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LOWER EXTREMITY REVIEW

August 23 / volume 15 / number 8

Mitigating Post-Operative Swelling

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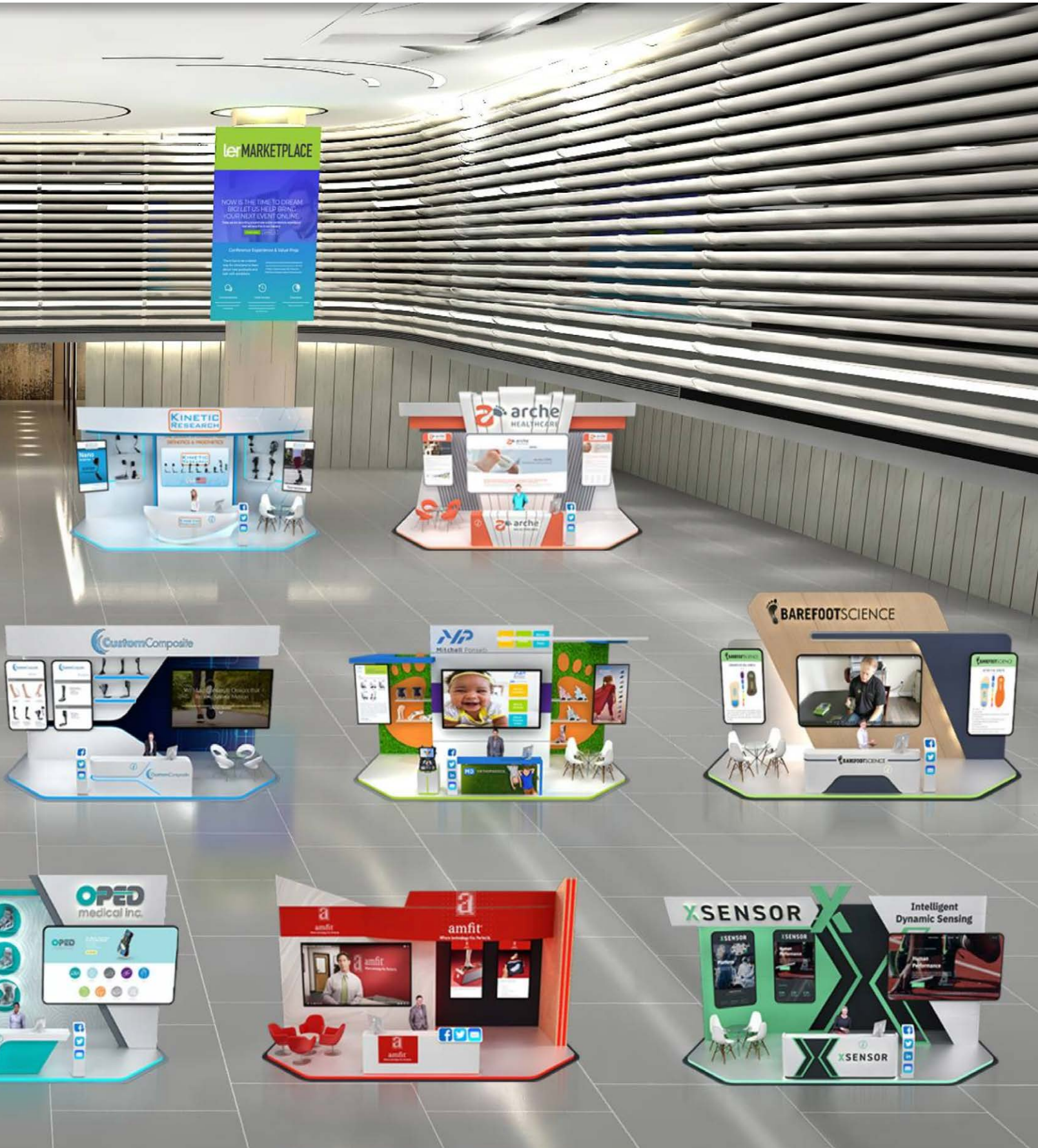

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Lower Extremity Review

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

Subscriptions may be obtained for $38 domestic and $72 international by writing to: LER, PO Box 390418, Minneapolis, MN, 55439-0418. POSTMASTER: Please send address changes to LER, PO Box 390418, Minneapolis, MN, 55439-0418.

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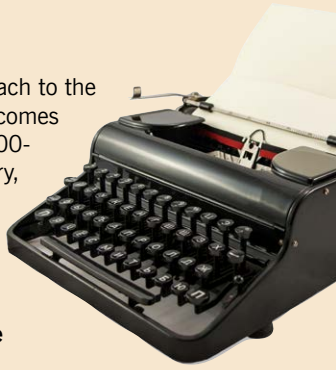

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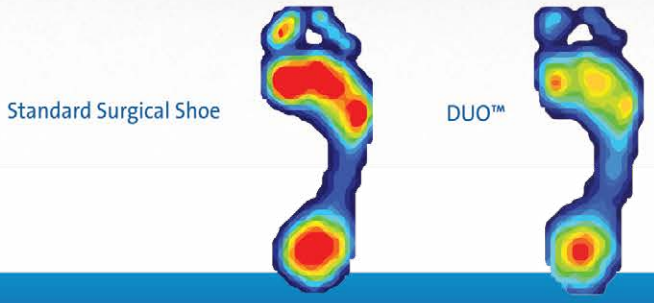

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Guest **Perspective**

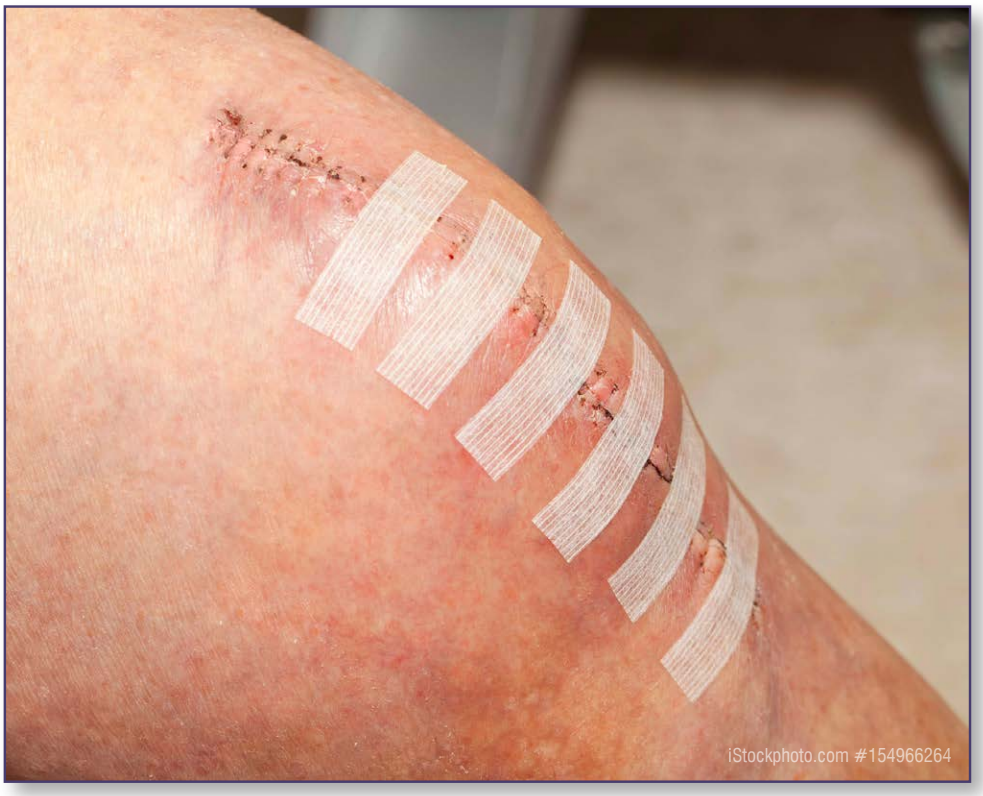
Addressing the Tsunami That Is To Come

By Matt Barber, MD

The article, "Mitigating the Post-operative Swelling Tsunami in Total Knee Arthroplasty: A Call to Action" (page 32) by Andrew Wickline and colleagues brings light to a very important topic and is likely to become one of the seminal works in this area.

Obviously, post-operative swelling is something that has been acknowledged for almost as long as surgery itself. Historically, this swelling has been known about and discussed primarily as an annoyance or something affecting patient satisfaction or pain. Their article helps to define this familiar sequalae as a common cause for many issues, and not just something that is noted alongside other complications. Their call to action is particularly important because it addresses post-operative swelling in the context of total knee arthroplasty (TKA) which is now the most common elective surgery performed in the United States. Indeed, they write that "over 1.025 million TKAs were performed in 2020 with estimated volumes growing to 3.4 million yearly TKAs by 2040."

With all of the specialization in today's healthcare/medicine sector, it is easy for us to think in silos. Difficulties and complications are considered to be in their own respective domains (especially if these issues tend to be treated by separate medical or surgical subspecialties) and as such, they are addressed and studied as separate entities. This article does much to break down those aforementioned silos and to identify the fact that swelling is not just seen in association with post-operative complications but may represent the underlying cause for many other complications. For example, failure to progress with therapy, deep vein thrombosis, dissatisfaction after surgery, chronic pain, and opioid use disorder may all have common roots in post-operative swelling.



Wickline et al do an excellent job of revisiting and explaining the basic science behind post-operative edema for those of us who may not have considered it in this level of detail in quite some time. They go on to further define how this condition can and should be quantified.

The authors present a proposed treatment/mitigation strategy. Their proposed strategies reference multiple other previously published works that deal with limiting swelling, inflammation, and bleeding. This algorithm may not end up being the definitive way that edema is addressed, but it proposes several strategies that are actionable for clinical practitioners. Ultimately, every listed strategy might not be practical in every practice or patient population, but they are very important in establishing a framework for further research and discussion.

Total knee arthroplasty is a tremendously important procedure. It relieves pain and restores mobility for millions of patients. Because of this, it has a massive impact on our country in terms of potentially lost work time, opioid consumption, repeat hospitalization for complications, and total healthcare spending. Limiting the complications of the TKA procedure, decreasing the complexity of the recovery, and returning patients to activity have enormous social and economic value. This article moves the field forward with 2 monumental steps: First, it defines—in a direct and comprehensive manner—a known, yet unaddressed, major challenge associated with the TKA surgical procedure. Second, it provides an array of evidence-based strategies for community clinicians to use to address the impending tsunami.

Matt Barber, MD, is an orthopedic surgeon who specializes in knee and hip replacement. He practices in Mobile, Alabama.

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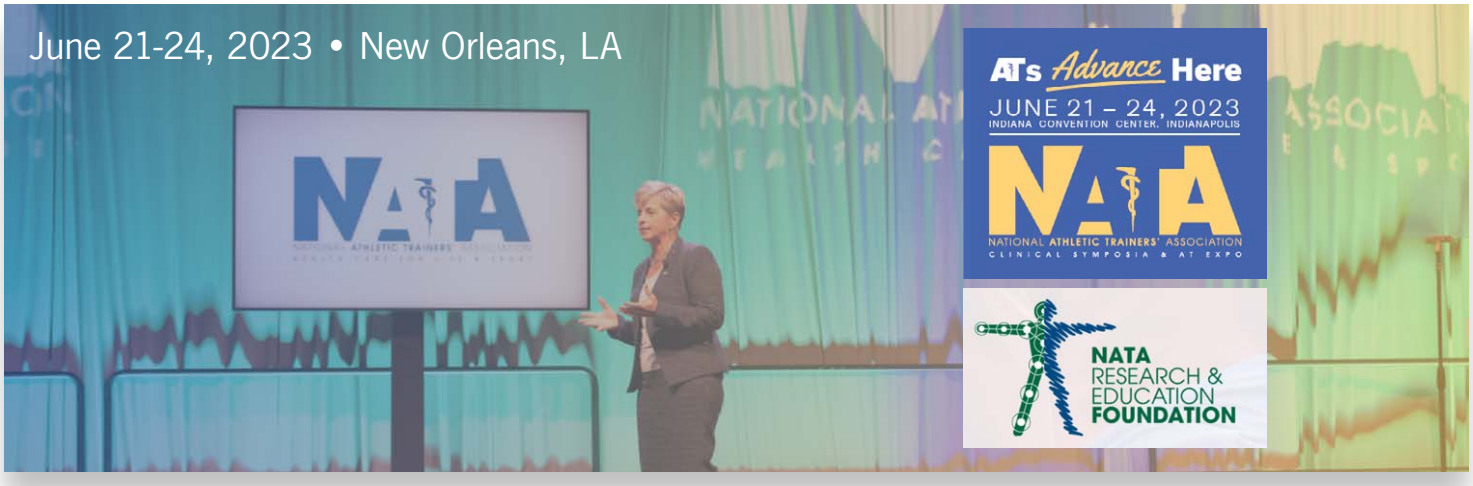

Meeting Highlights from the National Athletic Trainers' Association

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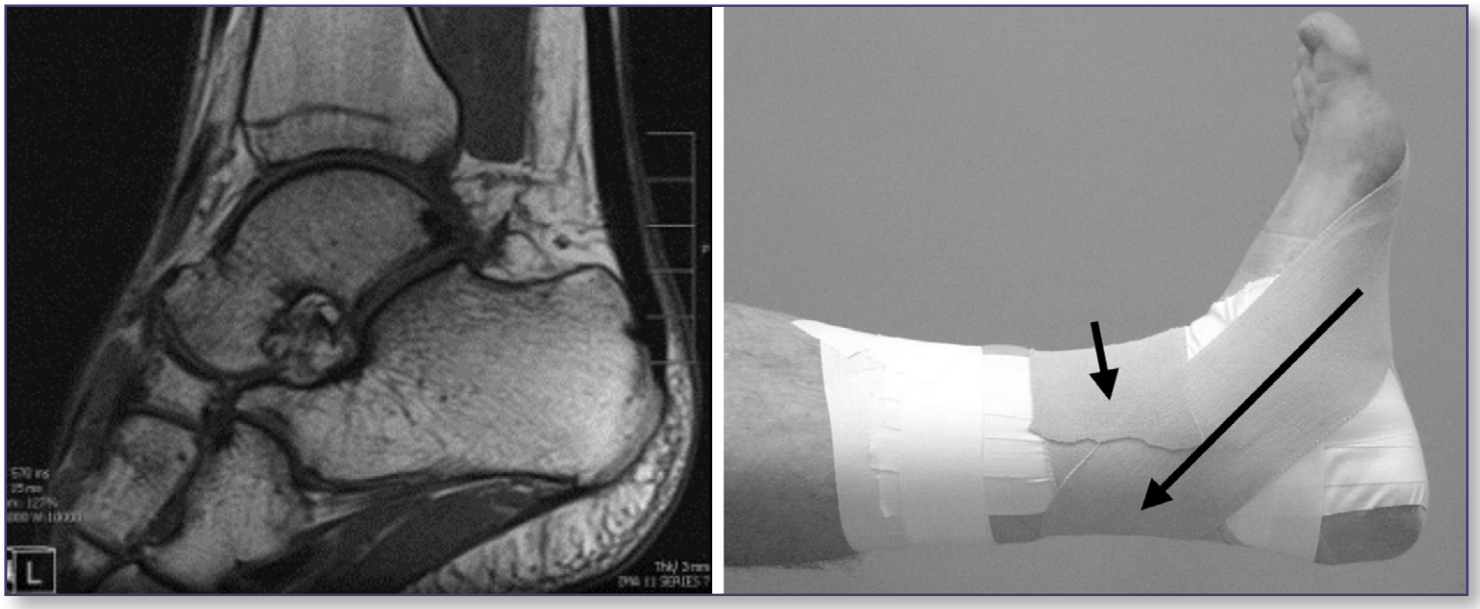

A CASE OF POSTERIOR ANKLE IMPINGEMENT IN A COLLEGIATE LEVEL SOCCER PLAYER

Background: Posterolateral ankle impingement typically presents as pain on the posterolateral aspect of the ankle that worsens with plantar flexion and passive or active great toe flexion. Typically, the condition is caused by repetitive low-grade trauma into plantar flexion. This is a type 3 case study on posterolateral ankle impingement in a collegiate soccer player.

Patient: The patient is a male collegiate soccer goalkeeper diagnosed with posterolateral ankle impingement. He initially complained of anterolateral ankle pain that moved into the posterolateral aspect of his leg during the fall season of 2020. The patient had an X-ray and MRI in 2020, at which time a peroneal resection was recommended. The patient also presented with Os trigonum. The patient underwent surgery in February of 2021 and completed rehabilitation that summer. The pain persisted, however, after being released.

Intervention & Treatment: Mid-September of 2021, the patient briefly found pain relief in noxious stimulation. In October 2021, the team physician diagnosed the injury as posterolateral ankle impingement. Rehabilitation consisted of strengthening both the gluteus maximus and medius, eccentric biased calf exercises and manual strengthening of the ankle. The eccentric exercises and manual strengthening exercises were performed with silicon cups on the working muscles. Additionally, a custom tape job was designed like a talar sling in combination with a reverse Achilles to reduce any symptoms the patient may have been experiencing. The athlete was also prescribed diclofenac by the team physician for pain and inflammation.

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Outcomes or Other Comparisons: Posterolateral ankle impingement is most common in dancers; however, we identified it in a soccer keeper as a result of excessive kicking. In 2018 about 27% of injuries from dance involved the ankle with over half of them being posterior ankle impingement syndrome or flexor hallucis longus tendinopathy (Rietveld et. al). The presence of Os trigonum may cause symptoms, however, the presence of the Os trigonum often remains asymptomatic.

In October 2021, the athlete opted for conservative treatment rather than surgical intervention. The athlete continued to rehabilitate through the spring of 2022. In September of 2022, the athlete decided to pursue surgery post-season to pursue a professional career but will continue conservative treatment to play in the fall of 2022 season.

Conclusions: This case of posterolateral ankle impingement presented with both anterolateral and posterolateral ankle pain and no pain with great toe flexion. Typically, there is no anterolateral ankle pain and there is also pain with passive and active great toe flexion. Treatment of previous cases typically included cortical steroid injections to continue play, whereas this case was treated with rehabilitation. There is no standardization to conservative treatment of posterolateral ankle impingement in athletes, so the rehabilitation was based on the patient's presentation.

