But more stunningly, it found that 126 million adults (55.7%) reported some type of pain in the 3 months prior to the survey.[1]

It will come as no surprise, then, that pain reduction is a major focus for those in the field of podiatric medicine and surgery, and as such, it is important to be well versed in the myriad of potential treatment options. Patients seek help for management of both acute and chronic pain. Most often, our patients are experiencing diabetic neuropathic pain or post-operative surgical pain. This review will focus on treatment options for these conditions.

One of the more common complaints is diabetic neuropathy. Podiatric physicians may treat the pain symptoms or refer to other specialties, such as the patient's primary care physician, physical medicine and rehabilitation, or a neurologist.

What is Peripheral Neuropathy?

Peripheral neuropathy (PN) is one of the more frequent pathologies seen in the lower extremities in the podiatric clinical practice. PN has a prevalence of 2.4% in the general population, but soars to 30% to 50% in patients with diabetes, in particular type 2 diabetes.[2,3]

PN is caused by damage to the peripheral nerves, those that reside outside of the brain and spinal cord. PN can cause weakness, numbness, and pain, usually in the hands and feet. Patients will often present with the concern of neuropathy affecting the feet. Patients will describe a "gloves and stocking" sensation.[4]

Over time, high blood sugar from poorly controlled diabetes can cause damage to the nerves. Symptoms range from mild numbness to pain that prevents activities of daily living.[5,6] Type 1 diabetes and type 2 diabetes differ in symptomatology time frames: Type 1 patients become symptomatic after chronic hyperglycemia, typically after having had insulin-requiring diabetes for 20 years or more. Symptoms of NP occur much earlier in type 2 patients, with onset as early as 5 – 10 years after diagnosis.[7] Testing should include peripheral neuropathic testing, vibratory sensation, light touch sensation, and monitoring pulses. Further testing includes glucose levels, Hemoglobin A1c, nerve conduction velocity testing, and Doppler exams.[8]

> Testing should include peripheral neuropathic testing, vibratory sensation, light touch sensation, and monitoring pulses.

Treatment Options

Management for neuropathic pain often presents a challenge to practitioners. Traditional treatments for PN include topical and oral medications. Other options include transcutaneous electrical nerve stimulation (TENS), physical therapy, lasers, focused ultrasound, or referrals to neurology. Combining treatment modalities is also often necessary and can lead to better patient outcomes.

Topical Medications

Topical pain control options include capsaicin cream, lidocaine patches, and compound creams. Topical analgesics provide decreased side effects compared to oral medications.[9]

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Capsaicin Cream: Capsaicin cream is derived from capsaicinoids, the spicy ingredient found chili peppers. When applied to the skin, it causes an initial sensitization followed by prolonged desensitization of nerves that are causing pain.[8] There are low concentrations available over-the-counter (OTC), as well as newer higher concentrations, including the capsaicin 8% patch, which is approved by the US Food and Drug Administration (FDA).

A Cochrane systemic review and other studies have reported that a single application of the prescription capsaicin patch with an 8% concentration was shown to provide 3 months of pain relief.[10,11] The single application helps avoid noncompliance, though the patch, which supplies about 100 times greater concentration than the OTC versions, must be applied by a healthcare provider under controlled conditions, typically under local anesthetic.

OTC capsaicin creams with concentrations of 0.025 or 0.075% have also shown effective with benefits in pain relief, sleeping, and ability to perform activities of daily living, but must be applied regularly.[12,13]

Topical Clonidine: Prescription topical clonidine is another option for managing PN. It is also used to treat hypertension as well as attention deficit syndrome. It has been shown to reduce excitability on microvasculature structures, improve blood flow, and reduce cytokine production.[14] In a study comparing it to placebo, topical clonidine delivered a 30% reduction in pain intensity, but no better than 50%. This study concluded that it should not be used as a first-line treatment but may be used if other topicals have failed or are contra-indicated.[15]

Topical Lidocaine: Prescription-strength topical lidocaine has also been shown to reduce neuropathic pain. Lidocaine blocks voltage-gaited sodium channels and reduces the pain transduction. One study compared lidocaine 5% medicated plaster patch directly with an oral standard of care, pregabalin 2x a day. The study concluded that with diabetic PN, the efficacy was comparable between the two. However, the lidocaine plaster patch showed a better safety profile as well as greater patient satisfaction.[16]

Compound Creams: Prescription compound creams are a combination of 2 or more forms of a topical agent. Compounding creams are an age-old pharmaceutical practice. The purpose of compounding is to provide patients with relief without the side effects of systemic oral medications. Topicals often have less risk of abuse as well.[17] Topical compounded medications for managing PN pain provide an anti-inflammatory medication, a tricyclic antidepressant and/or an anticonvulsant. Although they seem to be effective, more studies are needed.[18]

