Methodology for Use of a Neuroprosthetic to Reduce Plantar Pressure: Applications in Patients with Diabetic Foot Disease

Manish Bharara, Ph.D.,[1] Bijan Najafi, Ph.D.,[2] and David G. Armstrong, DPM, M.D., Ph.D.[1]

Foot-related complications remain among the most common causes of hospitalization, ulceration, amputation, and reduced productivity in people with diabetes.[1–3] The consistent entry point in this process involves neuropathy, which, with repetitive normal and shear stress over a prominent area, may lead to inflammation, ulceration, infection, and ultimately, amputation. Due to glycosylation of soft tissues and reduced activity, people with diabetes are at higher risk for developing foot-related deformities, which amplify this cycle.[4–6] This is particularly true in the Achilles tendon,[4–8] which leads to equinus deformity, increasing forefoot pressure.

In addition to nonsurgical options, such as shoes, insoles, and braces, clinicians have employed prophylactic and curative procedures to prevent or heal wounds, respectively.[9,10] Clinical researchers have suggested lengthening of the Achilles tendon or gastrocnemius complex as a potentially effective means of reducing pressure, improving healing time, and potentially reducing risk for ulceration or reulceration.[11–17]

Extremity-focused neuroprosthetic devices have increased in popularity in the treatment of various neurological conditions, most notably in treatment of foot drop following cerebrovascular events. The purpose of this brief report was to evaluate the ability of a neuroprosthetic or functional electrical stimulator[18–20] (WalkAide®, Innovative Neurotronics, Austin, TX) to modulate plantar pressure in the foot.

The functional electrical stimulation (FES)-based intervention include a single channel electrical stimulator that causes dorsiflexion through stimulating peroneal nerve. The stimulator is linked to a computer via Bluetooth® and also includes a heel tilt sensor for triggering. The authors designed a repeated-measures human performance laboratory study to evaluate four different device settings through in-shoe pressure measurements using the F-Scan® (Tekscan, Boston, MA) in-shoe plantar pressure measurement system. The FES device was connected to the right foot for the study subject. The study was conducted on a single healthy volunteer, and five gait cycles per setting were used for data collection. The study subject walked, shod condition, at normal gait speed with set stimulation parameters per the WalkAide device setting. Plantar foot contact area and the vertical ground reaction force were collected at 100 Hz.

Three outcomes were extracted using this toolbox, including (1) regression factor index (RFI), (2) magnitude of second peak plantar pressure, and (3) relative location of second peak pressure as a percentage of the stance phase. For

Author Affiliations: [1]Southern Arizona Limb Salvage Alliance, University of Arizona, College of Medicine, Tucson, Arizona; and [2]Center for Lower Extremity Ambulatory Research, Rosalind Franklin University of Medicine & Science, North Chicago, Illinois

Abbreviations: (FES) functional electrical stimulation, (RFI) regression factor index

Keywords: diabetic foot ulcers, functional electrical stimulation, neuroprosthetics, plantar pressure, wound healing

Corresponding Author: Manish Bharara, Ph.D., Southern Arizona Limb Salvage Alliance (SALSA), University of Arizona, College of Medicine, 1501 N Campbell Ave, Room 4318, Tucson, AZ 85724; email address manish.bharara@gmail.com

extracting the outcomes, we calculated the average of at least four steps taken from the middle of the walking trials, during gait steady state, when each person's gait was closest to a steady gait for each foot.

To summarize the algorithm, maximum pressure for each time sample was extracted, thereby creating a 'peak pressure' pattern for each step. Then, the time of toe-off and heel strike was detected by a peak detection algorithm, which estimated the gradient of peak pressure pattern. This allows separating each cycle as well as estimating the stance duration. The pattern of peak pressure was then time-normalized by setting heel contact to 0%, toe-off to 100%, and linearly interpolating to a fixed number of samples. This process was repeated for a certain number of steps (in this study, minimum four steps), and then the mean trajectory was computed for use in subsequent analysis. The magnitude of location of the second peak pressure as a percentage of stance time was estimated using the mean trajectory and a peak detection algorithm. This approach allows moderating the effect of variable stance duration in multiple gait cycles across pressure profiles of different steps. Estimation of RFI was explained in detail in our previous publication.[21]

Using the approach explained earlier, the dynamic of plantar loading was quantified while using four different device settings: standard drop foot, extended drop foot, maximum pulse width intensity, and soft pulse. The objective was to explore the best setting, which would yield the best plantar loading pattern. We assumed that an idea pattern represents an RFI closer to +1, a lower peak pressure magnitude, a better symmetry between right and left stance duration, and an earlier occurrence of second plantar pressure.