Clinical Bottom Line: Although not as common, posterolateral ankle impingement can occur in any athletic population, not just dancers. Through properly taping the ankle to decrease the symptoms and properly rehabilitating the injury, posterolateral ankle impingement can be treated conservatively to enable the athlete to continue to play. It is important for clinicians to understand the extent of the injury and how best to rehabilitate it to decrease the symptoms. ler

Source: *Becker L, Stevenson P, Norkus SA: A Case of Posterior Ankle Impingement In a Collegiate Level Soccer Player: Type 3 Case Study. J Athl Train. 2023;58(6S):161. Used with permission; all rights reserved.*

WHEN AN ANKLE INJURY ISN'T JUST A SPRAIN

Background: A 13-year-old male athlete with no history of injuries, was playing in a middle school football game when he was tackled while running the ball and the opposing player landed on his left foot. He had immediate pain in his ankle and was unable to walk after the incident. He described a sharp pain on the medial aspect of his ankle and had swelling over this area as well. Upon initial exam there was notable swelling over the medial ankle, without bruising. TTP over the tibiotalar joint, also over the deltoid ligament distribution and the ATFL distribution. ROM was limited in all planes and strength was also limited in all planes. Negative bump test, negative anterior drawer, although this caused pain. Unable to ambulate. Sensation intact, distal pulses intact.

Differential Diagnosis: Triplane Ankle Fracture, Deltoid ligament tear, Pilon Fracture, Tibial Fracture, Maisonneuve fracture, Juvenile Tillaux fracture, ATFL Sprain

Intervention & Treatment: We were able to get the athlete seen by a Sports Medicine Physician the day following the injury. The physician was able to perform an exam with similar findings to the athletic trainer and sent the patient for a 3-view ankle X-ray and bilateral weight bearing X-rays of the ankle. Findings showed a Juvenile Tillaux fracture of the left distal tibial epiphysis and physis. The patient was recommended to be non-weight bearing and his case was discussed with a pediatric orthopedic surgeon who recommended getting a CT scan as well. The CT scan confirmed the X-ray findings of Juvenile Tillaux Fracture. The athlete was placed in a cast for 4 weeks, then was transitioned to a walking boot for 4 weeks. Following this he was able to start physical therapy and return to football specific exercises at 12 weeks.

Uniqueness: A Juvenile Tillaux fracture is a traumatic ankle injury in the pediatric population – a Salter-Harris III fracture of the anterolateral distal tibia epiphysis. This is usually seen in children that are nearing skeletal maturity, so in a slightly older age range around 12–14. This type of fracture is caused by an avulsion of the anterior inferior tibiofibular ligament. The typical mechanism of action for this injury is a supination-external rotation injury. Management depends on level of displacement, if there is less than 2mm of displacement it can be treated non-operatively; however if there are more than 2mm, then it will need surgery. This is a very rare injury, accounting for only 3%–5% of pediatric ankle fractures.

Conclusions: The 13-year-old male, middle school football athlete had an in-game injury to his left ankle. It was important that an athletic trainer was present even at this middle school event to provide an initial evaluation and get the athlete quickly in to see a Sports Medicine physician. This athlete had a difficult to diagnose ankle fracture at the growth plate that could have required surgery, making this a can't miss diagnosis. Growth plate injuries are common in this patient population and it's important to be able to distinguish between a possible fracture and an ankle sprain. ler

Source: *Gray PA. When an Ankle Injury Isn't Just a Sprain. J Athl Train. 2023;58(6S):163. Used with permission; all rights reserved.*

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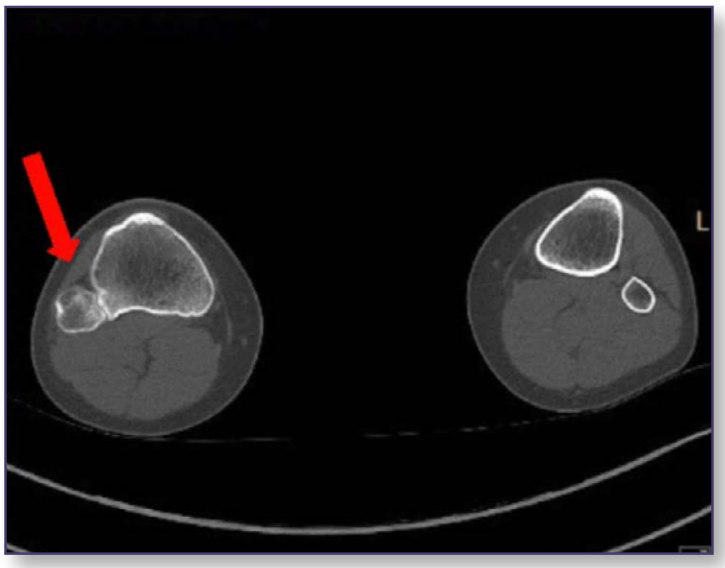
PROXIMAL TIBIOFIBULAR SYNOSTOSIS IN A FEMALE SOCCER ATHLETE



Background: Osteochondromas are the most prevalent benign bone tumor, occurring mostly in the long bones of the leg, thigh, and arm. Representing 20%–50% of benign tumors, osteochondromas are rarely symptomatic. Most symptomatic cases are linked to posttraumatic conditions or idiopathic causes. Although conservative management is recommended, surgical removal may be necessary for recalcitrant cases. This is a Type 3 clinical CASE study.

Patient: Patient is a 20-year-old female Division-3 soccer player who presented to her AT complaining of insidious onset right posterolateral knee pain. Past medical history of a right medial malleolus fracture, multiple ipsilateral inversion ankle sprains, bilateral medial tibial stress syndrome, and polycystic ovary syndrome. Patient was point tender over anterior tibialis and fibularis muscles, reported pain with active dorsiflexion and inversion, passive eversion, and pain without weakness during anterior tibialis and fibularis tertius MMT. Differential diagnoses included fibularis strain and anterior tibialis strain. After initial treatments failed, she was referred to the team physician 2-months after onset. Radiographs revealed increased bone density at the fibular head, indicative of a healing fracture. MRI confirmed diagnosis of a fibular head stress fracture. Patient was placed NWB in a walking boot for 8 weeks and began a rehabilitation program with her AT focused on pain modulation and general ankle and hip strengthening. Due to persistent pain, a CT scan and second MRI were ordered 7 months after initial onset. CT revealed a proximal tibiofibular synostosis secondary to an osteochondroma (figure).

Intervention & Treatment: Patient was given a tall walking boot to wear PRN and resumed rehabilitation as previously described. A cortisone injection within the interosseous space was administered 8 months after initial onset, however her pain persisted. Two months later she underwent a resection of the osteochondroma and neuroplasty of the common fibular nerve. Although outcomes for this type of surgery are generally positive, postoperatively the patient reported posterolateral knee pain and radiating pain into her foot despite continued therapeutic interventions including nerve desensitization therapy. Four months postoperatively she developed a foot drop and has since failed to make a full RTP.

Outcomes or Other Comparisons: In this case, the patient continued experiencing pain and developed foot drop postoperatively. Although fibular nerve lesions and symptomatic osteoarthritis are reported complications of surgery, resection of the fibular head is a commonly performed surgical technique for symptomatic proximal tibiofibular synostosis. Most of the previously documented cases are idiopathic, with no real causal events in the patient's medical history. Repetitive microtrauma is thought to be a possible mechanism for proximal tibiofibular synostosis in patients who do not report specific trauma, such as this case.

Conclusions: This case report presents the treatment of a proximal tibiofibular synostosis caused by an osteochondroma in a female soccer player. When symptomatic, the clinical presentation of osteochondromas may differ greatly, making accurate diagnosis difficult. As was the case with this patient, common symptoms include knee pain and pain with ankle dorsiflexion. Although diagnosis can be made through radiographs, this case highlights limitations of this imaging modality. CT or MRI are recommended for making a definitive diagnosis and for determining whether surgical intervention is necessary. Conservative treatment is recommended for patients with few symptoms, but surgical intervention is recommended when conservative treatment fails. The most common procedures include excision of the synostosis, arthrodesis of the proximal tibiofibular joint, and resection of the fibular head.

Clinical Bottom Line: While proximal tibiofibular synostosis caused by an osteochondroma is uncommon, clinicians should be aware of the potential causes, common clinical presentation, and diagnostic imaging required to make a definitive diagnosis. Often mistaken for muscle strains or sequelae of lateral ankle sprains, osteochondromas of the proximal tibia and fibula should be considered as a differential diagnosis in patients presenting with posterolateral knee or ankle pain.

Source: *Roth A, Bortz C, Wilkenfeld DA. Proximal Tibiofibular Synostosis in a Female Soccer Athlete. J Athl Train. 2023;58(6S):167.*

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EFFECT OF KINESIOLOGY TAPE ON MUSCLE ACTIVATION IN CHRONIC ANKLE INSTABILITY

Figure 1. Different ankle taping treatments: A) Kinesiology tape; B) athletic tape; C) sham tape; and D) no tape.

The purpose of the study was to determine the effect of kinesiology tape (KT) on lower limb muscle activation during computerized dynamic posturography (CDP) tasks and ankle kinesthesia in individuals with chronic ankle instability (CAI).

Thirty-five men with CAI participated in this study. The experimental procedure followed a repeated measures design. Muscle activation of lower extremity and ankle kinesthesia of participants were measured using four taping treatments, namely, KT, athletic tape (AT), sham tape (ST), and no tape (NT) in a randomized order. Muscle activation was assessed using surface electromyography (sEMG) synchronized with CDP tests from seven lower extremity muscles of the unstable limb. Ankle kinesthesia was measured by using a threshold to detect the passive motion direction of the unstable ankle. Parameters were analyzed by using a one-way repeated measures ANOVA and followed by pairwise comparisons with a Bonferroni correction.

No significant difference was observed among different taping treatments for the majority of parameters during CDP. Except for condition 4 with open eyes, sway-referenced surface, and fixed surround in the sensory organization test (SOT), gastrocnemius medialis root mean square (RMS) was 28.19% lower in AT compared with NT (P = 0.021, 95% CI = 0.002–0.039), while gastrocnemius lateralis RMS was 20.25% lower in AT compared with KT (P = 0.038, 95% CI = 0.000–0.021). In forward-small sudden translation from motor control test (MCT), for peroneal longus (PL), RMS was 24.04% lower in KT compared with ST (P = 0.036, 95% CI = 0.000–0.018). In toes-down sudden rotation from adaption test (ADT), for PL, RMS was 23.41% lower in AT compared with ST (P = 0.015, 95% CI = 0.002–0.027). In addition, no significant difference was observed for a threshold to the detection of passive motion direction among different taping treatments.

In conclusion, this study indicated that KT had minimal effect on the muscle activation of the unstable lower limb during static stance, self-initiated, and externally triggered perturbation tasks from CDP and ankle kinesthesia among individuals with CAI, suggesting that the benefit of KT was too small to be clinically worthwhile during application for CAI. (ler)

Source: *Yin L, Liu K, Liu C, Feng X, Wang L. Effect of Kinesiology Tape on Muscle Activation of Lower Extremity and Ankle Kinesthesia in Individuals With Unilateral Chronic Ankle Instability. Front. Physiol. 2023;12:786584. doi: 10.3389/fphys.2021.786584*

USING RESISTANCE BANDS IN PRACTICE APPEARS TO IMPROVE KICK PERFORMANCE

In a study out of Norway, researchers examined whether kicking with elastic resistance during warm-up could initiate postactivation potentiation (PAP), and thereby positively influence kinematics and performance on subsequent explosive roundhouse kicking. Five women and 11 men (n = 16) with a background in kickboxing (n = 10) or taekwondo (n =6) performed 2 warm-up strategies with 3 subsequent test kicks 5-8 minutes after a PAP-inducing exercise. Kicking performance, de-

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fined as roundhouse kicking velocity with the foot, was measured using 3D motion capture (500 Hz) with a 15 marker lower-body 3D model. In addition, electromyography of the prime movers—vastus lateralis, vastus medialis, and rectus femoris muscles—was measured to confirm the presence of PAP.

The team found that kicking velocity of the foot increased by 3.3% after performing a warming-up strategy including kicking with elastic resistance ($P = 0.009$, $\eta = 0.32$) in this group of trained martial arts practitioners. Increased muscle activity was recorded in vastus medialis (35.2%, $P = 0.05$, $\eta = 0.18$) and rectus femoris (43.9%, $P = 0.04$, $\eta = 0.20$). The researchers concluded that these findings indicate that performing a warm-up strategy including kicking with elastic resistance can have a positive effect on kicking performance in a roundhouse kick and could be a beneficial addition to a precompetition warm-up protocol. (ler)

Source: *Aandahl HS, Von Heimburg E, Van den Tillaar R. Effect of postactivation potentiation induced by elastic resistance on kinematics and performance in a roundhouse kick of trained martial arts practitioners. J Strength Cond Res. 2018;32(4): 990-996, 2018*

ADDING PLANTAR FLEXION RESISTANCE MAY IMPROVE VLU OUTCOMES

Venous or stasis ulcers account for 80% of leg ulcers, affect 1% of the population and contribute significantly to chronic wounds. They mostly develop along the medial distal part of the leg and can remain open for weeks or years, while are frequently recurrent. Women and older people tend to develop venous ulcers more frequently. Despite the low overall incidence, the refractory nature of these ulcers raises the risk of morbidity and mortality and has a significant negative impact on the quality of life of the patient.

Venous ulcers are recognized to be more painful and resistant to therapy than ulcers of other etiologies. Various methods have been used for the conservative treatment of venous ulcers, such as pulsed electromagnetic field (PEMF) and plantar exercise, which promote wound healing due to a range of physiological effects. This study aimed to examine the effect of combined pulsed electromagnetic field therapy and plantar flexion resistance exercise (PRE) on patients with venous leg ulcers (VLUs).

The study was a prospective, randomized controlled trial. A total of 60 patients between the ages of 40 and 55 with venous ulcers were randomly assigned to 1 of 3 groups. For up to 12 weeks, the first group received PEMF therapy and plantar flexion resistance exercise (PRE) therapy in addition to conservative ulcer treatment. The second group received only PEMF therapy in addition to conservative ulcer treatment, while the third group served as the control and received only conservative ulcer treatment.

At the 4-week follow-up, the 2 experimental groups revealed a

considerable variation in ulcer surface area (USA) and ulcer volume (UV), with no significant change in the control group. At the 12-week follow-up, there were significant differences between the 3 groups, while the PEMF+PRE group underwent the most significant changes, with mean differences at [95% confidence interval] of (−4.75, −3.82, −0.98) for USA and (−12.63, −9.55, −2.45) for UV, respectively (see Table).

The authors concluded that on a short-term basis, adding a plantar resistance exercise to the PEMF had no appreciable short-term effects on ulcer healing; however, their combination had more pronounced medium-term effects. Furthermore, combined plantar flexion resistance training and PEMF could be a non-invasive adjuvant treatment for venous leg ulcers and is proven to have more noticeable benefits on the healing process.

Characteristics		PEMF + PRE Group Mean (SD)	PEMF Group Mean (SD)	Control Group Mean (SD)	*p*-Value **		
					PEMF + PRE Group vs. PEMF Group	PEMF + PRE vs. Control	PEMF vs. Control
Ulcer surface area (cm^2)	Baseline	6.82 (1.34)	6.84 (1.20)	6.99 (1.40)	1.00	1.00	1.00
	4 weeks	4.87 (1.23)	5.36 (1.44)	6.57 (1.06)	0.79	0.001	0.02
	12 weeks	2.07 (1.15)	3.02 (1.05)	6.01 (0.99)	0.037	0.001	0.001
Ulcer volume (cm^3)	Baseline	17.05 (3.36)	17.11 (3.02)	17.49 (3.50)	1.00	1.00	1.00
	4 weeks	12.42 (4.05)	13.66 (3.84)	16.39 (2.60)	0.94	0.006	0.01
	12 weeks	4.41 (2.05)	7.56 (3.08)	15.04 (2.48)	0.003	0.001	0.001

Abbreviation: PEMF, pulsed electromagnetic field; PRE, plantar flexion resistance exercise (PRE); SD, standard deviation; vs: versus. Level of significance at $p < 0.05$. ** *p*-value adjusted for pairwise multiple comparison: Bonferroni.

Table. Comparison of outcomes across the three groups at three-point timelines.

Source: *Mohamady HM, Taha MM, Aneis YM, Aldhahi MI, Attalla AF. Effect of Combined Electromagnetic Field and Plantar Flexion Resistance Exercise on Wound Healing in Patients with Venous Leg Ulcers: A Randomized Controlled Trial. Medicina 2023, 59, 1157. https://doi.org/10.3390/medicina59061157*

STUDY SHOWS INCREASED RISK OF FALLS IN KNEE OA

The 2017 Global Burden of Diseases Study ranked falls as the 18th leading cause of disability-adjusted life years and the 2nd leading cause of death due to unintentional injuries. Those who fall 2 or more times per year—recurrent fallers—experience greater morbidity than those who are not recurrent fallers. Researchers from Canada wanted to better understand the effect of knee osteoarthritis in those who fall and to identify the factors that contribute to an individual with knee OA experiencing 1 or multiple injurious falls.

Using baseline and 3-year follow-up data from the Canadian Longitudinal Study on Aging, a population-based study of people ages 45–85 years at baseline, the researchers analyzed only individuals either reporting knee OA or no arthritis at baseline (n = 21,710). Differences between falling patterns among those with and without knee OA were tested using chi-square tests and multivariable-adjusted logistic regression models. An ordinal logistic regression model examined

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predictors of experiencing 1 or more injurious falls among individuals with knee OA.

Among individuals reporting knee OA, 10% reported 1 or more injurious falls; 6% reported 1 fall, and 4% reported 2+ falls. Having knee OA significantly contributed to the risk of falling (odds ratio [OR] 1.33 [95% confidence interval (95% CI) 1.14–1.56]), and individuals with knee OA were more likely to report having a fall indoors while standing or walking. Among individuals with knee OA, reporting a previous fall (OR 1.75 [95% CI 1.22–2.52]), previous fracture (OR 1.42 [95% CI 1.12–1.80]), and having urinary incontinence (OR 1.38 [95% CI 1.01–1.88]) were significant predictors of falling.

Looking at those with knee OA, the researchers found that those who reported multiple falls were more likely to report a previous injurious fall, knee symptoms, a lower-extremity fracture, and impaired performance on one-leg balance, TUG time, and chair rise tests. Interestingly, individuals with knee OA were significantly more likely to report failing indoors than individuals without knee OA (46.8% vs 38.7%), and significantly less likely to report failing outdoors (53.2% vs 61.3%)..