Cannabidiol Cream/Ointments: As multiple states have moved to legalize medical marijuana, studies with cannabidiol (CBD) oil and creams are ramping up. A recent study published in *Current Pharmaceutical Biotechnology* examined the effectiveness of topical CBD oil for relief of PN symptoms in the lower extremities. The study used a product containing 250 mg CBD/3 fl oz, and found a reduction in intense pain, sharp

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pain, and cold and itchy sensations.[19] CBD products have been shown to be cost effective and thought to have decreased side effects compared to pharmaceutical treatments. Several clinical trials are already underway in the United States: according to ClinicalTrials.Gov, 13 trials are recruiting and 2 more are preparing to recruit.

Pharmaceutical Medications: Over-the-Counter Medications

OTC oral medications include acetaminophen and several other well-known non-steroidal anti-inflammatory drugs (NSAIDS). NSAIDS reduce pain through decreasing the body's production of prostaglandin, an enzyme that sends pain messages to the brain. These are often used as a first-line option in patients with painful neuropathy. Acetaminophen is used for mild to moderate pain relief and to reduce inflammation. Common NSAIDS include aspirin, ibuprofen, and naproxen sodium.

Pharmaceutical Medications: Prescription Strength Medications

When OTC medications fail, prescription-strength medications may be used. FDA-approved treatments include duloxetine and pregabalin. Other prescribed medications include tricyclic medications, gabapentin, and tramadol.

Duloxetine: This antidepressant is FDA-approved for diabetic neuropathy. Research shows that it is effective in short-term studies (up to 8 weeks). It has been shown that 60 mg a day is both safe and effective. However, it should be avoided in patients with hepatic and renal impairment.[20] Several authors acknowledge that long-term evaluation is still needed.[21]

Gabapentin and Pregabalin: Gabapentin and pregabalin are antiseizure medications. Gabapentin may be taken with tricyclic antidepressants or duloxetine. In a head-to-head randomized controlled study that compared gabapentin and duloxetine, both were shown to be equally effective. While duloxetine had fewer side effects, gabapentin users reported pain relief was faster.[22]

Tricyclic Antidepressants: This class includes amitriptyline, nortriptyline, and desipramine. These have been shown to be superior to placebo. However, further studies are needed to compare efficacy. Amitriptyline and desipramine are commonly used.[23]

NSAIDS reduce pain through decreasing the body's production of prostaglandin, an enzyme that sends pain messages to the brain.

Other: Metanx® (Pamlab LLC, Covington, LA), a prescription medical food product/supplement, is specially formulated to meet the distinctive nutritional requirements for diabetic peripheral neuropathy and can only be used under the supervision of a physician for the clinical dietary management of this condition.[24] In a 24-week randomized trial of 214 patients with type 2 diabetes and neuropathy, the product was shown to alleviate peripheral neuropathic pain.[25] Metanx is a capsule made up of L-methyl folate calcium and other B vitamins that allows the body to address the symptoms of diabetic nerve damage by improving blood flow to help with nerve repair. Although shown to be effective in short-term treatment, long-term studies are still necessary.

Other Treatment Modalities

Many of today's patients are open to alternative pain-relief options. These can include focused ultrasound, TENS, lasers, and physical therapy.

Focused ultrasound therapy is an emerging therapeutic modality for a host of neurologic diseases. This non-invasive therapy is FDA-approved for unilateral treatment of essential tremor and clinical studies are underway in Parkinson's and chronic pain. Studies have shown that it temporarily blocks conduction of in vitro sural nerves and thereby modulates diabetic blood vessels, improves pain symptoms, and decreases neuropathic progression.[26]

TENS is used for pain control for both acute and chronic pain caused by myriad conditions. A TENS unit is a small device that delivers electrical pulses to stimulate nerve fibers at the point where pain is perceived and works by dampening the pain signals to the brain. A randomized controlled trial involving 31 participants showed that 15 of 18 (83%) patients receiving TENS had significantly improved pain scores (reduction from 3.17 to 1.44 on a 5-point scale; $P < 0.01$) versus 5 of 13 (38%) patients receiving sham treatments (reduction from 2.98 to 2.38). Although research is still not definitive, it has been shown to provide some relief in neuropathic pain.[27]

Laser therapy provides a non-invasive treatment. In this treatment, a low-level laser is used to irradiate the plantar and dorsal aspect of the foot. In one study of 19 patients with DPN, laser therapy demonstrated a significant decrease in the Visual Analogue Scale (VAS) pain scale—6.47 ± 0.84 to 1.21 ± 0.78 ($P < 0.001$).[28] The authors hypothesized that the decrease in pain was due to an increase in microcirculation in the periphery or the release of cytokines which cause vasodilation and new capillaries.