Table 1 summarizes the repeated-measures test[22] for 'baseline' condition (standard drop foot setting) for repeatability of plantar pressure and gait parameters assessment.

The standard drop foot setting was found to achieve the best results for pressure reduction based on the three outcomes studied, as described above. The authors noted a peak pressure reduction of 34% at the great toe, 11% at the first metatarsal head, and 19% for lesser toes. Second peak of plantar pressure had a 28% reduction from baseline for this setting. The location of the second peak was 86% versus 83% of stance time for baseline versus intervention. The second peak amplitude decreases 28% for the standard drop foot setting, versus 60% for the extended drop foot setting. This is equivalent to a dose response in a drug study. Higher reduction in the affected foot is available at the cost of reduction in the RFI factor and longer stance duration.

Mobility is an important daily requirement, so much so that any disruption to it severely degrades our perceived quality of life. Evidence suggests that surgical interventions such as Achilles tendon lengthening achieve 27–32% pressure reduction at the forefoot region.[11,23] This effect is temporary and may lead to high baseline pressures within 9 months of treatment. Commercially available FES systems, such as the one presented in this study (WalkAide), make it possible for an increasingly growing number of clinical researchers to evaluate the mobility training paradigm for diabetic lower extremity disorders.

Table 1.
Summary of the Repeated-Measures Tests for Plantar Pressure and Gait Parameters

	Right				Left			
	RFI	Second peak amplitude (KPa)	Second peak location (%)	Stance (seconds)	RFI	Second peak amplitude (KPa)	Second peak location (%)	Stance (seconds)
	0.37	664.2 ± 25.5	87 ± 0	0.74 ± 0.02	0.76	781.1 ± 22.1	84 ± 0	0.76 ± 0.0
	0.67	596.4 ± 39.2	87 ± 0.0	0.76 ± 0.0	0.67	622 ± 59.2	87 ± 1.0	0.78 ± 1.0
	0.55	631.9 ± 68.8	87 ± 1	0.78 ± 0.01	0.57	683 ± 62	87 ± 1	0.79 ± 0.02
	0.66	523.5 ± 103.8	87 ± 1	0.78 ± 0.02	0.73	740.5 ± 19.1	86 ± 2	0.78 ± 0.02
	0.59	636.2 ± 144	88 ± 0	0.77 ± 0.05	0.47	621.2 ± 34	87 ± 0	0.73 ± 0.01
Average of baseline	0.57 ± 0.12	610 ± 54	87.2 ± 0.4	0.77 ± 0.02	0.64±0.12	689.8 ± 71	86 ± 1.3	0.76 ± 0.04

We have provided efficacy data for the FES device (WalkAide) for nonsurgical pressure reduction equivalent to surgical interventions. This is achieved by using electrical stimulation to fire upon foot strike to reduce pressure in the forefoot by maximizing available dorsiflexion. This report presents results from a single case study on a healthy subject and provides a methodology for data analysis using objective outcomes. Further research is required to understand the benefits of this technology and proposed methodology in patients with diabetes and lower extremity complications.

References:

1. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA. 2005;293(2):217–28.
2. Vamos EP, Bottle A, Majeed A, Millett C. Trends in lower extremity amputations in people with and without diabetes in England, 1996–2005. Diabetes Res Clin Pract. 2010;87(2):275–82.
3. Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease. Lancet. 2005;366(9498):1719–24.
4. Lavery LA, Armstrong DG, Boulton AJ; Diabetex Research Group. Ankle equinus deformity and its relationship to high plantar pressure in a large population with diabetes mellitus. J Am Podiatr Med Assoc. 2002;92(9):479–82.
5. Lavery LA, Armstrong DG, Wunderlich RP, Tredwell J, Boulton AJ. Diabetic foot syndrome: evaluating the prevalence and incidence of foot pathology in Mexican Americans and non-Hispanic whites from a diabetes disease management cohort. Diabetes Care. 2003;26(5):1435–8.
6. Lavery LA, Armstrong DG, Wunderlich RP, Tredwell J, Boulton AJ. Predictive value of foot pressure assessment as part of a population-based diabetes disease management program. Diabetes Care. 2003;26(4):1069–73.
7. Grant WP, Sullivan R, Sonenshine DE, Adam M, Slusser JH, Carson KA, Vinik AI. Electron microscopic investigation of the effects of diabetes mellitus on the Achilles tendon. J Foot Ankle Surg. 1997;36(4):272–8.
8. Grant WP, Foreman EJ, Wilson AS, Jacobus DA, Kukla RM. Evaluation of Young's modulus in Achilles tendons with diabetic neuroarthropathy. J Am Podiatr Med Assoc. 2005;95(3):242–6.
9. Armstrong DG, Lavery LA, Frykberg RG, Wu SC, Boulton AJ. Validation of a diabetic foot surgery classification. Int Wound J. 2006;3(3):240–6.
10. Bus SA, Valk GD, van Deursen RW, Armstrong DG, Caravaggi C, Hlavácek P, Bakker K, Cavanagh PR. The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: a systematic review. Diabetes Metab Res Rev. 2008;24 Suppl 1:S162–80.
11. Armstrong DG, Stacpoole-Shea S, Nguyen H, Harkless LB. Lengthening of the Achilles tendon in diabetic patients who are at high risk for ulceration of the foot. J Bone Joint Surg Am. 1999;81(4):535–8.
12. Lin SS, Lee TH, Wapner KL. Plantar forefoot ulceration with equinus deformity of the ankle in diabetic patients: the effect of tendo-Achilles lengthening and total contact casting. Orthopaedics. 1996;19(5):465–75.
13. Armstrong DG, Stacpoole-Shea S, Nguyen H, Harkless LB. Lengthening of the achilles tendon in diabetic patients. J Bone Joint Surg Am. 2000;82-A(10):1510.
14. Mueller MJ, Sinacore DR, Hastings MK, Strube MJ, Johnson JE. Effect of Achilles tendon lengthening on neuropathic plantar ulcers. A randomized clinical trial. J Bone Joint Surg. 2003;85-A(8):1436–45.
15. Holstein P, Lohmann M, Bitsch M, Jørgensen B. Achilles tendon lengthening, the panacea for plantar forefoot ulceration? Diabetes Metab Res Rev. 2004;20 Suppl 1:S37–40.
16. Maluf KS, Mueller MJ, Strube MJ, Engsberg JR, Johnson JE. Tendon Achilles lengthening for the treatment of neuropathic ulcers causes a temporary reduction in forefoot pressure associated with changes in plantar flexor power rather than ankle motion during gait. J Biomech. 2004;37(6):897–906.
17. Mueller MJ, Sinacore DR, Hastings MK, Lott DJ, Strube MJ, Johnson JE. Impact of achilles tendon lengthening on functional limitations and perceived disability in people with a neuropathic plantar ulcer. Diabetes Care. 2004;27(7):1559–64.
18. Weber DJ, Stein RB, Chan KM, Loeb G, Richmond F, Rolf R, James K, Chong SL. BIONic WalkAide for correcting foot drop. IEEE Trans Neural Syst Rehabil Eng. 2005;13(2):242–6.
19. Metz WD. Bioengineering: "drop foot" corrected by electrical stimulation. Science. 1972;176(4037):897–900.
20. O'Keeffe DT, Donnelly AE, Lyons GM. The development of a potential optimized stimulation intensity envelope for drop foot applications. IEEE Trans Neural Syst Rehabil Eng. 2003;11(3):249–56.
21. Najafi B, Crews RT, Armstrong DG, Rogers LC, Aminian K, Wrobel J. Can we predict outcome of surgical reconstruction of Charcot neuroarthropathy by dynamic plantar pressure assessment?--A proof of concept study. Gait & posture. 2010;31(1):87–92.
22. Lavery LA, Vela SA, Lavery DC, Quebedeaux TL. Reducing dynamic foot pressures in high-risk diabetic subjects with foot ulcerations. A comparison of treatments. Diabetes Care. 1996;19(8):818–21.
23. Pataky Z, de León Rodriguez D, Allet L, Golay A, Assal M, Assal JP, Hauert CA. Biofeedback for foot offloading in diabetic patients with peripheral neuropathy. Diabetic Med. 2010;27(1):61–4.