In conclusion, the authors wrote that their findings support the idea that knee OA is an independent risk factor for falls. The circumstances in which falls occur differ from those for individuals without knee OA. The risk factors and environments that are associated with falling may provide opportunities for clinical intervention and fall prevention strategies. ler

Source: *Wilfong JM, Perruccio AV, Badley EM. Examination of the Increased Risk for Falls Among Individuals With Knee Osteoarthritis: A Canadian Longitudinal Study on Aging Population-Based Study. Arthritis Care Res. 2023. https://doi.org/10.1002/acr.25163*

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BIOLOGICAL TEST DETECTS PARKINSON'S DISEASE BEFORE SYMPTOMS PRESENT

Test can detect build-up of abnormal protein deposits linked to Parkinson's disease in cerebrospinal fluid, according to Penn Medicine researchers

A technique that identifies the build-up of abnormal protein deposits linked to Parkinson's disease in cerebrospinal fluid can accurately detect patients with the disease, according to research published in *The Lancet Neurology*. In addition, the findings suggest that the test can identify at-risk people and those with early, non-motor symptoms prior to diagnosis, which could in the future, support a framework for early detection and prevention of disabling motor symptoms, like tremors.

Researchers at Penn Medicine, along with the Parkinson's Progression Markers Initiative (PPMI) and Michael J. Fox Foundation (MJFF), confirmed that the technique– known as α-synuclein seed amplification assay (αSyn-SAA) – is highly accurate at identifying Parkinson's disease patients, and classifying them based on genetic and clinical markers.

"This research is a step forward for understanding the different pathologies of Parkinson's disease," said corresponding author Andrew Siderowf, MD, a professor of Neurology in the Perelman School of Medicine at the University of Pennsylvania and director of Penn's Parkinson's Disease and Movement Disorders Center. "The αSyn-SAA technique is a crucial tool to further our understanding of how Parkinson's disease develops in patients with and without risk factors. Going forward, we will be able to use the test to connect patients with the most promising clinical trials based on their underlying biology. In the future, tests like αSyn-SAA could likely form the basis for personalized medicine for Parkinson's disease."

This technique amplifies very small amounts of misfolded aggregates of α-synuclein in samples from Parkinson's patients to the point that they can be detected using standard laboratory methods. This approach builds on the ground-breaking discovery of synuclein protein deposits as a biological hallmark of Parkinson's disease by researchers including Penn Medicine's Virginia MY Lee, PhD, the John H. Ware 3rd Professor in Alzheimer's Research in Pathology and Laboratory Medicine, and the late John Q. Trojanowski, MD, PhD, a former professor of Geriatric Medicine and Gerontology in Pathology and Laboratory Medicine.

The *Lancet Neurology* paper outlines αSyn-SAA results from more than 1,100 participants from PPMI, including individuals with Parkinson's disease, those with genetic or clinical risk factors but not yet diagnosed with Parkinson's, and control volunteers. Samples of cerebrospinal fluid – which surrounds the brain and spinal cord – were analysed using αSyn-SAA. The large-scale analysis confirms previous, smaller reports that αSyn-SAA gives positive results in 88% of all participants with Parkinson's disease, including sporadic and genetic cases. Over 95% of control volunteers had negative test results.

In addition, a portion of participants had conditions that are known precursors to Parkinson's disease, without a diagnosis. These

conditions include rapid eye movement (REM) sleep behavior disorder, and unexplained loss of sense of smell. Among those recruited based on their loss of smell, 89% had positive αSyn-SAA results. Similarly, in REM sleep behavior disorder, positive αSyn-SAA results were present in 85% of cases. Results were also positive in some participants who carried genetic variants associated with Parkinson's disease but had no clinical manifestations of disease.

PPMI is an international study conducted at 33 academic centers in 12 countries. Penn's Parkinson's Disease and Movement Disorders Center has been a leading recruiting site for PPMI for over a decade.

"This is a very important milestone for Parkinson's disease research," Siderowf added. "Penn Medicine is proud to be one of the top recruiting sites for PPMI studies, bringing patients to clinical trials that will not only alter the course of their own disease, but move forward the science for detecting and treating the disease in future patients." ler

Source: *Siderowf A, Concha-Marambio L, Lafontant DE, et al for the Parkinson's Progression Markers Initiative. Assessment of heterogeneity among participants in the Parkinson's Progression Markers Initiative cohort using α-synuclein seed amplification: a cross-sectional study. Lancet Neurol. 2023 May;22(5):407-417. doi: 10.1016/S1474-4422(23)00109-6. PMID: 37059509.*

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Effects of Sensory Prosthesis for Peripheral Neuropathy

By Lars I. E. Oddsson, Teresa Bisson, Helen S. Cohen, Ikechukwu Iloputaife, Laura Jacobs, Doris Kung, Lewis A. Lipsitz, Brad Manor, Patricia McCracken, Yvonne Rumsey, Diane M. Wrisley and Sara R. Koehler-McNicholas

Persistent problems with gait and balance function may lead to falls, fractures, and other serious injuries in older adults.

Persistent problems with gait and balance function may lead to falls, fractures, and other serious injuries in older adults. In addition to other age-related risk factors, sensory peripheral neuropathy (PN), leading to impaired plantar sensation, is an independent risk factor for falls. The incidence of injuries due to falls is 15 times higher in patients with diabetic PN than in healthy individuals.

Although strength and balance training in patients with PN may help reduce fall risk falls, strength training in patients with PN appears to have less impact on balance. Its effects are mainly compensatory and do not address impaired somatosensation, the root cause of balance problems related to PN. Further, balance training activities must be specific and conducted with sufficient intensity and frequency to be helpful. Clear guidelines regarding frequency of balance exercises are currently lacking although 3 sessions a week may be a minimum necessary to see an improvement. Although falls can be prevented, they continue to be a large problem in older adults, indicating a continued need for novel solutions. One such novel solution is Walkasins, a wearable non-invasive sensory prosthesis intended to substitute nerve function related to impaired plantar sensation (Figure 1).

This article reports on the extended long-term use data after 26 weeks of Walkasins use in the walk2Wellness Clinical Trial—data from the 10-week home-based use of Walkins has already shown that individuals with PN and a high risk of falls improved their Functional Gait Assessment (FGA) scores, Gait Speed, and Timed Up and Go (TUG) times. The data also showed a decrease in the number of fall risk factors as well as fall rate from baseline to 10 weeks for individuals who reported falls in the 6 months preceding study participation.

Methods

Forty-four people at 4 study sites participated in the walk2Wellness trial. Inclusion criteria included the following: male or female; ages 21–90; a formal diagnosis of sensory PN prior to participating in the study; self-reported problems with balance; ability for transfers or ambulation on level surfaces at fixed cadence as assessed by trained study personnel; FGA score < 23, the cut-off score for high fall risk; foot size to allow the Walkasins device to function properly; and ability to complete all functional outcome measures without the use of an assistive device. Use of an assistive device during daily activities was permissible.

Participants agreed not to initiate any balance training or balance-related therapy during the first 10 weeks of the trial. They provided information on number of falls experienced and any injuries sustained in the previous 6 and 12 months, as well as a list of their medications, indication, dose, and frequency, which was updated over the course of the study.

Participants then completed the Activities-Specific Balance Confidence (ABC) Questionnaire and the Vestibular Activities of

This article has been excerpted from "Extended Effects of a Wearable Sensory Prosthesis on Gait, Balance Function and falls after 26 Weeks of Use in Persons with Peripheral Neuropathy and High Fall Risk—The walk2Wellness Trial" Frontiers in Aging Neuroscience. 2022;14:931048. doi: 10.3389/fnagi.2022.931048. Editing has occurred, including the renumbering of tables, and references have been removed for brevity. Use is per CC BY.

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Figure 1. (Left) The two components of the Walkasins prosthetic device, the pressure sensitive flexible foot pad that is placed in the shoe and connects to the leg unit that contains a rechargeable battery, a microprocessor, supporting electronics, and four mechanical tactile stimulators. The embedded software algorithm evaluates pressure data and activates the mechanical tactile stimulators at relevant times during standing and walking to signal balance-related information to the afferent nervous system. (Right) A Walkasins user wearing the device in the process of turning it on. The Walkasins system is worn bilaterally (unilateral components depicted).

Daily Living Scale (VADL). At baseline, week 10, and week 26, participants were assessed using the Weinstein Enhanced Sensory Test (WEST) monofilament foot test (0.5, 2, 10, 50, and 200g). Site staff also performed a vibration sensation test using a Rydel-Seiffer Tuning Fork to document loss of sensation. Scoring values ≤4 at the first metatarsal joint is categorized as abnormal.

During the baseline visit, participants donned the Walkasins devices and performed a standardized set of standing and walking balance activities focused on orientation and familiarization with the device. Additional outcomes assessments included the 10-Meter Walk Test, TUG, and 4-Stage Balance Test. Participants also completed several self-reported outcome measures: Patient Health Questionnaire (PHQ-9), PROMIS Pain Interference Short Form 6b, PROMIS Pain Intensity Form 1a, Ability to Participate Short Form 8a, and Satisfaction with Participation in Social Roles Short Form 8a. Participants left the baseline visit with the device and a calendar on which to note any fall events they experienced as well as their use of Walkasins.

Participants returned for in-person visits at weeks 2, 6, 10, and 26, except when prohibited due to COVID-19 restrictions. These visits followed most of the same procedures as the baseline visit. ABC to FGA ratios were calculated at each assessment to measure the degree of internal self-perception of balance capability (ABC score) in relation to the externally observed walking balance performance (FGA score).

Study sites contacted participants via telephone at weeks 14, 18, and 22 to remind them of study requirements and to collect follow-up information regarding health changes, falls, adverse events, pain scores, device usage, and device functioning, as well as whether they had begun any physical therapy for their balance problems. If participants reported adverse events and/or falls during these contacts, site personnel recorded the details.

A post hoc analysis was conducted to compare participants at baseline who reported falls in the previous 6 months (Pre-Fallers [Pre-F], n = 25) to those who did not (Pre-Non-Fallers [PRE-NF], n = 19).

Results

Due to circumstances related to COVID-19, 14 of the 44 participants were unable to participate in the 26-week in-person outcomes testing (FGA, 10MWT, TUG, and 4-Stage Balance Test). However, all were assessed on self-reported outcomes over the phone, and all provided reports of falls.

Average reported weekly device use was 5.1 ± 0.4 days. Participants reporting that they used the device weekly either "Every Day" or "At least 5 Days" was 71.8 ± 10.5%. An average of 94.8 ± 3.3% of reporting participants stated they used the device "1–2 Days" or more per week.

Baseline self-selected gait speed and ABC scores were significantly different between the Pre-F and Pre-NF groups, 0.83 vs. 0.97 m/s and 57.8 vs. 69.6%, respectively. A higher observed mean value in PHQ-9 score for the Pre-F group was nearly statistically significant (5.7 vs. 3.3, respectively, $P = 0.052$). Mean values for all PROMIS measures were near 50, and any observed differences were minor.

After 26 weeks of device use, FGA scores increased across all individuals from 15.0 to 19.2 ($P < 0.00001$) (Figure 2); self-selected gait speed increased from 0.89 m/s to 0.97 m/s (P

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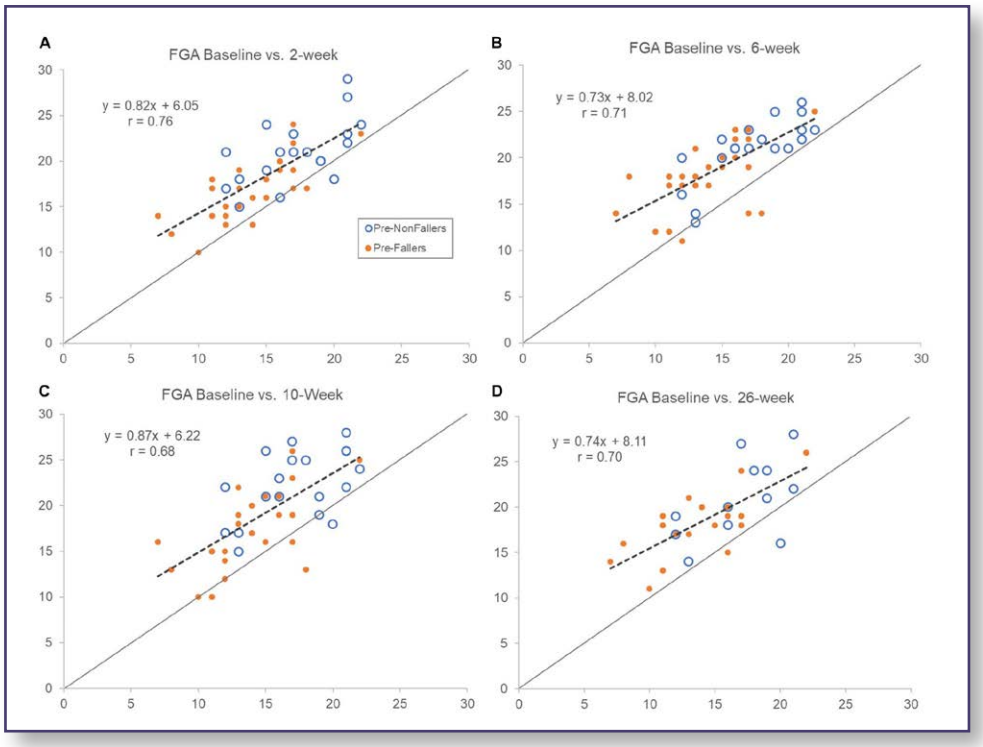

Figure 2. Comparing FGA scores at baseline (horizontal axes) with assessments after 2 (A), 6 (B), 10 (C), and 26 (D) weeks (vertical axes) of device use. Open symbols represent pre-study non-fallers and filled ones are pre-study fallers. Dashed lines show regression line for the whole group. Forty-four participants completed in clinic outcomes testing up to 10 weeks (primary endpoint), and 30 participants completed the 26-week assessment in person. Scores above line of equality indicate improvements and below a decrement in FGA score compared to baseline scores. Notice that regression line slopes are less than 1 indicating slightly larger improvements in FGA score for those with lower baseline scores. Overall, improvements observed after 2 weeks of use appeared sustained throughout the 26 weeks of use.

= 0.02); and the 4-Stage Balance Test improved from 25.6 s to 28.4 s ($P < 0.01$). An increase seen in fast gait speed (1.30 to 1.37 m/s) did not reach statistical significance ($P = 0.07$). Changes in Rydel-Seiffer tuning fork testing scores suggested a small decrease in sensitivity at the site of the lateral malleolus (mean 3.8 to 3.2, $P = 0.032$, while a noted decrease at the metatarsophalangeal (MTP) joint did not reach statistical significance ($P = 0.07$).

The Pre-F cohort improved their mean FGA score from 13.7 at baseline to 18.1 at 26 weeks ($P < 0.0001$). Their observed increases in self-selected gait speed from 0.82 to 0.90 m/s and from 1.13 to 1.23 m/s for fast gait speed were not statistically significant ($P = 0.12$ and $P = 0.07$, respectively). The Pre-F group showed a decrease in vibration sensation at the first MTP joint (mean 2.9 to 1.8, $P < 0.005$) and at the lateral malleolus that did not reach statistical significance (mean 3.75 to 3.25, $P = 0.07$).

The Pre-NF group increased their mean FGA score from 17.0 at baseline to 20.8 at 26 weeks ($P < 0.004$). A small increase in self-selected gait speed from 1.00 m/s to 1.08 m/s was not statistically significant ($P = 0.06$). Other clinical outcomes, including Rydel-Seiffer tuning fork sensitivity testing scores, remained unchanged at 26 weeks compared to baseline.

Regarding self-reported outcomes, across all participants, a slight but statistically significant increase was seen in PROMIS Ability to Participate scores after 26 weeks of device use (49.9 to 52.6, $P < 0.05$). All baseline values were maintained at 26 weeks for the Pre-F group while an increase in the PROMIS Satisfaction with Social Roles scores (49.9 to 55.5, $P < 0.006$) for the Pre-NF group was noted.

The ABC/FGA ratio for the overly confident individuals gradually decreased from high values at baseline to week 6 when the ratio essentially aligned with the low self-confidence participants, who maintained a consistent ABC/FGA ratio of about 3.5 throughout the 26-week trial. However, both groups increased their FGA scores in a similar fashion although the overly confident participants showed higher levels of improvement.

Falls were reported throughout the 26-week period for all 44 participants and separately for the Pre-F (n = 25) and Pre-NF (n = 19) groups. The 44 participants reported a total of 53 falls over 6 months prior to participating in the trial while 39 falls were documented during the 26 weeks of the trial, corresponding to a pre-study mean fall rate of 6.7 falls/1000 patient days (median = 5.6 falls/1000 patient days) and a post-study mean fall rate of 4.8 falls/1000 patient days (median = 0 falls/1000 patient days). Across all participants, the median of the post-study fall rate was lower than the pre-study fall rate ($P = 0.044$), reflecting a 28% decrease in fall rate. Of the 44 participants, 25 had fallen in the past 6 months (Pre-F); and after 26 weeks, 20 of the 44 participants had reported falling. Overall, 31 of the 39 falls required no treatment while 8 falls (~20%) required treatment with 4 of those (~10%) causing severe injury (2 fractures).

The Pre-F cohort reported 31 falls after 26 weeks compared to 53 falls pre-study corresponding to a pre-study fall rate of 11.8 falls/1000 patient days (median = 11.1), which decreased to 6.7 falls/1000 patient days at 26 weeks (median = 5.0), a 43% decrease in fall rate ($P = 0.0043$). During the study, 12 did not fall, a 48% statistically significant decrease ($P < 0.0001$). Of the 31 falls experienced by the Pre-F cohort, 6 (~20%) required treatment. Three of the 4 falls that led to severe injury occurred in the Pre-F group.

Seven of the 19 Pre-NF participants reported falling during the trial ($P < 0.0001$) indicating an increase in fall rate from 0 to 2.3 falls/1000 patient days at 26 weeks that was statistically significant ($P = 0.023$). Eight falls were reported by the 7 Pre-NF participants who fell during the study; 2 required treatment and 1 sustained a severe injury. (See Figure 3.)