Physical therapy modalities have also been shown to be effective, as strength training can improve muscle function leading to decreased pain. Regular exercise can help to better control blood sugar and delay progression of neuropathic pain as well. However, some diabetic patients may have limitations in performing physical exercise, which is why multiple alternative treatments are necessary.[29,30]

Conclusion

Peripheral neuropathy is an all-too-common long-term complication of diabetes. Improving blood glucose control is a first line of defense, but long-standing diabetes is notoriously difficult to control. While long-term studies are still needed to determine which treatments are most efficacious, today's patients have a multitude of treatment options for pain reduction. Clinicians are advised to understand each patient's pain experience and offer appropriately customized therapy options. ler

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Inventor's CORNER

BioSensics' Wearable Technology Supports Aging in Place

In 2007, wearable sensor technology was just gaining traction. Applications (known as apps) largely focused on fitness and wellness, measuring things like numbers of steps and hours of sleep. However, Ashkan Vaziri, Ph.D., and a few friends had an idea for a different approach: They believed that wearable sensors with medical applications could help older adults remain independent as they age.

"The need was very clear," said Vaziri, "because society is aging, and a lot of people are living longer." The friends, then all scientists at Harvard University, started a company called BioSensics to execute their vision for technology to help older adults maintain their independence.

More than a decade later, the company's success — spurred by National Institute on Aging (NIA) and National Institutes of Health Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) funding — has led electronics retailer Best Buy to acquire a portion of BioSensics' assets. But BioSensics isn't about to slow down now.

From Idea to Reality

Back in 2007, one of the new company's first projects was the development of a sensor to detect falls. Every year, more than one in four older adults has a fall, but estimates indicate that less than half tell their doctor. In addition, each year, 3 million older adults are treated in emergency rooms for fall injuries. These injuries can result in disability and reduced quality of life.

Someone who has fallen once is at higher risk of falling again. Fear of falling can lead older adults to be less physically and socially active.

A wearable device that can detect falls could help older adults get help faster and more reliably. If the device could gather data on how people move, Vaziri's team thought, it might also be able to help predict who is at risk of falling. But there were obstacles to overcome, including minimizing false alarms and undetected falls, which had been pitfalls for other medical alert devices.

BioDigit Home, developed by BioSensics, collects data from wearable sensors, mobile applications, and other digital technologies at a patient's home — all in one place.

Armed with pilot data to demonstrate the idea's feasibility, BioSensics applied for and received Phase I small business funding from NIA to develop the algorithms and technology. Later, a Phase II award — and a collaboration with Baylor College of Medicine, the University of Arizona, and Partners Healthcare — enabled the company to test its sensor in real-world settings.

"From that project, we developed one of the world's largest databases gathered from older adults in their home environments," said Vaziri, who is now BioSensics' chief executive officer. The company used the data to improve its solutions and algorithms to detect as many falls as possible while avoiding false alarms.

With subsequent Phase IIB awards in collaboration with Baylor College of Medicine, BioSensics added capabilities and features aimed at improving usability — and commercial potential. BioSensics also conducted additional clinical studies to further validate its algorithms.

NIA's support boosted the company's credibility. "NIA funding shows that the scientific

Inventor's Corner is a new occasional feature that highlights the development of products relevant to LER readers. Our goal is to highlight the inherent creativity and perseverance of the inventors in their product development journey. To nominate a product for consideration, please complete the Inventor's Corner Nomination Form.

Continued on page 54

Continued from page 53

rationale behind your technology and efforts has been validated," Vaziri said. "It was definitely helpful in our conversations with our partners, and it played acritical role in our commercialization success."

A Focus on Commercialization

Commercialization was a goal for BioSensics' technology from the beginning. Figuring out how it could get into the market — for example, through engaging licensing partners or by selling directly to consumers — helped the company make concrete, detailed plans and timelines, Vaziri said.

The company also kept users in mind when designing and refining the technology. For example, the wearable sensor monitors activity, not just events like falls, making the technology more engaging for users. The sensor was also designed to have a long battery life, making it more user-friendly and improving user experience and adoption. These additional consumer-oriented features helped set it apart from other products on the market.

BioSensics successfully secured multiple licensing partnerships that helped deploy its technology to thousands of users. In 2018, Best Buy acquired one of those licensing partners, GreatCall, Inc., and in August 2019, Best Buy acquired BioSensics' predictive health care technology business.