Discussion

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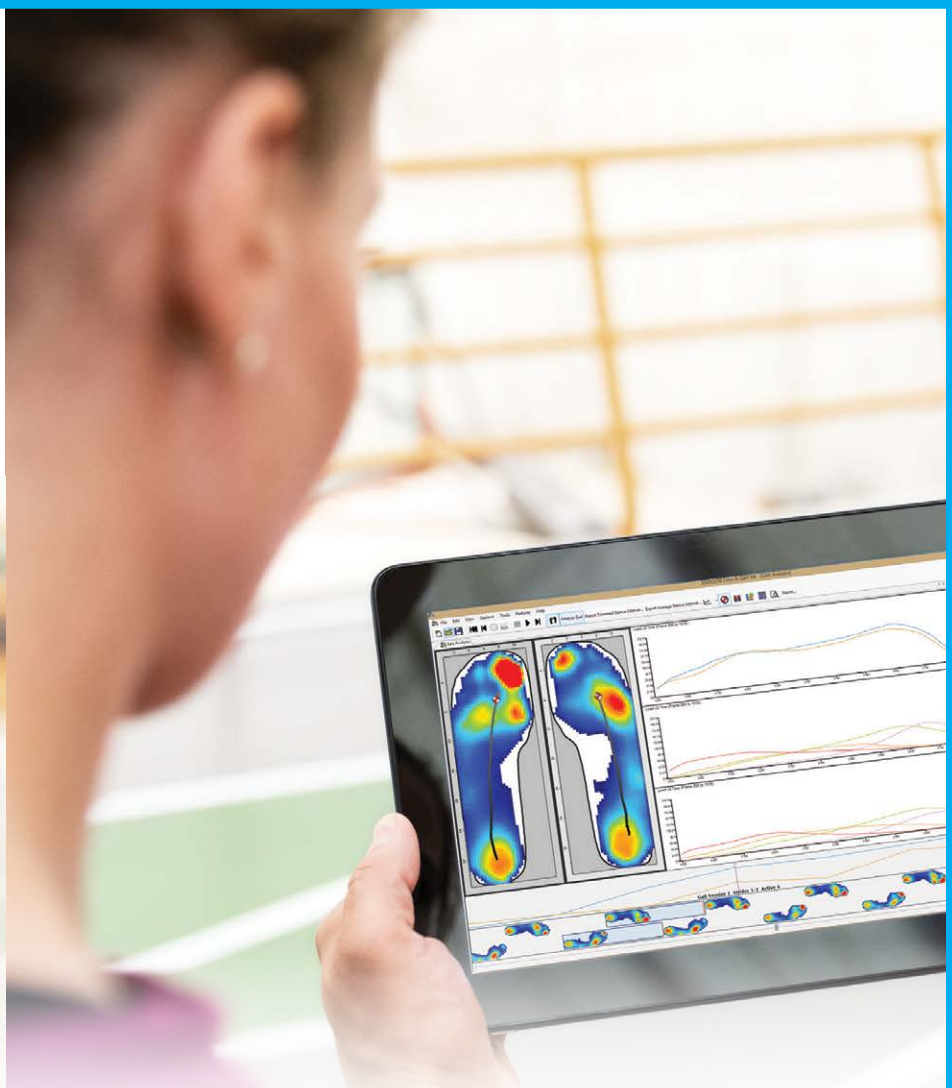

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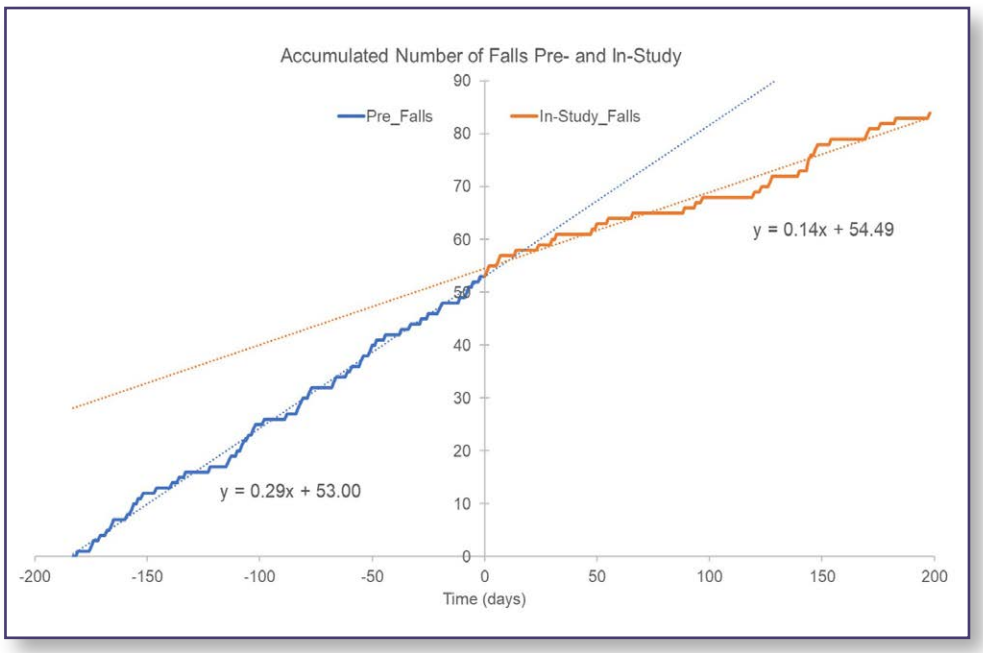

Figure 3. Accumulated number of falls reported 6 months pre-study (blue trace and blue dotted linear regression line) and falls documented in-study (orange trace and orange dotted regression line). The 53 falls reported for the prior 6 months would correspond to 0.29 falls/day (53/180 ~0.29), which represents the slope of the regression line (blue trace). For illustration purposes, the 53 pre-study falls were randomly distributed across the 6 months since their exact time occurrence was unknown. In-study falls are shown as they occurred and were reported by participants throughout the 26 weeks. Notice how the rate of in-study falls appear to begin deviating from pre-study fall rate (slope of dotted blue line) after approximately 20 days of device use.

Walkasins is a device that provides mechanical tactile stimuli related to foot pressure for individuals with PN and gait and balance problems. Overall, the study authors' findings from analyzing outcomes after 26 weeks of wearing Walkasins show that improvements in outcomes seen after 10 weeks of use are sustained longer term.

FGA scores were improved across all participants. Interestingly, these improvements were seen for individuals across the full range of baseline FGA scores (Figure 2) with a tendency to be higher for individuals in the lower FGA range. Similar improvements were seen for the Pre-F and Pre-NF cohorts. Moreover, the 46% decrease in fall rate, compared to pre-study falls that were reported after 10 weeks of use, was sustained at 43% after 26 weeks.

All clinical outcomes improved compared to baseline, but changes in TUG and 4-Stage Balance did not reach statistical significance, likely because the study was underpowered for these measures. It is encouraging to report a statistically significant 0.08 m/s increase in gait speed across all participants in this trial, which is beyond a small meaningful change (0.05 m/s) and close to the range for a substantial meaningful change (0.10 m/s).

Participants had a decrease in sensitivity to vibration, an overall small decrease at the lateral malleolus and a larger change at the MTP joint in the Pre-Faller group. Such changes did not occur at the 10-week assessment. This decrease in tuning fork vibration perception may indicate a progression of some participants' PN and increased sensory loss.

The improvements in clinical outcomes were gained from a single training visit on the use of the device and then simply by wearing it during regular daily activities. In fact, during the first 10 weeks of use, participants were prohibited from doing any physical therapy or balance-related exercise activities to help isolate the effect of the device. Knowing, however, that such interventions may help improve gait and balance function, the participants were permitted to engage in such after the 10 weeks. Therefore, to control for any potential effects of balance exercise interventions, participants were asked during follow-up phone calls at 14, 18, and 22 weeks whether they had begun any physical therapy for their balance problems. Only 1 of the participants answered "yes," further suggesting that long-term use of the device was the main cause of improvement in clinical outcomes and not exercise or balance interventions.

Interestingly, early observations from a pilot study of 5 participants in the cohort studied here, who completed 26 weeks of device use, show neuroplastic changes in brain network connectivity related to postural control and balance that were associated with improved changes in FGA scores. This finding indicates a direct effect of the sensory prosthesis initiating plastic changes related to sensorimotor interaction and postural control.

One of the most important findings from this trial is the 43% decrease in fall rate for participants with a fall history following 26 weeks of device use. The data on injuries reported from falls are probably clinically significant. In this study, 57% of participants reported falling in the 6 months prior to the study while 45% fell during 6 months of the trial. Eight of the 39 falls during the trial (20.5%) led to injuries where treatment was sought, half of those considered serious. Consequently, both fall rate and injury rate are lower than previous reports of similar populations.

Conclusion

Patients with PN who have gait and balance problems with a high risk of falls including a history of falls can improve their walking balance and decrease their fall rates from long-term use of a wearable non-invasive sensory prosthesis. ler

KNEE RECONSTRUCTION

Mitigating the Post-operative Swelling Tsunami in Total Knee Arthroplasty: A Call to Action

By Andrew Wickline, MD, FAAOS; Windy Cole, DPM, CWSP, FACCWS; Mark Melin, MD, FACS, RPVI, FACCWS; Suzie Ehmann, PT DPT, PhD(c), CWS, CLT-LANA; Frank Aviles, PT, CWS, FACCWS, CLT-LANA, ALM,AWCC, MAPWCA; and Jennifer Bradt, PT,DPT,CLT-LANA

Total knee arthroplasty is a treatment option for individuals with symptomatic osteoarthritis who have failed conservative therapy. In this manuscript the authors describe the pathophysiology of post-operative edema and explore the patient dependent factors potentially contributing to lymphatic dysfunction and thus directly influencing the TKA post-operative course. A proposed multimodal perioperative protocol is presented that focuses on identifying limb edema/lymphedema preoperatively, intraoperative technique changes that may decrease swelling post-TKA.

Total knee arthroplasty (TKA) is a treatment option for individuals with symptomatic osteoarthritis who have failed conservative therapy. The primary goal of this surgical procedure is to decrease pain, improve mobility, and increase patient quality of life. The incidence of total knee replacement internationally is approximately 175 procedures/100,000 population with the highest of 234 procedures/100,000 population for the United States. While there appears to be no clear accounting of TKA volume in the US, it has been estimated that over 1.025 million TKAs were performed in 2020 with estimated volumes growing to 3.4 million yearly TKAs by 2040.

Although TKA has proven to be an effective surgical option for osteoarthritis, this surgical intervention is not free from complications. Potential post-operative complications include surgical site and joint infection, edema, hematoma, joint instability, continued pain, limitations of range of motion, implant failure, joint dislocation, vascular injury, and nerve damage. Studies have reported that the dissatisfaction rate after TKA is as high as 19% with most of the patient concerns attributed to lack of pain relief, chronic edema, and lack of knee joint function. Significant joint swelling is common following TKA surgery. One report noted a post-operative swelling prevalence of 15.6% among patients after TKA. Additionally, total knee arthroplasty is noted to be the most common cause of non-cancer surgery-related post-operative causation of lymphedema. As the number of TKA procedures continues to increase at an accelerated rate, it is imperative to sufficiently mitigate potential preventable complications, both prior to and after the surgical procedure, to address the patient post-procedure dissatisfaction rates.

Herein the authors will describe the pathophysiology of post-operative edema and explore the patient dependent factors

This article has been excerpted from "Mitigating the Post-operative Swelling Tsunami in Total Knee Arthroplasty: A Call to Action" by the authors listed above. *Journal of Orthopaedic Experience & Innovation*. August 2023. https://doi.org/10.60118/001c.77444. References have been removed for brevity. Reprinting is with the Editor's permission;

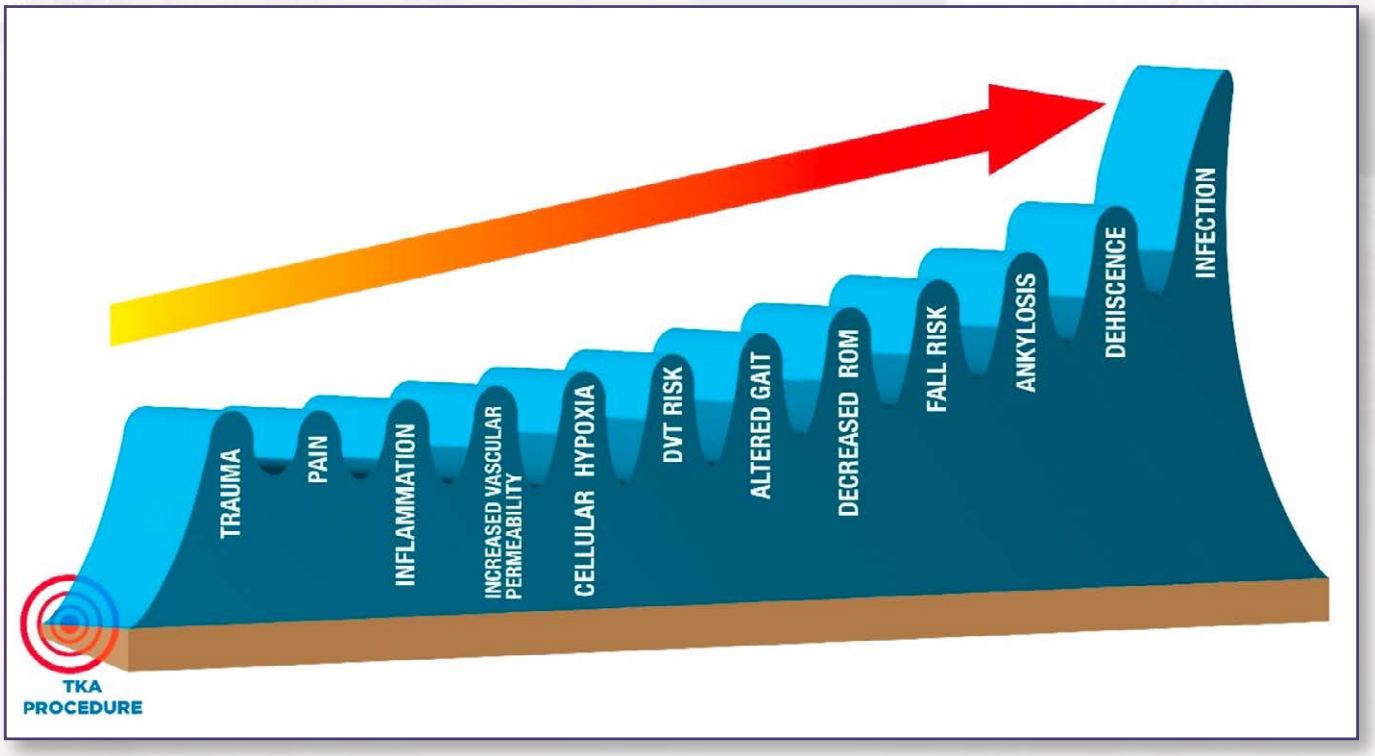

Figure 1. The elements of the TKA Post-operative swelling Tsunami

potentially contributing to lymphatic dysfunction and thus directly influencing the TKA post-operative course. The authors will also present their thoughts on a proposed multimodal perioperative protocol focused on identifying limb edema/lymphedema preoperatively, intraoperative technique changes that may decrease swelling, and lastly mitigating acute post-operative swelling response with the intent of decreasing pain, improving patient outcomes, and reducing the morbidity of chronic post-operative edema.

THE PATHOPHYSIOLOGY OF POST-OPERATIVE EDEMA

The universal response of tissue to injury, whether traumatically or surgically induced, is inflammation. If left unchecked, a swelling tsunami can ensue. Increased vascular permeability enables extravasation of fluid into the extracellular tissue spaces. Much of the fluid becomes displaced to the subcutaneous tissue. Increases in vascular permeability are believed to be the result of histamine and histamine-like permeability factors released because of the surgical intervention. Additional theories adhere to the belief that increased vascular permeability is directly due to overt vascular or cellular injury. Extensive surgical dissection results in endothelial cell disruption and may take several days to weeks for repair and regeneration to begin. The more extensive the procedure, the more damage cellular structures sustain, resulting in a prolonged state of edema. If leg edema (lymphedema, chronic venous insufficiency, or lipedema) existed prior to the surgical procedure, the edema is typically exacerbated post-operatively, prolonging recovery and potentially increasing complication occurrence.

Lymphatic vessels play a key role in removing the protein-rich fluid from the tissues and rapidly dilate to several times their nor-

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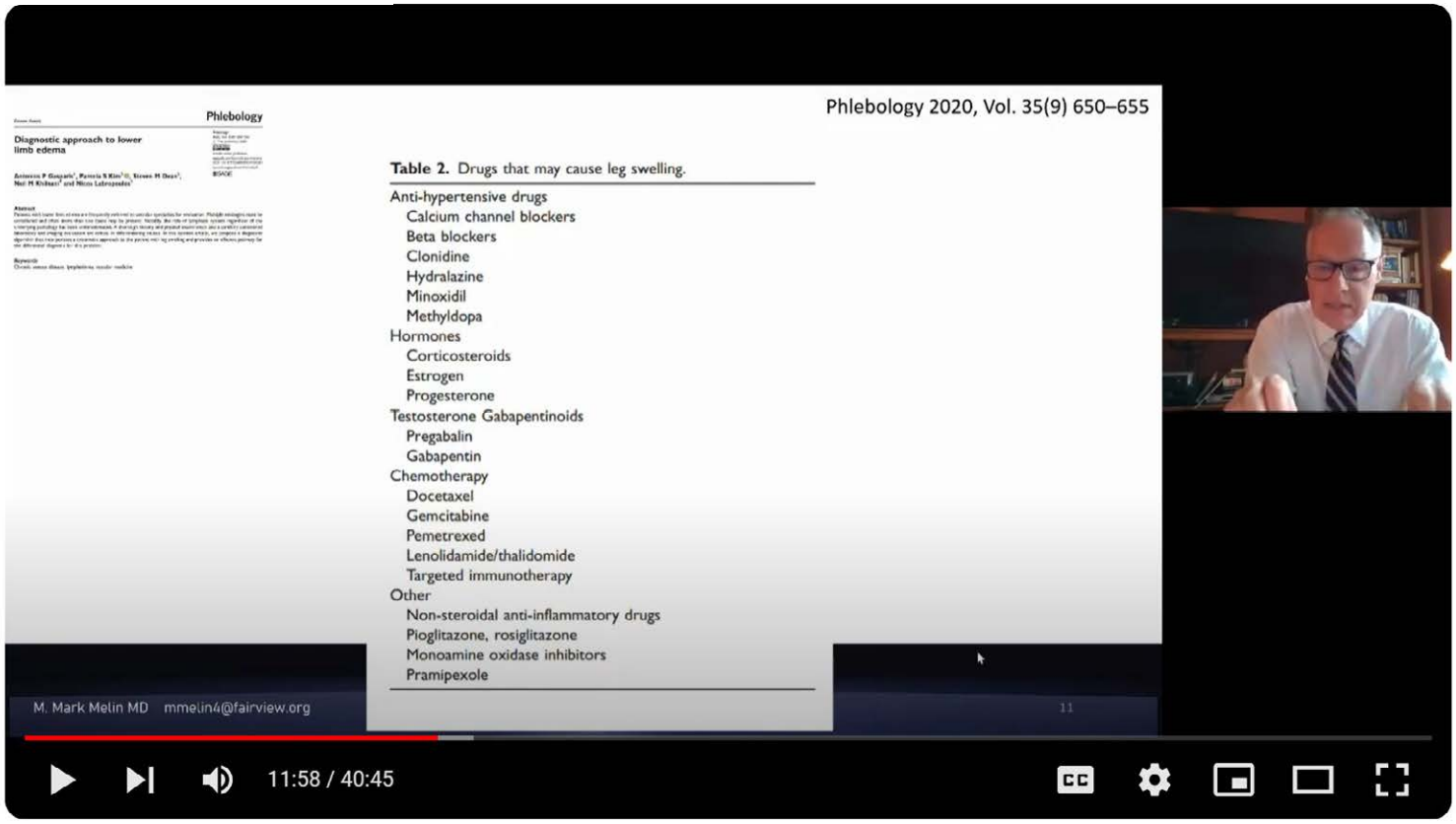

Dr. Mark Melin Discusses Medications That Contribute to Edema

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"Now Tony Gasparis, Pam Kim, Steve Dean, Neil Khilnani and Nicos Labropoulos wrote this really good article in Phlebolo-

gy in 2020.1 I would encourage everybody to get this article, read it, and highlight it.

...Now their Table 2 is important. We always talk about how we can get rid of edema with medications. Obviously, diuretics don't work and actually, diuretics overtime may make the situa- tion for lymphedema worse because it concentrates the proteins and getting those proteins out – they're very tenacious, very sticky – and to get them into the lymphatics and out is very diffi- cult, if not impossible. So the medications that specifically lead to lower extremity swelling --and the one that we consistently stop in our wound clinic is amlodipine and amlodipine is a phe- nomenal blood pressure control medication. It's often used in synergy with other medications, but it is well known to be one of the most significant causes of lower extremity edema. So, when you're doing your medication checklist. If they're on amlodipine,

I just look at patients and say you need to stop this. You're going to call your primary care physician today. Tell them you need to stop it because it's contributing to the lower extremity edema. It can be idiosyncratic, so patients could have been on it for years and all of a sudden something changes or tips, and now they've got lower extremity edema. Lidocaine, of course, falls under that general category of calcium channel blockers. ... Beta blockers can contribute to edema. And hormones – we certainly know that estrogen is one of the ones that can contribute, as can testos- terone. Patients on chemotherapy for malignancies may be using non steroidal anti-inflammatory drugs. So if patients are taking high levels of NSAIDs that can contribute and we know high dose NSAIDs actually result in shedding of the glycocalyx. So this is a very good list to have. "

1.Gasparis AP, Kim PS, Dean SM, Khilnani NM, Labropoulos N. Diagnostic ap- proach to lower limb edema. Phlebology. 2020;35(9):650-655. doi:10.1177/0268355520938283. Table in image used with publisher's permission; all rights reserved.

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mal caliber early in the inflammatory phase to increase overall lymphatic flow rates. Increased tissue edema and dermal lymphatic stasis results in a proinflammatory state. Normal functioning lymphatic mechanisms and venous drainage are required for the body to remove inflammatory mediators from the subcutaneous tissues. Impaired vascular perfusion at the microvascular level results not only in subcutaneous fluid build-up in the tissues, but also an accumulation of pro-inflammatory substances which have been attributed to the continuous nociceptor activation and related pathophysiological states including central nervous system sensitization and neuroinflammation. It is well-established that persistent, peripheral nociceptive sources can initiate, maintain, and perpetuate chronic pain states, with tissue injury and inflammation leading to the local release of substances including glutamate, serotonin, bradykinin, Substance P, nerve growth factor, and norepinephrine. These substances are transmitted to the central nervous system by primary afferent nociceptors resulting in a lower set point for nociceptor activation thresholds in the periphery, hence contributing to chronic pain. To put it succinctly, swelling and associated dermal lymphatic stasis directly contribute to acute post-operative pain and play a part in the initiation of chronic pain states.

Swelling and pain related to joint replacement procedures are the most frequent post-operative patient complaint, being associated with increased emergency department visits, readmissions, poorer patient outcomes, and contributing to escalating total cost of care. Following TKA, 13.8% of patients will have at least one emergency department visit. The most frequent symptoms were pain (15.8%) and swelling (15.6%). The thirty-day readmission rate for primary TKA and revisional TKA was 4.8% and 7.2% respectively. In the acute post-operative phase of healing, uncontrolled post-operative swelling and pain can lead to hospital re-admission for pain management and/or arthrofibrosis and excessive scarring. Arthrofibrosis can contribute to decreased range of motion (ROM) and alterations in gait mechanics which may subsequently increase the likelihood of DVT development and increase fall risks. Additionally, chronic tissue edema leads to cellular hypoxia which can lead to surgical site infections (SSI), surgical site dehiscence, scar tissue formation, and joint ankylosis. These multiple effects can result in a post-operative swelling Tsunami. (Figure 1)

MEASURING POST-OPERATIVE EDEMA

Post-operative edema is an anticipated sequela of TKA. However, swelling has extreme patient variability, as some patients have minimal swelling, and others develop remarkable post-operative edema. This variability may be due to preoperative undetected or underappreciated edema/lymphedema, chronic venous insufficiency, lipedema, genetics, or variation in operative technique and post-operative protocols. Consistent, reproducible, economical measuring of preoperative and post-operative edema can be a challenging task. Localized assessment of edema can be done with simple circumferential measurements using a tape measure. However, this method does not differentiate edema volume and muscular volume and provides only a rough estimate of volume changes at best. Thus, these measurements are likely the least reliable for the assessment of post-orthopedic edema trends. Quantitative measurement of peripheral edema of the leg can be measured either directly by water-displacement, bioimpedance spectroscopy (BIS), ultrasound (US), MRI, or indirectly by calculation of the volume based on circumferential measurements. At present, it appears that bioimpedance devices may have the most utility and validated published data of the available options.

Various edema measurement methods are further described in Table 1, along with the authors' clinical experience and observed advantages and disadvantages.

Two important studies quantified post-operative swelling using bioelectrical impedance technology. In 2015, a study by Pua and colleagues examined the time course of knee swelling post total knee arthroplasty (TKA). Eighty-five patients with unilateral TKA were enrolled in the study. Extracellular fluid volume was quantified using BIS preoperatively and on post-operative days 1, 4, 14, and 90. Knee swelling increased ~35% from preoperative levels when measured one day post-op. Additionally, knee swelling reduced but remained at ~11% above preoperative levels on post-op day 90. In longitudinal, multivariable analyses, knee swelling was associated with quadriceps weakness ($P<0.01$) and slower gait speed ($P=0.03$). The investigators concluded that interventions to reduce post-TKA knee swelling may be indicated to improve patient function and satisfaction.

A second study by Loyd et al in 2020 provided the first published data regarding normative reference data following TKA. Like Pua, Loyd and his group used bioelectrical impedance assessment (BIA) to track post-operative swelling. From this information, the research group used statistical predictions to develop a swelling curve for the first 7-weeks after TKA. (Figure 2) The researchers observed that edema increased approximately 10% per day for the first 3 post-operative days peaking between post-op days 6-8. Patients in the 10th percentile demonstrate a peak swelling of approximately 22%, while patients in the 90th percentile peak at 46%. This work highlights that patients who have excessive swelling immediately post-op will have long-term swelling issues compared to their counterparts who had less swelling. Loyd et al observed that even at 7 weeks after surgery, the patients that reached the 90th percentile swelling remained approximately 34% more swollen than preoperatively while the lowest centile still contended with 12% more swelling. The investigators concluded that the use of their reference chart provided a novel framework to monitor swelling following total knee arthroplasty, providing an objective measure to guide clinical decisions in order to improve post-operative swelling management.

How common the assessment of edema is performed before or after TKA is unknown. Judging from the relative lack of swelling research papers in the past decade, there appears to be a paucity of providers routinely

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Table 1

Method	Description of technique	Advantages	Disadvantage	Able to distinguish edema from effusion or muscle atrophy
Circumferential Measure	Single measure at a specific location versus multiple measurements in order to calculate volume of limb	Quick, inexpensive, no skill required	Change not specific to edema	NO
Bioimpedance spectroscopy (BIS)	Measure of resistance and reactance to electrical charge allowing estimation of body composition	Differentiate body composition (extracellular fluid, intracellular fluid, fat free mass, fat mass)	Cost of the device	YES
Ultrasound (US)	2-,3-,4-D image created based on tissue composition.	Non-invasive, diagnostic for location and amount of swelling, diagnostic for vascular co-morbidities contributing to edema	Cost of equipment and procedure	YES
Perometer	Non-invasive optoelectrical scanning produce limb volume	More accurate compared to circumference measure	Cost and size of equipment	NO
Tissue Dielectric Constant (TDC)	Measures local resistance and reactance to electrical charge	Localized measurement of water in tissue	Cost of the equipment, body hair impacts measurement, spatial and gender variations	YES
Handheld 3D camera	Specialized camera and software sed to created 3D image and volume of limb	Non-invasive, accurate limb or segmental volume	Cost of equipment, requires patient to stand for 1 minute	NO
Long wave infrared thermography	Infrared camera capturing levels of thermal energy	Quick, Noninvasive, Objective measurement, potential for differentiate inflammatory response	Cost of device, Subjective interpretation	YES

assessing perioperative leg swelling. Historically, if measurements were obtained, it was through the rudimentary use of a tape measure. There is a need for a simple, validated, cost-effective edema measuring device to accurately assess the efficacy of edema reducing interventions. Ideally, this tool would enable providers to initiate edema reducing interventions in a consistent and timely manner to better mitigate swelling complications.

Of the devices available on the market, the lead author uses a bioelectrical impedance spectroscopy tool as it can be easily performed by a medical assistant pre- and post-operatively, and it discretely assesses for edema. Two clinically available devices are the In Body system, a BIA (Bioelectrical Impedance Analysis) device, and the SOZO which uses BIS. The recently published research utilizing these types of devices provides some basis upon which to measure a patient's edema status post-operatively allowing appropriate management if/when edema is trending higher than the mean. Furthermore, with advances in remote monitoring technologies, one could easily envision an app-based system that would allow the provider to track a patient's progress regarding edema, ROM, activity, and intervene when data demonstrates values falling outside the norm. Widespread adoption of swelling monitoring would be welcomed and feasible in the space by providers and patients alike.

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PERI-OPERATIVE PROTOCOLS

This section summarizes the authors' recommendations for peri-operative protocols gleaned from evidence-based practices. The aim of this work is to provide surgeons with a pre-, peri-, and post-operative protocol to minimize the negative impact of edema on post-surgical outcomes. These algorithms were designed to improve lymphatic and immune function, decrease post-op swelling, and reduce post-operative pain therefore improving patient mobility, decreasing surgical site complications, and potentially accelerating post-operative patient outcomes. Additionally, the authors hypothesize that attention to this topic will decrease hospital readmission rates, reduce need for post-surgical care related to post-operative complications, reduce ER visits and the use of narcotics/opioids, and most importantly improve patient outcomes and satisfaction.

PREOPERATIVE STAGE

Based on clinical experience, it is the authors' belief that individual patients have a unique inherent inflammatory response to trauma. Therefore, each patient will exhibit a distinctive swelling recovery curve based on various local and systemic factors including the efficiency of their lymphatic transport system and the function of their venous tributaries. Primary and secondary lymphedema impacts a significant demographic of the general population. General prevalence is estimated to be 5.4 per 1,000 people in individuals aged >65 and 10.3 per 1,000 individuals aged >85 years. The incidence may be higher in patients that have had deep venous thrombosis, significant trauma, prior history of malignancy with lymph node resection. A thorough preoperative patient assessment should include screening for chronic venous insufficiency (CVI) and lymphedema. CVI has been demonstrated to increase implant-related complications, venous thromboembolism events (VTE), length of stay (LOS), overall costs of care, and readmission rates. Chronic lymphedema is often associated with advanced CVI (known as Phlebolymphedema) and may be associated with increased surgical site infections (SSIs) and progressive post-operative edema secondary to progressive lymphedema.

Orthopedic surgeons performing hip and knee replacement should implement a peri-operative patient swelling optimization pathway within their practice. This algorithm would be in addition to other optimizations goals such as tobacco cessation, controlling sleep apnea, HBA1C, anemia, albumin, etc. The authors propose the following decision tree and subsequent lifestyle interventions be implemented in the weeks to months prior to surgical intervention. The authors propose dividing patients preoperatively into 3 groups, with the understanding that there is no current validated classification system. (Figure 3)

Clinicians should also complete the following patient assessments:

1. Evaluate medication list. Work with primary care provider to modify/stop medications that contribute to lower extremity edema (such as Amlodipine/Norvasc), ideally 4 weeks prior to the planned surgical procedure.

2. Patients >70 years of age or <70 and a history of current or previous tobacco use and/or diabetes may have increased risk for peripheral artery disease (PAD). Consider an arterial vascular evaluation (such as Ankle Brachial Index and/or arterial ultrasound) in these at-risk patients.

3. For those patients with clinical evidence of chronic venous disease (hemosiderin deposition, varicose veins, history of venous leg ulcers, history of deep vein thrombosis, chronic leg edema) a venous competency ultrasound should be performed to evaluate both superficial and deep venous anatomy for valvular reflux. Consider consultation with vascular surgery or vein specialist if significant venous reflux is present. This type of ultrasound is distinctly different than a "rule out DVT ultrasound." The authors recommend meeting with a vascular specialist and certified lymphedema specialist prior to implementation to:

a. review your goals

b. understand how treatments differ based on underlying edema etiologies (arterial issues, CVI, lymphedema, mixed causes),

c. reassess program at quarterly intervals until steady state.

All 3 specialists need to "buy-in" to 21st treatment. Otherwise, this step will likely lead to frustration for patient and orthopedic surgeon. In addition, create education pamphlet for patients describing what benefits they will see with this additional intervention (eg, reduced complications) to drive patient compliance.

In addition to the above, all clinicians should recommend the following patient lifestyle modifications.

1. Ideally, normalization of BMI with a target between 20-30, but even a small drop in BMI has been correlated with lower post-op complications. Consider nutritionist evaluation/consult.

2. Initiation of an anti-inflammatory diet (Mediterranean diet style food choices).

3. Cessation of all tobacco use, including cigarettes, vapes, and smokeless tobacco.

4. Limit alcohol intake to 1 drink daily.

5. A low sodium diet and no added salt to foods supports a decrease in dermal edema and improved microvascular function.

6. Begin exercise plans to improve leg lymphatic and muscle pump function. The following are sample regimens.

a. Walk, bicycle, swim, or use elliptical or rowing machine for 15-30 minutes daily based on pain tolerance.

b. During breakfast, lunch, and dinner do 10 calf raises and 20 march in place exercises.

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c. Diaphragmatic breathing 2x/hr while awake.

7. Initiate nutritional supplements 2-4 weeks preoperatively to support post-operative healing (protein [egg whites, protein powders or drinks], vitamins A, B [B12, B6, folic acid], C, D, and zinc). Additionally, diosmin micronized purified flavonoid fraction (MPFF) has been demonstrated to decrease tissue edema in patients with lymphedema or chronic venous disease. MPFF should be initiated in patients demonstrating venous disease or lymphedema 2 weeks to 2 months preoperatively and continued for 2-4 months post-op for the best result.

PREOPERATIVE COMPRESSION UTILIZATION IN THE TKA POPULATION

Routine/traditional prescription and utilization of compression garments in this patient population can be a challenge in both the pre- and post-operative phase due to limited ROM and difficulty with donning compression over the surgical site. Innovative textiles such as the longitudinal elastic stockinette or Velcro adjustable wraps applied from foot to thigh offer post-surgical patients an alternative to 'old school' knee high compression stocking. The authors of this work have had significant reduction of edema in both the preoperative and post-operative patient following the inclusion of the longitudinal elastic stockinette. This innovative textile is inexpensive, patient friendly and effective at edema reduction without impairing the patient's functional movement. The authors want to caution the reader regarding the antiquated utilization of TED stockings or elastic wrap (ace wrap) to manage lower extremity edema in the peri-operative phase, as there is no validated data for either. TED stockings should only be used for post-operative DVT prevention and must be used per manufacturers standards and only in non-ambulatory patients. TED stockings are contraindicated for use in ambulatory patients.

INTRA-OPERATIVE STAGE

The authors recommend incorporating the following intra-operative/PACU checklist into TKA algorithms. This list was developed through a culmination of personal experiences and best practices noted in current literature.