"That's a great success story for our team," Vaziri said. "This acquisition can significantly increase the impact of the technologies that we developed."

Keys to Small Business Funding Success

In addition to funding from NIA, BioSensics has obtained support for various projects from multiple NIH Institutes. Vaziri credits the company's success in part to careful preparation before applying for grants. He suggests that applicants make sure that their idea and their application align with the current focus of the Institute they are targeting, review any special funding announcements released by the NIH Institutes and Centers, and reach out to program officers to discuss their proposal before applying.

Ashkan Vaziri, Ph.D., chief executive officer of BioSensics.

Having the right team is also critical. Applicants should try to collaborate with leading institutions in their subject area, Vaziri said. And when the preparation is done? "Put a solid application together and submit it —and be a bit patient."

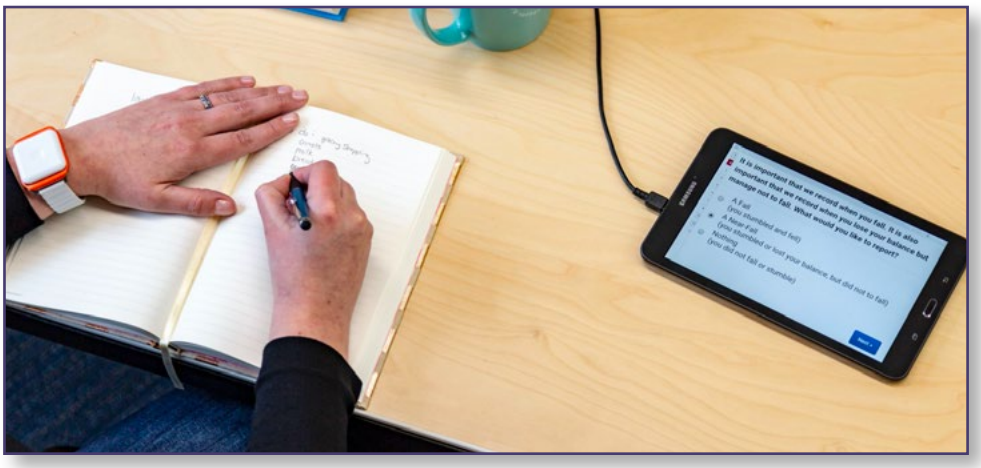
Taking on New Challenges

The fall detection technology was one of BioSensics' first ideas. But the company hasn't limited its focus to falls. With early-stage investment from NIA and other NIH Institutes, BioSensics has been able to pursue innovative ideas in a variety of areas. NIA has supported the company's development of a wearable technology for measuring frailty in older adults, a game-based exercise program that chronic kidney disease patients can use while receiving hemodialysis, and a method to assess the risk of bone fracture.

With BioSensics' most recent NIA SBIR award, the company is creating a platform to help caregivers and medical professionals better manage care for older adults. The team is also working on sensors to continuously monitor cognitive function, technology that could help detect dementia and neurodegenerative diseases. One goal is to identify disease onset or changes in disease state early on, when interventions could be most effective.

Although the technologies are still early in research and development, Vaziri said commercialization remains a key goal. "We want to have the technology available to the market by the end of the small business award."

That way, the company's new ideas can start making an impact in people's lives. "As scientists and entrepreneurs, that's one of the things you like to see — how many people have benefited from what you've created," Vaziri said.



BioDigit Home, developed by BioSensics, collects data from wearable sensors, mobile applications, and other digital technologies at a patient's home — all in one place.

With NIA's SBIR and STTR funding to help BioSensics lay the groundwork for success, the company is striving to make that goal a reality.

Could SBIR or STTR funding help you translate your idea into impact? Learn more about bringing innovations to market with support from NIA's small business programs (https://www.nia.nih.gov/research/osbr).

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MEDIUM		9-11	8.5-10	
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New & Noteworthy

Noteworthy products, association news, and market updates

WARM SERIES INSOLES: NEVER GET COLD FEET AGAIN

Warm Series insoles from Digitsole are the first connected heated insoles designed to keep feet warm. The dedicated application, available on iOS and Android, allows users to connect their insoles to their smartphones via Bluetooth and regulate the temperature inside shoes, between 20°C to 45°C/68°F to 113°F. The insoles are suitable for a variety of cold-weather activities. Warm Series insoles can also provide relief for people with blood circulation disorders or Raynaud's disease. They are recommended by the American Raynaud's Association. As an added feature, if the user is inactive, the insoles will stop heating. They will be reactivated once movement results. Additionally, built-in sensors provide activity tracking. These Digitsole insoles are made with antibacterial fabric and are water resistant. They provide strong arch support, a block-heel system to prevent ankle movement, and foot stability while facilitating movement.