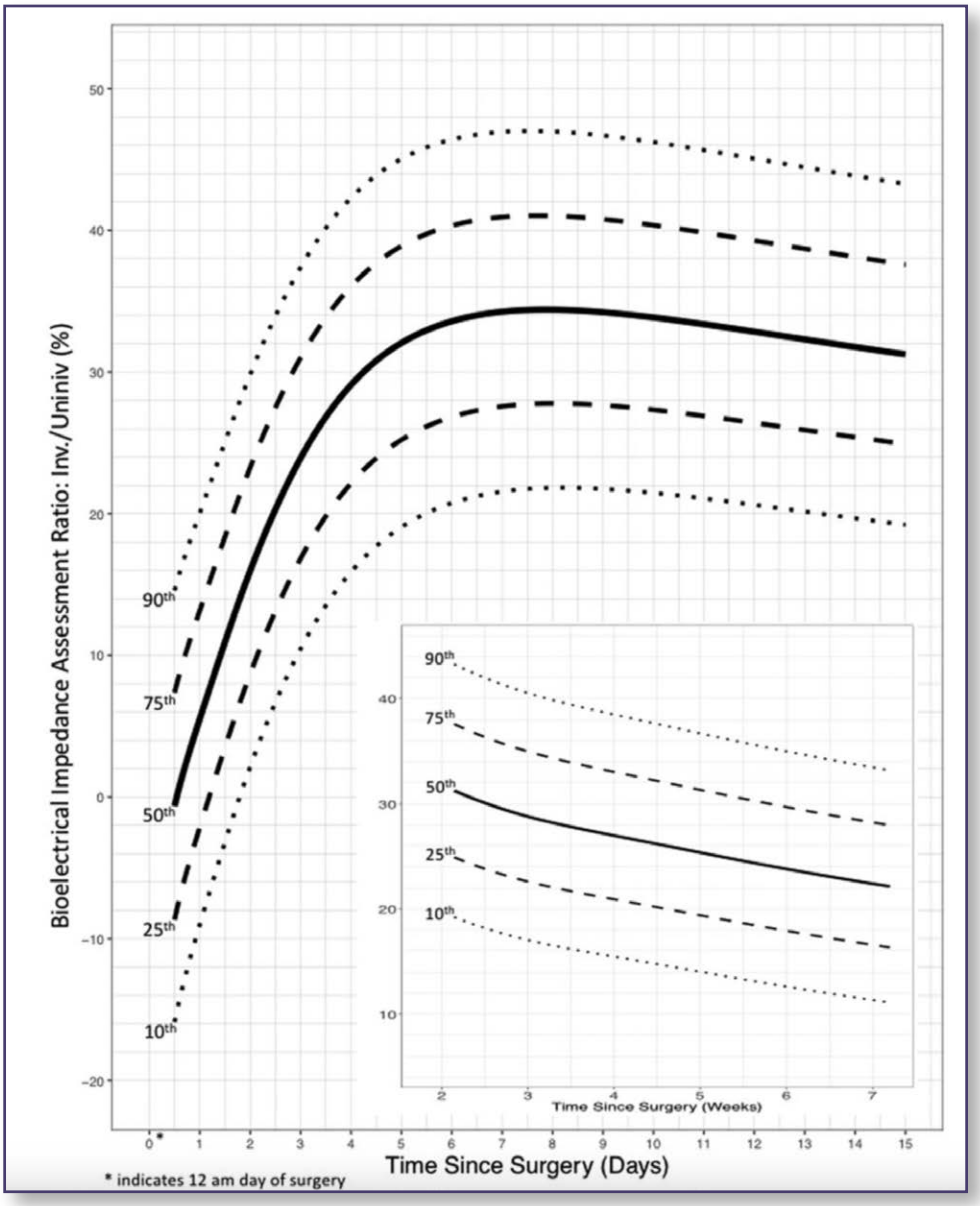

Figure 2. Loyd et al (Loyd et al. 2020) swelling curve. Reprinted with permission.

1. Sequential compression device to the non-operative leg.

2. Consider foregoing intraoperative tourniquet use, as there is theoretical risk of injury to the ventromedial lymphatic bundle that could increase post-operative edema/lymphedema occurrence. A study found that TKA with tourniquet use was associated with increased risk of skin necrosis and deep wound infection, also noting this group had less post-operative swelling and a lower incidence of wound complications in the early post-operative period ($P<0.05$).

3. Surgical atraumatic technique. Consider using a scalpel versus electrocautery.

4. Leave medullary canal undisturbed.

5. Consider kinematic alignment versus conventional mechanical alignment for less ligament releases.

6. Closure of the capsule and skin in flexion.

7. Adding topical Tranexamic acid (TXA) in addition to IV or PO route. The authors preferred method of delivery is closure of capsule followed by injection of 10cc (1GM) TXA into

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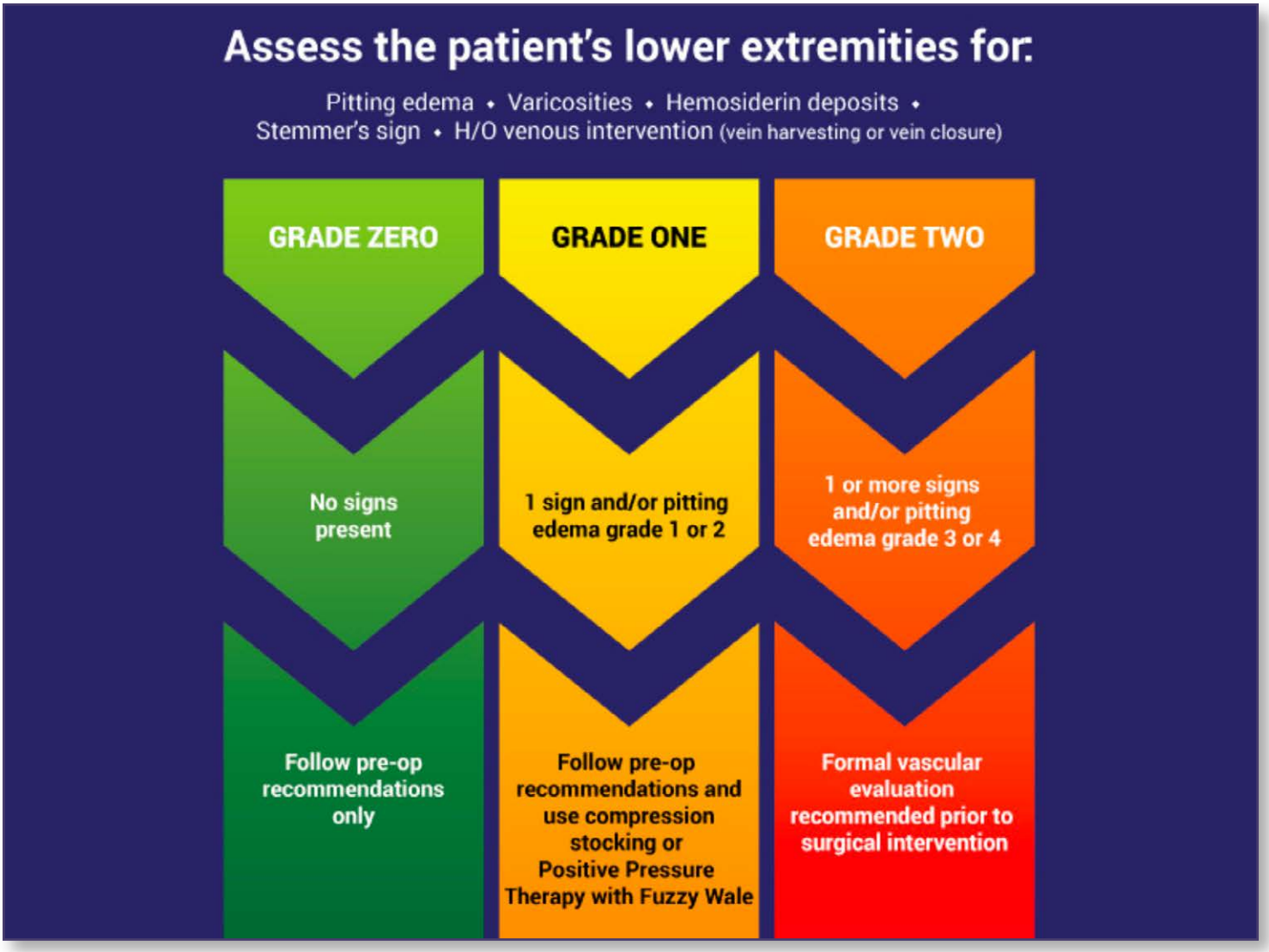

Figure 3. Patient groups based on preoperative risk assessment.

the suprapatellar pouch.

8. Consider applying compressive post-operative dressing or garment. The authors currently recommend the patented EdemaWear® product (Compression Dynamics) as it provides dermal interaction and light compression (8-12mmHg) using the thigh high "small-shaped" product for patients with thigh circumference less than 24" and the medium thigh high product for thighs measuring >24". It is easier for patients to apply, making compliance more likely and has characteristics not found in other devices on the market at present.

9. Leave the knee in 90 degrees flexion post-operatively until physical therapy for up to 6 hours maximum or until physical therapy is initiated to decrease bleeding and decrease downstream edema.

POST-OPERATIVE COURSE

Postop protocols vary widely from surgeon to surgeon, and few are comprehensive and multidisciplinary. Up until the initiation of Bundled Payments for Care Improvement (BPCI) and other bundled payment programs, many patients were discharged to an inpatient rehabilitation center followed by outpatient therapy for multiple more weeks. Home-based physical therapy has shown merit and can result in overall cost savings and improved patient satisfaction. The trend toward home-based therapy was significantly accelerated by the Covid pandemic. Contemporaneously, the opioid epidemic helped push innovation in the post-discharge arena with many surgeons redefining post-operative protocols.

The following protocol is what we believe to be the ideal post-op protocol to reduce swelling at the present time. It is the amalgamation of the authors' experiences with post-operative patients combined with the Loyd et al swelling curve chart as well as swelling interventions from the literature. Importantly, patients need education preoperatively regarding the protocol using written and video tutorials to explain why adherence leads to better outcomes and lower pain and swelling. Post-operative education in a daily method for the first 4 weeks after TKA describing normal findings and encouraging

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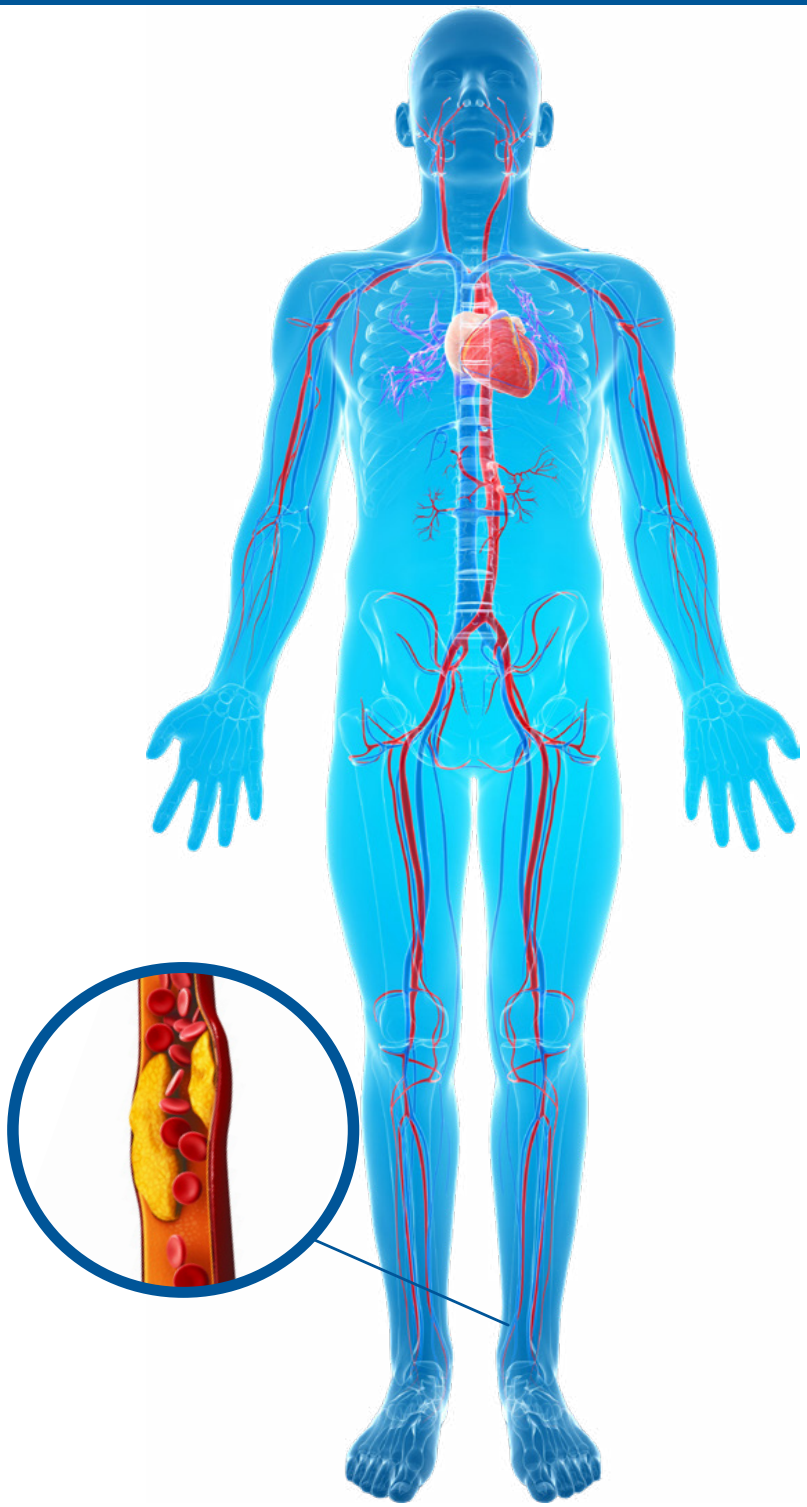

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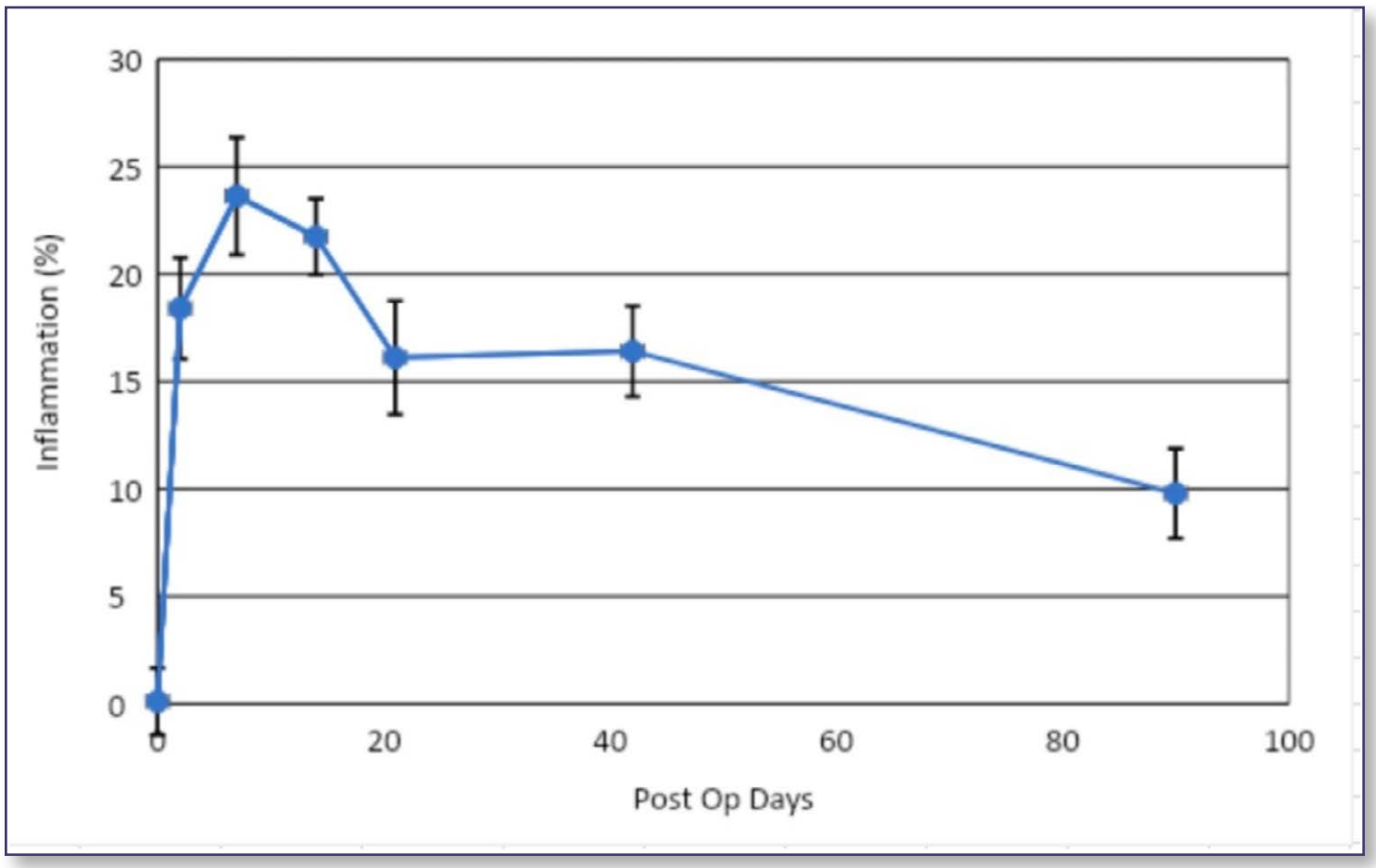

Figure 4. Lead author's data showing a roughly 20%/10% reduction in max/avg swelling at POD7 and 14

adherence to the protocol is the key to success.

HOME RECOVERY WEEKS 1 THRU 2

1. Tranexamic acid plan (3 additional doses q 4 hours OR one dose daily for 14 days). Multiple TXA TKA studies have been published without reports of patient seizures, but the lead author believes that a single daily dose for 14 days may be the best option.

2. Continue low sodium, anti-inflammatory diet.

3. Continue micronutrient supplements as previously detailed in the lifestyle modification section (amnio acids and micronized purified flavonoid fraction [MPFF]).

4. Employ an easy-to-use compression device or bandage such as longitudinal elastic stockinette or Velcro adjustable wrap covering the limb from foot to mid-thigh.

5. Physical therapy to include:

a. Limited weightbearing with assistive device for 1 week minimum

b. 5-8 minutes of range of motion exercises per hour while awake.

i. seated knee flexion/heel slides (10/hr)

ii. passive/active assisted knee extension (10/hr)

iii. 10 ankle pumps/hr

iv. walk 5-10 steps/hr

v. 10-minute heel hang 3x/day

c. Elevation of limb 40min/hour for first 10-14 days (toes above nose)

d. Ice 40 minutes/hour to surgical limb for first 10-14 days

e. Limit stair descent/ascent as much as possible

f. Isometric quadriceps sets in full extension, no isotonic or closed kinetic chain strengthening

g. Focus on ROM with minimum goal of 0-110 by POD #14

6. Step count

a. 750 steps/day maximum WEEK 1

b. 1200 steps/day maximum WEEK 2

7. Consider additional intervention for patients not meeting post-operative milestones (ROM <90 or >35% edema at POD 7, ROM <105 and edema >25% at POD #14) such as manual lymphatic drainage, sequential compression device and/or electrical muscle stimulation devices.

HOME RECOVERY WEEK 3-6

1. Continue anti-inflammatory diet

2. Continue micronutrient supplements and

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MPFF for 2-3 months to assist in edema reduction

3. Employ an easy-to-use compression device

4. Physical therapy to include:

a. progress away from assistive devices as tolerated

b. 5-8 minutes of range of motion exercises 6x/day

c. elevation and icing of limb 40min 3x/day at minimum, more if needed

d. isometric quadriceps sets in full extension, no isotonic or closed kinetic chain strengthening until 6 weeks post-op

e. focus on ROM—ideally achieving maximum intra-op best ROM by week 4.

5. Step count

a. 2000 steps/day maximum WEEK 3

b. 2750 steps/day maximum WEEK 4

c. 3500 steps/day maximum WEEK 5

d. 4500 steps/day maximum WEEK 6

e. progress by 1000 steps/day in each subsequent week letting pain/swelling be the guide

6. Consider additional intervention such as manual lymphatic drainage, sequential compression device, electrical muscle stimulation device if needed

7. Carefully consider returning to work prior to 6 weeks post-op. It is the authors' experience that this generally results in loss of range of motion and may lead to a less than optimal outcome for many patients. Consider patient progress and job requirements and how the job specifics will influence the potential for increased swelling (standing/stairs/lifting increases swelling) to develop the appropriate return to work plan.

CONCLUSION

While knee arthroplasty is routinely performed by orthopedic surgeons, an interdisciplinary approach to collaborative patient care can improve management and mitigation of the common malady termed post-operative swelling. Given the high incidence of post-operative swelling, it remains an enigma that upstream consistent therapy application remains largely absent in most orthopedic practices. The national rates of 30- and 90-day readmissions after primary TKA were 4% (95% CI, 3.8%-4.0%) and 7% (95% CI, 6.8%-7.2%), respectively. Decreasing these readmission rates may be possible by preoperative identification of potential peri-operative factors contributing to lymphatic dysfunction and post-operative edema development. This specifically allows upstream management and accelerated outcomes for pain control, decreased opioid use, improved ROM and decreasing the complications of SSI, DVT, and limited mobility. A positive impact on these negative post-operative outcomes has a high potential to improve patient satisfaction.

The identification, treatment, and long-term management of lymphedema and lower extremity edema is not a commonly taught discipline within medical education (allopathic, podiatric, physician assistants, nurse practitioners). Too often, this undiagnosed swelling tsunami negatively impacts surgical outcomes, leaving the surgical team with the challenge of treating "in the moment" the costly effects of a SSI, DVT, or a joint infection, while in fact the source of the issue existed long before the incision on the skin overlying the knee was performed.

Perioperative patient assessments and interventions can have multiple tangible effects on patient outcomes, limiting swelling, decreasing pain, and increasing joint function. Early intervention and dedicated post-operative protocols have proven to be beneficial in the lead author's clinical practice. Using the same bioelectrical impedance assessment measuring device and by applying some, but not all, of the principles outlined in this manuscript, the lead author has been able to demonstrate a roughly 20%/10% reduction in max/avg swelling at POD7 and 14. (Figure 4—Y axis BIA, X axis post-op days)

Upstream thinking and checklist applications preoperatively can vastly improve TKA outcomes for the orthopedic surgical teams, though most importantly for the patients and families we serve. To successfully achieve this goal, the authors suggest the following "call to action" steps:

1. Develop a standardized swelling grading system for the TKA population

2. Validation of cost-effective swelling measurement devices and accompanying reference curves

3. Development of a multicenter data registry to compile swelling data based on perioperative protocols

4. Set the following clinical goals

a. Identification of those patients at-risk preoperatively

b. Develop a consensus on optimal interventions to reduce swelling and limb volume

c. Follow RTW (Return to Work) data, opioid usage, 90-day costs, and 90-day recidivism

d. Determine current actual secondary lymphedema occurrences related to TKA and then determine whether or not aggressive intervention for all patients is beneficial

e. Prove/disprove that swelling reduction yields faster RTW, lower opioid use, decrease complications and/ or lower 90-day costs

Preparation is the key to success. Optimizing patient outcomes following knee replacement requires proactively managing the expected post-operative total knee swelling tsunami.

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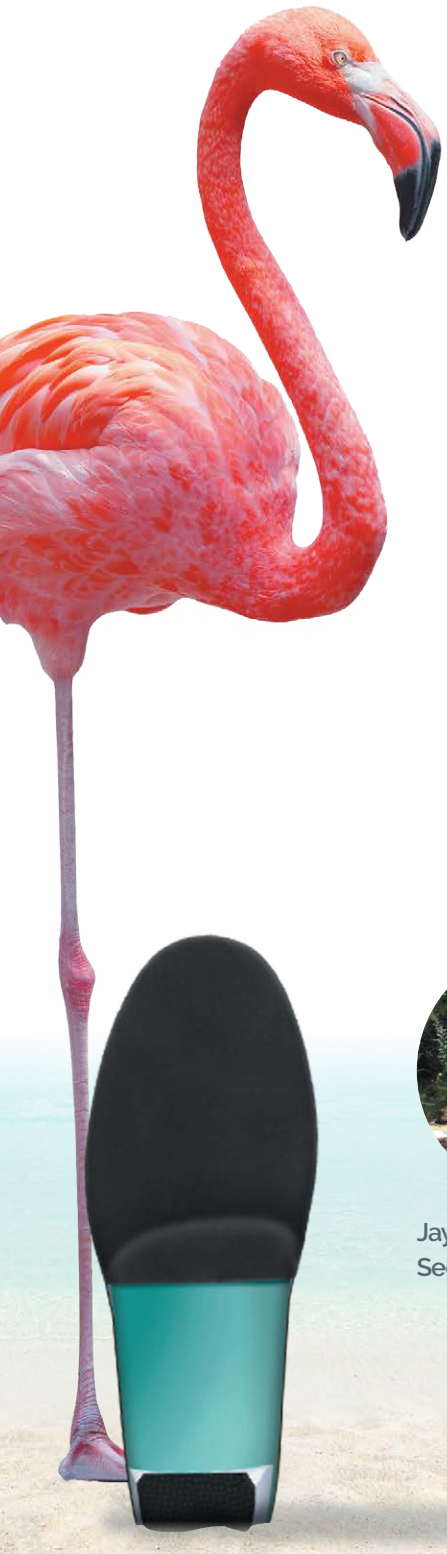

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Presentation of an Intelligent Plantar Pressure Offloading System

By Sarah L. Hemler, Sofia Lydia Ntella, Kenny Jeanmonod, Christian Köchli, Bhawnath Tiwari, Yoan Civet, Yves Perriard, Zoltan Pataky

A need exists for user-friendly, offloading footwear that reduces high plantar pressure to prevent and treat foot ulcers.

Introduction

The high prevalence of lower extremity ulceration and amputation in people with diabetes is strongly linked to difficulties in achieving and maintaining a reduction of high plantar pressures (PPs), which remains an important risk factor. The effectiveness of current offloading footwear is opposed in part by poor patient adherence to these interventions, which have an impact on everyday living activities of patients. Moreover, the offloading devices currently available utilize primarily passive techniques, whereas PP distribution is a dynamically changing process with frequent shifts of high PP areas under different areas of the foot. Thus, there is a need for pressure offloading footwear capable of regularly and autonomously adapting to PPs of people with diabetes. The aim of this article is to present a review of the advancements toward this goal made by a multi-centered team from the Geneva University Hospitals (HUG), University of Geneva (UNIGE), and École Polytechnique Fédérale de Lausanne (EPFL). The team is developing intelligent offloading footwear that is designed to use a pressure feedback loop to automatically sense and redistribute PPs to prevent and treat diabetic foot ulcers.

Figure 1. Schematic of the outer and inner (removable insole system) parts of the shoe.

The study authors are creating this intelligent footwear with an auto-contouring insole, which will continuously read PPs and adapt its shape in the forefoot and heel regions to redistribute high PP areas. The PP-redistribution process is to be performed consistently while the footwear is being worn. To improve adherence, the footwear is designed to resemble a conventional shoe worn by patients in everyday life. Preliminary pressure offloading and user perceptions assessments in people without and with diabetes, respectively, exhibit encouraging results for the future directions of the footwear. Overall, this intelligent footwear is designed to prevent and treat DFUs while enhancing patient usability for the ultimate prevention of lower limb amputations.

Intelligent Insole System

The intelligent footwear presented in this article consists of outer and inner (removable insole system) parts (Figure 1). Within the removable insole system, there is a pressure-sensing system coupled with miniaturized pressure-offloading modules. The system is designed to automatically detect the location of high PPs and correspondingly adjust the contour of the insole according to the user's individual pressure needs (Figure 2).

Inside the footwear, there is a removable, intelligent insole system (Figure 1 - inner), which is made of several components working together to redistribute high PP. The system consists of a housing insole in which the pressure-offloading modules, batteries, and control electronics rest, and above which the comfort insole and

This article has been excerpted from "Intelligent plantar pressure offloading for the prevention of diabetic foot ulcers and amputations," Front. Endocrinol. 14:1166513. doi: 10.3389/fendo.2023.1166513. Editing has occurred, including the renumbering or removal of tables and figures, and references have been removed for brevity. Use is per CC BY.

Continued on page 51

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Continued from page 49

pressure-sensing insole sit. The pressure-offloading modules operate independently and are connected to the control electronics via flex PCB through channels on the underside of the housing insole. Each pressure-offloading module consists of 3 primary parts: 1) Top - deformable bellow filled with magnetorheological (MR) fluid and top plug, 2) Middle – flow channels and valve, and 3) Bottom - deformable reflow membrane and auxiliary reservoir (Figure 3). The pressure-sensing insole consists of piezoresistive sensors (dynamic range: 0-800kPa; sampling frequency: 200 Hz) aligned directly over each corresponding pressure-offloading module. The thin-protective layer is the interface between the foot and the removable insole system with a goal of providing a moisture-absorbing and comfortable barrier between the mechanics and the foot.

The design of the removable insole system is such that when pressure is applied by the foot to the area above a module (eg, from standing or walking), the module will be triggered to operate in 1 of 2 states: 1) valve *off*, or 2) valve *on*. When the valve is *off*, the MR material remains in its fluid state and can move through the flow channels and the annular gap in the valve to be dispensed into the auxiliary reservoir (Figure 4A). The resultant movement of the MR material results in a maximum module compression of 2.5mm. When the force is removed, the reflow membrane forces the fluid to return into the deformable bellow above. However, when the valve is *on*, the exciting magnetic field (magnetic flux)

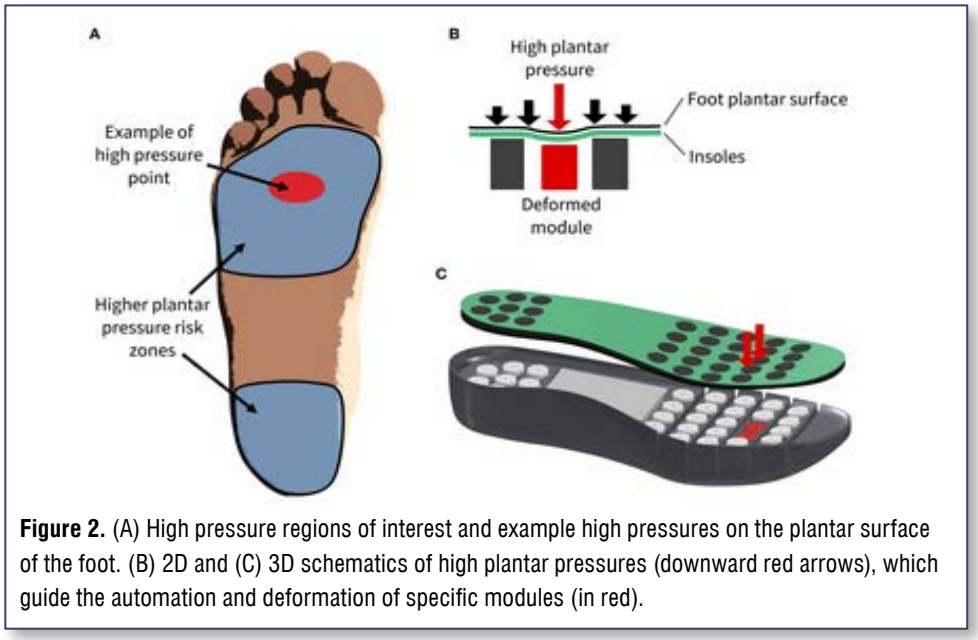

Figure 2. (A) High pressure regions of interest and example high pressures on the plantar surface of the foot. (B) 2D and (C) 3D schematics of high plantar pressures (downward red arrows), which guide the automation and deformation of specific modules (in red).

Continued on page 53

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Continued from page 51

causes the MR material to solidify in the valve channels and prevents the fluid from traveling to the auxiliary reservoir (Figure 4B). In the *on* state, there is a maximum module compression of 0.5 mm due to mechanical stabilization.

A baseline decision algorithm (based on the maximum peak pressure sensed above a module) will be employed to determine which modules will be turned *off* according to the user's pressure needs. There will be a set number of modules that may be turned *off* at 1 time (Xred) to redistribute pressures. In the future, a trained and validated machine learning algorithm will be used to intelligently control which modules are *off* or *on*.

The design of the inner components is based on previous research and tailored to be suitable for footwear conditions. The size of the region above each module that can be deformed to achieve the intended pressure redistribution is a compromise between the complexity of the control system (in terms of both the hardware and the algorithm) and the accuracy in the determination of the magnitude and location of the peak PPs. In this respect, previous research underlined that in most cases, a sensor having a surface area of 1cm^2 is sufficient (accuracy of ≈ 90%) to define the position and the proportions of the peaks of PPs. Thus, the reference value for the surface area exposed to loading (above each pressure-offloading module) is fixed to 1.6cm^2, being a compromise between sufficient sensing/actuation resolution and system complexity. Each of the modules is waterproof and future designs will incorporate this same quality for all other electrical components. Further tests will also address safety features such as componentry heating and falls risk due to the elevated height of the footwear (measurement of ground to foot plantar height = 6.3cm).

The module's performance and the system's ability to reduce PP across the insole have been tested. In the module's *on* state, it could sustain a load of 55N, which corresponds to 357kPa with a residual deformation of only 0.5mm. Thus, the performance of the module while *on* meets performance standards; with a PP of this magnitude, the module would likely be turned *off* to offload that region to prevent a foot ulcer. When the module was turned *off* during the tests, the module instantaneously deformed to 1.5mm which was the maximum deformation allowed for this test, and the force was reduced to 30N (corresponding to 214kPa). This final force was linked to the features of the deformable bellow and the hydraulic resistance. Furthermore, a preliminary walking study with 4 healthy, male adults was conducted to assess the PP reduction. Participants wore the prototype of the footwear with surrogate modules as they walked 10m at a comfortable walking speed. The deformation of the module between the *on* and *off* states allowed for a maximum reduction of PP of 18–24% directly over the module and 6–10% reduction in the area around the module when the peak starting PP ranged from 273–607kPa. Furthermore, for cases with an initial peak PP above 400kPa, there was a 20–32% reduction in peak PP.

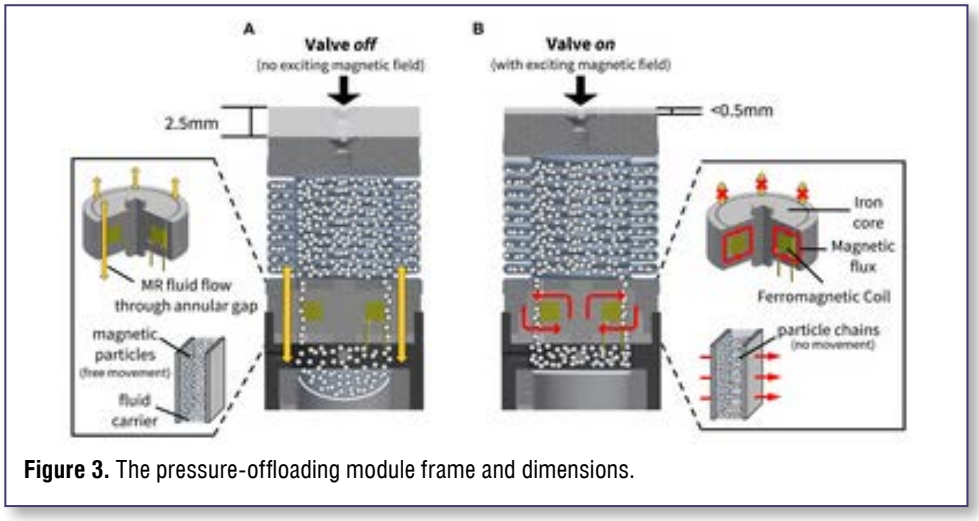

Figure 3. The pressure-offloading module frame and dimensions.

Design for Patient Use and Adherence

Adherence is an essential aspect of medical device use. To understand the user perceptions and potential adherence barriers to this footwear, a pilot, in-person questionnaire and a larger, online questionnaire were conducted concerning the intelligent footwear presented in this article. Across the 2 questionnaires, people with diabetes (n=48), caregivers of people with diabetes (n=10), and healthcare professionals working with people with diabetes (n=65) from 30

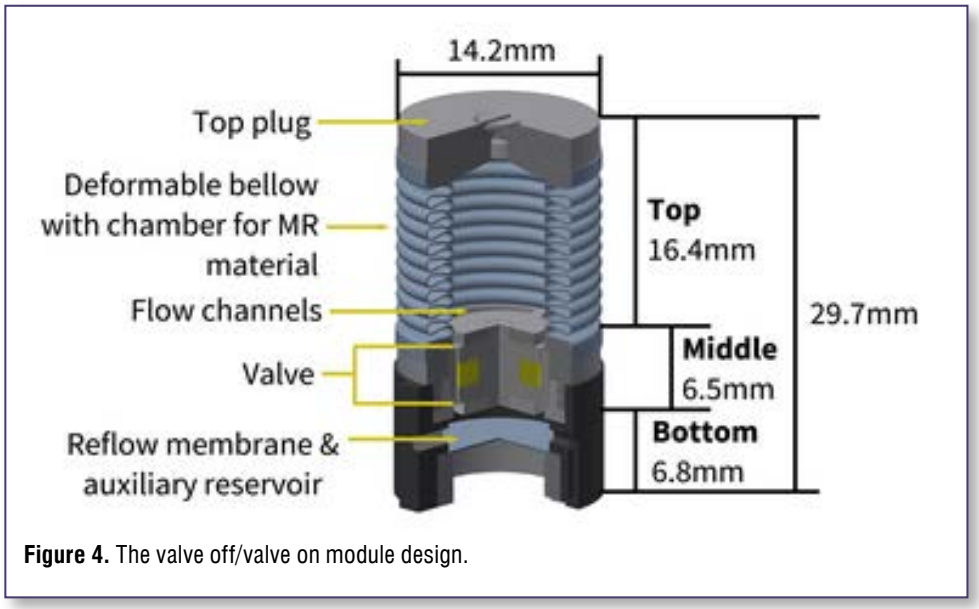

Figure 4. The valve off/valve on module design.