Digitsole
digitsole.com

ASU TEAM CREATES SOFT, ROBOTIC AFO

Most ankle-foot orthoses (AFOs) are stiff and uncomfortable, so a team of student researchers at Arizona State University (ASU)—Marielle Debeurre, Tiffany Hertzell, and Carly Thalman—has been working to create a dynamic, soft robotic AFO, or SR-AFO, that assists with gait rehabilitation by adjusting itself with each step. Their prototype uses 2 groups of soft inflatable actuators that actively adapt to the patient while they are using the device. One set of actuators braces the leg while the other assists with push-off during motion.

Thalman started the project during her first year as a systems engineering doctoral student in spring 2018. She began the AFO project by developing, modeling, and creating the fabric-based contracting actuator. The design was originally developed to help individuals with foot drop. Her fabric actuator design helped users achieve multiple degrees of freedom for ankle mobility. She went on to improve supportive actuators for lateral buckling prevention.

A soft, robotic AFO designed to assist with foot and ankle rehabilitation. The project was awarded the top prize at the WearRA Innovation Challenge earlier this year.

"Soft robotics are more innovative because they are lighter weight, comfortable for the user, inexpensive, and can still achieve the motions and force outputs of rigid robotics," said Hertzell.

Future directions for this project involve investigating more advanced methods of gait detection to allow the SR-AFO to easily adapt to the user's needs. Examples include assisting the ankle in various directions for increased support and encouraging fast, more fluid walking patterns. The idea is for the SR-AFO to easily adapt to any type of impairment with little adjustment and be comfortably worn during rehabilitation, like a piece of clothing.

ADAPTTECH INTRODUCES THE INSIGHT SYSTEM

INSIGHT from Adapttech is now available in North America through Cascade Orthopedic Supply. The system is designed to improve the socket fitting process involved with lower-limb prostheses. INSIGHT combines a 3D scanner, sensors, wearable technology, and a mobile app to make it faster and easier to reach a comfortably fitting prosthesis and monitor a patient's rehabilitation process. The scanner creates a 3D model of the inner surface of the socket in less than 90 seconds. The wearable device uses sensors to gather real-time data between the residual limb and the socket. The mobile app shows the clinician where issues are occurring in the 3D model, and also allows results to be registered and assessed at any time and in any place. With INSIGHT, prosthetists can anticipate and finalize changes to the socket from the first visit.

Adapttech Ltd.
800/888-0865 (Cascade Orthopedic Supply)
www.adapttech.eu

CORD-FREE, BLUETOOTH-ENABLED IN-SHOE PRESSURE MAPPING SYSTEM

Tekscan has introduced the F-Scan64, an easy-to-use wireless in-shoe pressure mapping system with a quick setup configuration that is designed for clinicians and clinical researchers seeking a simple and fast in-shoe gait analysis solution. Featuring quick-connect, Bluetooth-enabled data acquisition electronics, F-Scan64 allows for natural gait data collection free from cords and restrictions of movement. The device features an ultra-thin (0.3 mm) and flexible pressure-sensing array of 64 sensing points that fits within the patient's shoe. The sensors are connected to data-acquisition electronics that collect pressure data onto a device worn by the patient for analysis after data collection or transmitted wirelessly to a PC software program. The software captures pressure, force, and temporal gait data, while also providing users access to the raw data for analysis. F-Scan64 comes with 6 different sized sensors to fit most adult footwear.

Tekscan
617/464-4500
tekscan.com/f-scan64

PODIATRYINTERNATIONAL LAUNCHES NEWS WEBSITE

PodiatryInternational has launched a dedicated news website to support and promote podiatrists and foot care professionals so they can grow and advance their practices and businesses through increasing awareness of the profession and developing greater global access to new advances and technology within the profession. The intent was to develop an avenue to the most respected and extensive resources in foot care and to ensure all have access to the latest techniques, research, technology, statements, initiatives, and products. The website also offers a forum to connect with others in the profession worldwide and a platform for listing podiatry jobs and internships globally.

To access the website, visit www.podiatry-international.com.