Continued on page 55

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Continued from page 53

countries on 6 continents gave important insight regarding the functionality, potential adherence, self-image, and aesthetics of the footwear. The questionnaires addressed the potential use and barriers to using this intelligent footwear based on previous work; questionnaires were administered and processed by the researchers with aid from clinicians. Generally, 95% of respondents thought that it would be beneficial to use the footwear and over 70% in each role stated that they would use the footwear or recommend it to their patients when available. Several parts of the questionnaire addressed self-image while wearing the footwear and perceived efficacy of using the footwear. The results informed aspects of this intelligent footwear design such as implementation of a sports shoe design which was the most preferred style among others. Future designs of this footwear will include styles of shoes for all occasions for men and women.

One of the limitations of other "smart" offloading footwear is the need for the patient to interact with a device and alter gait to relieve areas of high PPs. To lessen the required user-involvement and thus increase the likelihood of adherence, this intelligent footwear will have an autonomous, pressure-redistribution algorithm. As the individual wears the shoes, the insole will regularly read the PPs and automatically change the contour of the insole eliminating the need for the patient to interact directly with the device during the day. The only required interaction is the need to charge the shoes each day after wear. With a current of 0.7A, activating the *on* state of a module (200 ms) for 5,000 steps (recommended daily step count per foot for people with diabetes) would require 195mAh per module. One shoe of size EU 43 has 31 modules, which would require a total of ~6,000mAh. Therefore, a battery with 9,000mAh of energy (footwear has the capacity to house two batteries) is sufficient to provide a day's worth of charge for each shoe. To apprehend complications with charging that could possibly reduce adherence, the footwear is designed to have a charging mechanism similar to technology that users may already operate (eg, cellphones, tablets). Furthermore, assessments of other adherence parameters have been performed and are ongoing in order to increase footwear adherence.

Conclusion

The presented intelligent footwear is designed to automatically and autonomously redistribute high PP under the feet of people with diabetes and specifically those with neuropathy. The mechanisms to offload the pressures use an intelligent, removable insole system which will actively adapt to the person's foot while they are wearing the intelligent footwear. The footwear is designed to improve adherence through simplicity of user involvement and aesthetics resembling footwear not associated with a medical condition. Future versions will improve upon the technical and human factors aspects of the footwear to enhance flexibility, durability, battery life, usability, and aesthetics. The technological and adherence aspects of the footwear will continue to be tested and improved through clinical trials. ler

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MEDIUM		9-11	8.5-10	
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FIBERGLASS UNIBODY PROSTHETIC FOOT

Building on the success of META® Shock X, WillowWood has launched the Fiberglass META® Shock X. META feet combine responsive energy return with balance, stability, and impact protection, and feature the industry's first unibody platform, free of hardware for a minimal and light weight, but durable design. Fiberglass META Shock X has an ultra-low build height—just under 5.5" (138mm)—which allows versatile fitting options for a variety of limb lengths. This prosthetic foot features an integrated shock unit atop the fiberglass plate, combining vertical impact protection and torsional rotation inside the smallest form factor on the market. The dual-action shock unit boasts category-leading 40 degrees of rotation and 8mm of compression. PDAC approved for L5987 and L5984.

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PASSIVE PROSTHETIC ANKLE DESIGNED TO REDUCE FALLS

A team from Northeastern University, Boston, has designed a passive prosthetic ankle that lifts the toe during swing phase (to reduce falls) while providing full stance phase energy storage and return. The ankle recycles energy captured at heel strike to lift the toe during the next swing phase. It uses a novel linkage mechanism that locks the ankle during stance phase, allowing the foot to store and release energy. The mechanism works by moving a remote center of rotation (red dot in figure) to lock the joint during stance phase and dorsiflex the ankle in swing phase. A small compression spring dorsiflexes the ankle in swing. The ankle improved foot clearance by 13mm, which is enough to make a clinically significant difference in the number of falls experienced by real-world users.

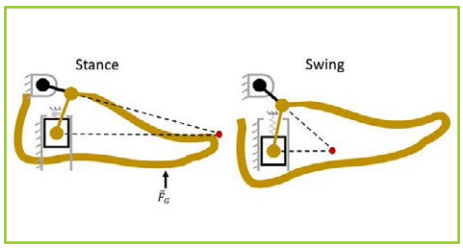

Image courtesy of Harrison Bartlett, PhD, Little Room Innovations, Ann Arbor, MI, via Twitter.

FOOT ICE WRAP

Cool Relief has expanded its product range to include the Soft Gel Foot Ice Wrap for the treatment of pain, muscle inflammation, and swelling. The company's proprietary gel pack design with Inner Ice Technology is engineered to stay colder for longer while still providing flexibility and range of movement. The gel ice wrap can be used to treat foot pain, swelling, ankle sprains, plantar fasciitis, bursitis, heel pain, and post-surgery treatment. The adjustable elastic straps allow the ice wrap to fit most people comfortably, covering the ankle and foot to provide continuous cold compression therapy deep into injured areas. If heat treatment is required, the wrap insert can also be warmed in the microwave. The product, with its removable inserts, is convenient for coaches and athletes to keep on hand to treat foot and ankle injuries immediately.

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PhysioPedal is a cordless, light weight, and portable self-pedaling cycling machine. Designed to support Assisted Cycle Therapy, the PhysioPedal helps the elderly, the injured, and those with limited voluntary movement improve their health outcomes and overall wellness. Its features allow users to perform exercises with the aid of a motor. The self-powered function allows those who are physically disabled to start passive cycling. All they need to do is step into the device, and the battery-powered pedals will handle the rest. Studies have clinically proven to increase users' ability to exert themselves longer and at higher intensities than they would be able to do on their own. This can lead to fitness, improved blood circulation, mobility, and healthy lifestyle changes. The PhysioPedal comes with a built-

in safety function and oversized pedals. Other notable features include forward and reverse operation, ease of use, and durability.

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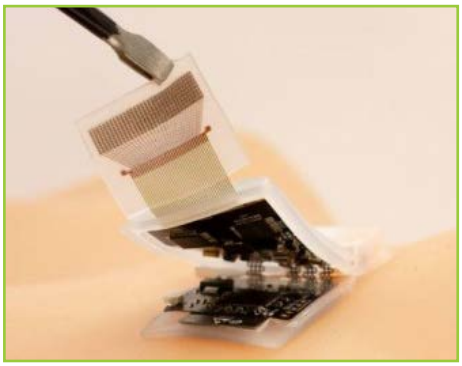
WIRELESS WEARABLE ULTRASOUND PATCH DEVELOPED

Wearable ultrasound patches have the potential to revolutionize health care, facilitating the remote monitoring of critical physiological functions in the comfort of a patient's home. But most patches in development have a major limitation: they require cables to power the device and transmit the ultrasound data, physically tethering the wearer to a control system. That is, until now.

A fully wireless ultrasound patch that can continuously track critical vital signals such as heart rate and blood pressure was pioneered by Sheng Xu, PhD, an associate professor and Jacobs Faculty Scholar at the University of California San Diego (UC San Diego). The patch, which can capture detailed medical information and wirelessly transmit the data to a smart device (such as a laptop or smartphone), could represent a major step forward in at-home health care technology.



A view of the ultrasound probe and the interior of the circuit. Image courtesy of Xu lab at UC San Diego.

The ultrasound system is composed of a probe, a circuit, and a battery. The probe is attached to a flexible circuit, which activates the ultrasound transducers, collects the ultrasound echoes, amplifies and filters these echoes, and transmits the digitized signal to a terminal device. The entire system is powered by a commercial rechargeable lithium polymer battery.

While the device was mainly evaluated on its ability to monitor cardiovascular functions, the researchers also demonstrated that the patch can be applied to the abdomen for diaphragm monitoring or to limbs for peripheral artery monitoring. "The system holds the potential to perform measurements at multiple spots in the body, and we can easily tailor the probe design to fit diverse tissue monitoring requirements," said Xu.

NEW POROUS ITERATION OF ANATOMIC KEELED TIBIA

The Persona® OsseoTi® Keel Tibia for cementless knee replacement is the latest addition to the clinically proven Persona Knee System by Zimmer Biomet. This product features a new porous version of the Persona anatomic tibia with the company's OsseoTi Porous Metal Technology, which uses anatomical data in combination with 3D printing technology to build a structure that directly mimics the architecture of human cancellous—or spongey—bone. This material is combined with a keeled design to deliver stable initial and biological fixation. Key features of Persona OsseoTi include an anatomic tibia for less micromotion and optimal bone coverage and 3D-printed, porous OsseoTi technology for biological fixation. The Persona OsseoTi Keel Tibia is also complemented with a new cemented implant option to enable seamless versatility for the surgeon during the procedure.

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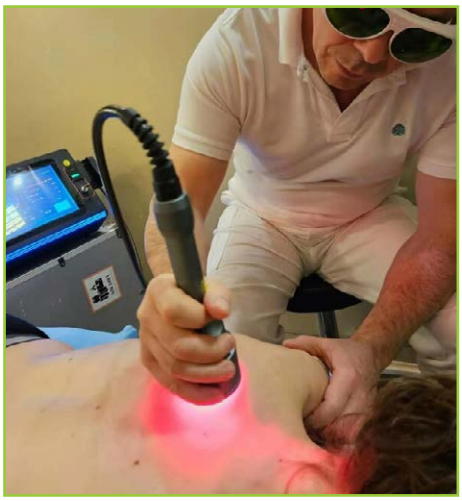
LASER AND SHOCKWAVE THERAPY SYSTEMS



Smart Physiotherapy Systems utilize cutting-edge technology to solve pain, inflammation, wound healing, and soft tissue repair. These artificial intelligence–integrated systems offer a 1-stop solution for pain patients from home to professional markets. Smart/Smart Ice laser therapy system offers 4 working modes and 4 wavelengths(635nm/810nm/915nm/980nm) and can penetrate up to 15cm into the subcutaneous tissue. It's designed for the treatment of deep tissue penetration. PowerCure/PowerCure Pro is a portable handheld laser device that uses 808nm and 650nm low-level diode laser with power up to 1060mW/1300mW, which can be used to stop pain and heal its source. SWAVE-200 shockwave therapy machine was developed to treat tendinopathy throughout the musculoskeletal system. This therapeutic apparatus offers a helping hand toward optimal health and can alleviate pain in just 10 minutes.

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FRACTURE DETECTION DEVICE IN TESTING PHASE

People who fracture their tibia usually get hardware surgically implanted to hold the bone in place. After about 6 months, 10% of patients are diagnosed with a non-union fracture; they require additional surgery to implant new hardware. The standard method to diagnose a non-union fracture is through x-ray, but x-rays cannot capture the subtle mechanical details of how well bone tissue is mineralizing and stiffening soon after the injury. What if there was a way this stiffening could be detected much earlier than 6 months post-injury, so doctors could intervene faster?

Nearly 2 decades ago, Colorado State University biomedical researcher Christian Puttlitz first put his mind to this question, wondering whether innovations in engineering and biomechanics could provide insight into the healing potential of bone. From that inspiration sparked a series of experiments that led to a present partnership with UC Health doctors and patients, who are currently helping test a fracture-detection device Puttlitz and his lab have been working on for the last several years.

CSU research scientist Kevin Labus demonstrates the tibia fracture device, now being used in a study with patients.

The device consists of an enclosure that applies gentle, non-painful pressure on the patient's fracture site. An external radio antenna sensor measures deflection under loading, and the sensor is calibrated to measure bending stiffness of the fracture callus. Down to 10-micron precision—with much more accuracy and detail than an x-ray—the device lets the researchers assign a value to how well the bone is stiffening—an indication of normal healing—starting about 6 weeks after the initial injury. That's much sooner than the 6-month mark patients usually have to wait to find out whether their fracture is mending properly.

PERSONALIZED TRAIL RUNNING SHOES

GS:PGH is a limited-edition highly cushioned, customizable shoe designed for maximum performance for trail running. This is a durable, high stacked, maximally cushioned shoe built for longer distance training days and races. It features the PerformFit™ Wrap activated by the BOA® Fit System featuring dual-dial Li2, allowing for zonal control and a connected, secure fit. This fourth commission features a unique beaded HTPU outer midsole with a removable, blended Pebax midsole section. Together, the full 37/30mm midsole stack provides high energy return without sacrificing compression, increasing the lifespan of the shoe beyond that of standard trail running footwear. A spacer mesh upper with strategic, high-tenacity fiber reinforcements provides breathability and security, while the Michelin Fiber Lite outsole ensures a sticky grip over any surface. An optional Carbitex GearFlex carbon fiber plate adds propulsion and protection, and is sold separately for the ultimate customization.

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Loceryl® Enamel is an antifungal therapeutic enamel. The medication can be used as sole therapy in initial cases of nail mycosis or cases associated with a systemic antifungal, also acting as an adjuvant therapy. Loceryl Enamel contains amorolfine, an antifungal active ingredient that acts in the elimination of

2 fungi that cause infection. This therapeutic polish penetrates even the deepest layers of the nails, with just one application, eliminating the fungus over the next 2 to 7 days, and can be used in this way once a week. In addition to its long-lasting effect, it combats various kinds of fungi that cause mycosis. This therapeutic nail polish also allows the use of cosmetic nail polishes without loss of product effectiveness.

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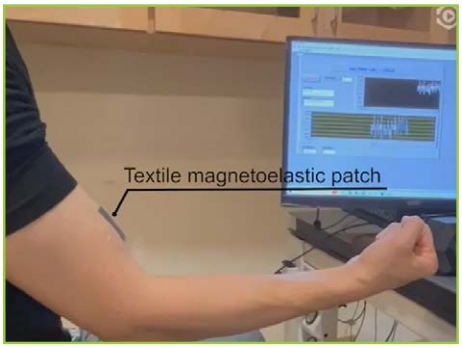
NANOMAGNET-EQUIPPED PATCH DETECTS MUSCLE MOVEMENT



The smart textile can convert muscle movements into distinct electrical signals. Image courtesy of Jun Chen.

Using nanomagnet composites and conductive yarn, scientists at the University of California, Los Angeles have invented a smart textile that can sense and measure body movements—from muscles flexing to veins pulsing. The device is self-powered, stretchy (extending 3.5 times in length), durable, and waterproof, and it can be made with a sewing machine for a few dollars. It may one day aid clinicians in assessing muscle injuries and support patients' recovery.

The smart textile is not technically made of fabric but has a cloth-like texture. It's made of a nanomagnet-filled rubber patch that is roughly the size of 2 postage stamps. Using a sewing machine, the researchers stitched silver-coated conductive yarn onto the patch in a coil design. Mechanical forces, such as a finger tap, can deform the pattern of magnetic fields within the rubber, thus creating an electric current through the yarn.

The device is not only sensitive, but it's also precise, detailing body movements down to each muscle group. Attaching the device to different body parts, researchers distinctly measured throat movements while drinking water, ankle movements while walking, and even monitored a person's pulse from their wrist. When affixed to a person's bicep, the device can show whether they are bending their arm or gripping their fist and to what degree or force. Based on these types of information, a clinician can find the Goldilocks zones to prevent over-excursion and encourage moderate activities, tailoring recovery and physical therapy goals for their patients.

BRAIN-COMPUTER-LEG INTERFACE FOR POST-STROKE LOWER LIMB REHABILITATION

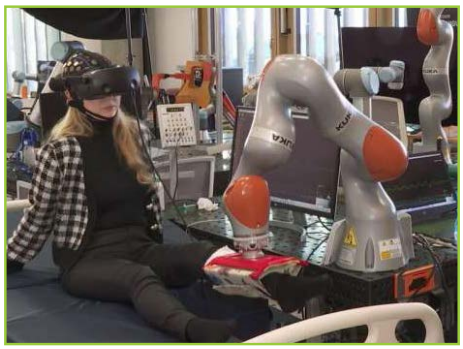


Image courtesy of the Skolkovo Institute of Technology.

Researchers at the Skolkovo Institute of Technology, Russia, have devised a novel method for leg rehabilitation after injury or stroke that uses a brain-computer interface (BCI) and electrical stimulation of the spine delivered through the skin. Created by scientists from the institute's neuro and engineering centers, the solution incorporates virtual reality (VR) and enables paralyzed patients to regain control of their lower limbs and master natural movements by reestablishing the connection between motion and intention.

The neural interface used by the researchers is an off-the-shelf device, a cap with electrodes picking up the electrical activity of the brain. However, the software part has been augmented by the scientists, who modified the protocol responsible for identifying an intention to move. The robot is an industrial collaborative manipulator equipped with highly accurate torque sensors. It is capable of guiding the patient's leg in the direction corresponding to the goal they choose in the VR. Specially written software enables the robot to emulate natural limb movements, reproducing the trajectory that the leg of a healthy person would follow.

The VR goggles display multiple targets that a patient attempts to move their leg toward. Once the intended motion has been read out from the brain by the BCI and the robot performs the motion, the patient can actually see their limb moving in the VR, but the robotic assistant is invisible. This causes the motion to be perceived as initiated and controlled by the brain, helping bridge the brain-muscle divide.

The last component of the system is non-invasive electrical stimulation of the spinal cord through electrodes taped to the back of the patient. The idea behind this is that neurons might be getting so-called subthreshold signals from the brain that are not strong enough to result in activation. External electrical stimulation allows this barrier to be overcome and leads to the formation of reliable neural connections that eventually will function without this artificial support.

EFFECTS OF RUNNING ON THE DEVELOPMENT OF KNEE OSTEOARTHRITIS

Reference: Dhillon et al. Orth J Sport Med 2023

Designed by @YLMSportScience

KINESPORT

17 studies, with 7194 runners and 6947 nonrunners were included in this meta-analysis to determine the effects of running on the development of knee osteoarthritis.

Runner group

Mean age: 56 years
Mean follow-up time: 56 months

VS

Non-runner group

Mean age: 62 years
Mean follow-up time: 100 months

Images provided by PresenterMedia

RESULTS

A There was a higher prevalence of knee pain in the non-runner group

B Although 1 study found a higher prevalence of osteophytes in the tibiofemoral and patellofemoral joints within the runner group, multiple studies found no significant differences in the prevalence of radiographic knee osteoarthritis or cartilage thickness on MRI between runners and non-runners

C One study found higher risk of knee osteoarthritis progressing to total knee replacement among non-runners :

CONCLUSION

In the short term, running is not associated with worsening presence of knee pains or radiological signs of knee osteoarthritis and may be protective against generalized knee pain

Source: Dhillon J, Kraeutler MJ, Belk JW, et al. Effects of running on the development of knee osteoarthritis: an updated systematic review at short-term follow-up. Orthop J Sports Med. 2023;11(3):23259671231152900. doi: 10.1177/23259671231152900.

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