MOTUS SMART DIABETIC FOOT STABILIZATION AND OFFLOADING SYSTEM

According to the 2019 International Working Group on the Diabetic Foot (IWGDF) guidelines, the preferred treatment for neuropathic foot ulcers is a non-removable knee-high offloading device, either a total contact cast (TCC) or a removable walker rendered (by the provider fitting it) irremovable. Motus Smart Powered by Sensoria is the first smart footwear system to meet that criteria and provide Remote Patient Monitoring (RPM), quantified patient adherence, and activity data. When made non-removable, efficacy is on par with the TCC. The RPM system is comprised of proprietary hardware sensors and software to monitor patient adherence to offloading and patient activity, Sensoria Core microelectronics: 9-axis IMU, dedicated mobile application, and a clinician dashboard providing a more meaningful patient-clinician interaction and potential escalation of care (i.e., the clinician is able to make the boot non-removable). Motus Smart L-Code 4386 PDAC verified and reimbursable. It is a Class one FDA-registered medical device.

Sensoria Health
sensoriahealth.com
425/533-2928

HIGH SCHOOLER CREATES APP TO HELP REDUCE RISK OF ACL INJURIES IN SCHOOL-AGED ATHLETES

Research has proven that participation in stretching courses can reduce the possibility of an anterior cruciate ligament (ACL) injury in play by about 72%. After implementing these stretching courses at many Chicago, Illinois, public schools in basketball and soccer, researchers found participation in them during warm-ups reduced ACL tears by 80%, knee sprains by 70%, and ankle sprains by 62%. Toward this end, Maya Malackowski, a high school student and volleyball player in the Chicago area, sought to create a solution to offer stretching exercises outside of school courses, thus making them more widely available.

The result is MayaVate, a free web-based mobile training and conditioning application designed to reduce the risk of ACL injuries in school-aged athletes. The program is comprised of static and dynamic plyometric training exercises to increase mobility and stability of the knee. Players are taught to self-train, and incentives are provided for successful, repeated use of the program. The instructional video application teaches athletes not only how to stretch their ACL correctly but also helps to motivate them to stretch every time before practice or play. Making the video into a mobile application means the exercises will be more accessible to a broader range of children and will be a fun way to complete the stretches. Additionally, MayaVate is working to

spread awareness of ACL injuries in adolescent volleyball play by making the exercises something that teams and individuals want to participate in.

"As a volleyball player, I have found that ACL injuries can be career-changing and can be reduced by simply stretching before practice or play," said Maya. "MayaVate makes stretching something fun and that you want to accomplish and be a part of."

The application exercises are based on a program developed and shared by the Santa Monica Institute of Sports Medicine to help spread awareness and reduce the risk of knee injuries in sports.

To utilize this free application, visit app.mayavate.com.

SKINEEZ HYDRATING COMPRESSION SOCKS

Skineez Skin-Reparative Hydrating Compression Socks are the only gradient 10–20 mmHg mild-moderate compression, hydrating socks on the market. They are infused with 5 key healthy ingredients that hydrate and repair the skin. In clinical trials 80% saw softer, firmer skin in just 1 hour, and 100% felt this was the most comfortable sock they had ever worn. This patented product delivers 24-hour hydration. The socks are made from moisture wicking fibers and are 100% latex free. They are great for people who stand or sit for long periods of time, as they are designed to help reduce swelling and increase circulation. After the first 10 washes, use the Skineez's patented Garment Replenishing Spray (sold separately) to reinfuse the socks. Simply wash, turn inside out, spray, and allow to dry. The socks are ready to deliver hydrating, protecting benefits for another 10 washes. Doctor recommended. NDC-coded with skin protectant.

Skineez
978/261-5326
www.myskineez.com

HANGER ANNOUNCES EXECUTIVE APPOINTMENTS

Hanger, Austin, Texas, announced that Regina Weger has been promoted to president, products & services, and Pete Stoy will join Hanger in the newly formed position of chief operating officer (COO), to lead the patient care segment.

Weger joined Hanger's national provider of orthotics and prosthetics (O&P) componentry distribution, Southern Prosthetic Supply (SPS), Alpharetta, Georgia, over 20 years ago. She assumed increasingly larger and more complex roles in customer service, marketing, sales, and operations, until she became SPS president in November 2019. As president of Hanger's Products & Services segment, Weger will now also oversee Hanger's Accelerated Care Plus (ACP) therapeutic solutions subsidiary. Together with SPS, these business units constitute over 17% of Hanger's revenue thus far in 2020. She will continue to serve on the Senior Leadership Team for Hanger.

Stoy brings nearly 20 years of healthcare experience to Hanger with leadership in large, complex organizations, and his designation as a Fellow of the American College of Healthcare Executives (FACHE). He has led large-scale commercial, operational, supply chain, and finance functions and is experienced with managing strategic relationships at the most senior levels in some of the country's largest integrated healthcare delivery systems. Stoy joins Hanger from the healthcare business of Sodexo, where he most recently served as East Region president, responsible for all operations, including thousands of provider and hospital-based support service employees.

PODIMETRICS SMARTMAT

Podimetrics is a virtual care management company dedicated to preventing diabetic amputations, one of the most debilitating and costly complications of diabetes. The company combines its FDA-cleared SmartMat with wraparound care management to spot early signs of diabetic foot complications weeks before they usually would present clinically. By combining cutting-edge technology with best-in-class care management, Podimetrics earns high engagement rates from patients, and allows clinicians to achieve unparalleled outcomes saving limbs, lives, and money, keeping vulnerable populations healthy at home.

Podimetrics
podimetrics.com

FIRST-IN-HUMAN TRIAL COMPLETED FOR A NOVEL TREATMENT FOR OSTEOPOROSIS

Haoma Medica, London, England, announced the completion of a first-in-human trial for NaQuinate, a naphthoquinone carboxylic acid, which is being developed as a novel orally administered therapeutic for osteoporosis. The first-in-human trial initiated last year in healthy adults studied single and multiple doses of the drug. The primary objective was to assess the safety, tolerability, and pharmacokinetics.

"There were no significant safety or

tolerability concerns up to the highest doses tested which underlines our expectation that NaQuinate is safe and well tolerated," said Dr. Cenk Oguz, Haoma Medica's chief medical officer.

AFO PUTS SPRING-CAM BACK INTO STROKE PATIENTS' STEPS

A research group from Tohoku University in Japan has developed a new, lightweight and motor-less device to aid stroke patients in their rehabilitation, improving their gait, and preventing falls. The new device can be easily attached to an ankle-foot orthosis (AFO).

A light weight and motor-less spring-cam attached to an AFO provides stroke patients with greater push-off power, stabilizing their walking, and reducing falls. Image courtesy of Tohoku University.

Stroke patients often suffer from motor paralysis as a result of damage to the brain, significantly affecting their walking. Gait disorder results in restrictive disabilities and increased healthcare costs. Rehabilitation is key to stroke recovery. Yet around 40% of stroke patients struggle to function properly due to problems with their walking abilities. One part of the problem is due to insufficient knee flexion during walking. This leads to lower toe clearance and causes patients to fall. To overcome this, patients frequently hip hike on the affected side to move their foot, thus creating an awkward movement.

To help this population, the research group—comprised of Professor Shin-Ichi Izumi, MD, PhD, and Associate Professor Dai Owaki, PhD, from Tohoku University's Graduate School of Medicine and Graduate School of Engineering, along with Takeo Nozaki and Dr. Ken-ichiro Fukushi from NEC Corporation, Tokyo, Japan—created a device that gives the ankle greater push-off power using a spring-cam mechanism. The elliptical shaped cam rotates in conjunction with the AFO, pushing against the spring. The resultant reactive force from the spring generates significant ankle push-off power.

The research group conducted clinical experiments on 11 stroke patients with paralysis on one side of the body, demonstrating that the device generated greater ankle power. This in turn aided knee flexion while the affected foot was in the swing phase of walking.

"Our device will pave the way for positive impacts on the rehabilitation of stroke patients," said Owaki. "It will prevent falls and make patients feel more confident in their walking abilities."

AETREX NEXT-GEN 3D FOOT SCANNING SYSTEM

Aetrex has launched the Albert 2, the company's next-generation intelligent 3D foot scanning technology; it will be available to retailers in February 2021. This system is engineered to help customers find the right-fitting footwear and orthotics and provide an enhanced customer experience at retail. The quick, easy-to-use, 2-foot-at-once scanning process takes 20 seconds or less and can capture static and dynamic pressure as well as 3D measurements of the foot. The data is then used to help customers find the best-fitting footwear or orthotics on the first try; the proprietary FitHQ software syncs to retailers' point-of-sale systems to suggest the best footwear by brand, style, and size. The lifelike, 3D-animated Albert character guides users through the scanning process, while also responding to voice commands. The data can then be sent via email, allowing users to access their information after they leave the store.

Aetrex
888/526-2739
aetrex.com

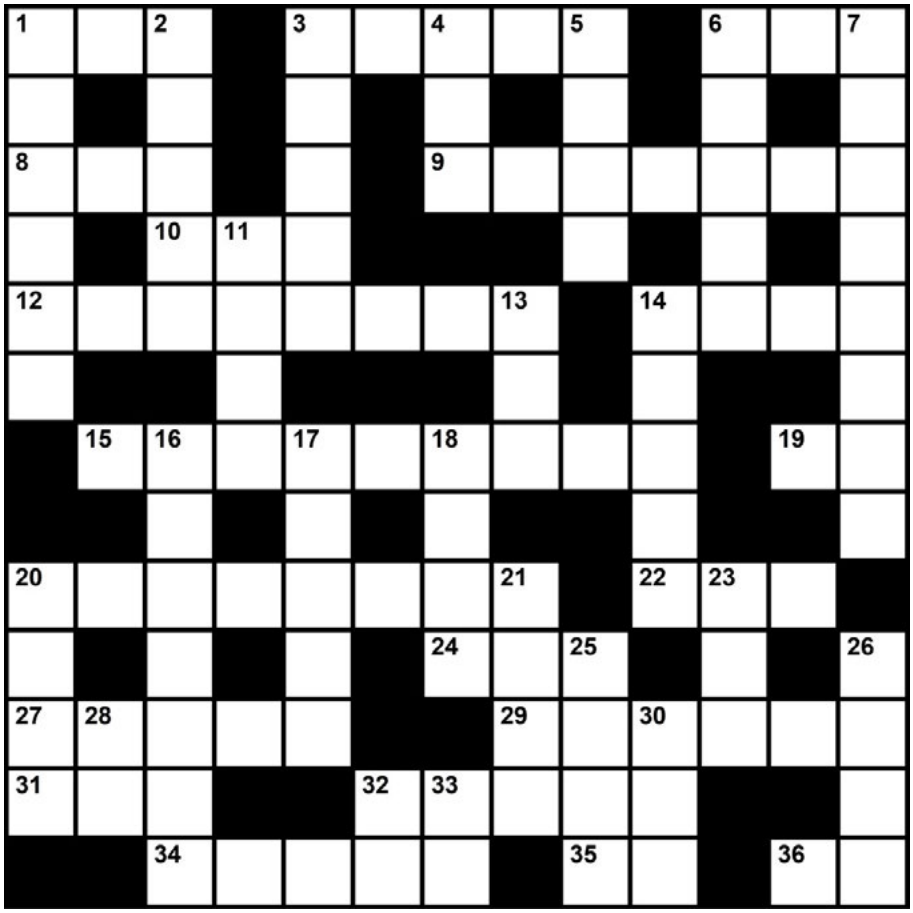
REVOFLEX DORSIFLEXION AFO

RevoFlex by Click Medical is an AFO solution for safely progressing a patient through therapy. The dorsiflexion kit can be easily fabricated into plastic-hinged AFOs to give on-demand support while enabling patients to safely dial in when fatigued or in unstable situations. With this orthotic solution, the patient can tune their progressive tension levels to safely and independently dial in optimal support and increase their mobility faster. RevoFlex allows muscle development by reducing device dependence and enabling progression toward full range of motion, thus reducing the risk of re-injury. Using 1 adjustable device to progress patients through therapy eliminates the cost of multiple fabrications and refitting appointments. The powerful dial provides patients with limited strength and/or dexterity to effectively adjust the device. With RevoFlex, practitioners can create AFOs that work for patients, not against them.

Click Medical
970/670-7012
clickmedical.co

How Well Did You Read This Issue?

Test your knowledge of information from this issue of *Lower Extremity Review* and the world in general with our crossword puzzle feature. The answer box can be found online at lermagazine.com.



ACROSS

1 Cerebrovascular disease, abbr.
3 Geriatrician's study
6 French for yes
8 Employ
9 Nerve which is the largest branch of the lumbosacral plexus
10 Sports org where ACL tears are quite common
12 Type of gait abnormality
14 Tibia or fibula
15 Nerve that supplies the adductors of the thigh
19 Two-fold
20 Complex condition that can have significant impact on independent ambulation, 2 words
22 Trauma centers, abbr.
24 Short sleep
27 One requesting something
29 Lower region of the back
31 Informal wear
32 One of these a day keeps the doctor away, in a saying
34 _____flexion: backward bending and contracting of the hand or foot
35 Lane, abbr.
36 Raise

DOWN

1 Vertebrae in the tail area
2 Chemical that causes a reaction
3 _____ skeleton
4 Passports, for example
5 Manner of walking
6 Prefix with -pedic
7 Local anemia in a body part
11 Angler's lure
13 Type of imaging scan
14 Guillain-_____ syndrome
16 Stopped from flowing, as a nerve channel
17 Anesthetized
18 Neural transmitter
20 ____ foot, having an arch that is lower than usual
21 Explore by touch
23 Massage
25 Apply force towards
26 Clutch tightly
28 Compass direction, abbr.
30 Broad demographic
32 Good grades in exams
33 Circle ratio

CROSSWORD BY MYLES MELLOR

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