

## Control of lower extremity edema in patients with diabetes: double blind randomized controlled trial assessing the efficacy of mild compression diabetic socks

Stephanie C. Wu,<sup>1</sup> Ryan T. Crews,<sup>1</sup> Melissa Skratsky,<sup>1</sup> Julia Overstreet,<sup>2</sup> Sai V. Yalla,<sup>1</sup> Michelle Winder,<sup>1</sup> Jacquelyn Ortiz,<sup>1</sup> Charles A. Andersen<sup>2</sup>

<sup>1</sup>Center for Lower Extremity Ambulatory Research (CLEAR), Dr. William M. Scholl College of Podiatric Medicine at Rosalind Franklin University of Medicine and Science, North Chicago, IL; <sup>2</sup>Madigan Army Medical Center, Tacoma, WA, USA

### Introduction

Lower extremity edema is often an early sign of significant fluid retention that could result in cardiac overload and conditions such as heart failure and is a common clinical finding in persons with diabetes.<sup>1-3</sup> Persons with type-2 diabetes mellitus especially, have a higher prevalence of peripheral edema than healthy subjects.<sup>4,5</sup> However, the lack of reliable measures to objectively quantify peripheral edema makes it difficult to assess the true prevalence in this population.<sup>6</sup> Once systemic pathology has been managed or ruled out, peripheral edema is most often treated with graduated compression therapy.<sup>7-9</sup> However, patients with diabetes have a 2-5 times greater risk for developing peripheral arterial disease (PAD)<sup>10-12</sup> as compared to those without diabetes, and compression therapy has long been considered risky practice in patients with diabetes because of the fear of compromising vascularity.<sup>13-15</sup> As a result, foot elevation as opposed to graduated compression has generally been recommended to reduce lower extremity edema in diabetic patients, and the diabetic socks currently advocated by healthcare professionals offer either no compression or minimal compression, no greater than 8-15 mmHg, to preemptively guard against exacerbating symptoms of lower extremity PAD. A four-week open label pilot study involving 20 subjects with diabetes and lower extremity edema suggested diabetic socks designed to provide mild compression (18-25 mmHg) (Sigvaris Inc, Peachtree City, GA, USA) can be used to decrease lower leg edema without compromising vascular flow.<sup>16</sup> The primary

objective of this five week, multi-center, double blind randomized controlled trial was to assess the effectiveness of a diabetic sock that provides mild compression (18-25 mmHg) as compared to a non-compression diabetic sock in patients with both diabetes and lower extremity edema. The secondary objective was to assess the effect of the mild compression diabetic sock *versus* the non-compression diabetic sock on lower extremity macro and microcirculation.

### Materials and Methods

80 subjects with LE edema and diabetes were randomized to receive either mild-compression knee high diabetic socks (18-25 mmHg) or non-compression knee high diabetic socks. Subjects were instructed to wear the socks during all waking hours. Follow-up visits occurred weekly for four consecutive weeks. Edema was quantified through midfoot, ankle, and calf circumferences and cutaneous fluid measurements. Vascular status was tracked via ankle brachial index (ABI), toe brachial index (TBI), and skin perfusion pressure (SPP).

### Results

77 subjects (39 controls and 38 mild-compression subjects) successfully completed the study. There were no statistical differences between the two groups in terms of age, body mass index, gender, and ethnicity.

Repeated measures analysis of variance and Sidak corrections for multiple comparisons were used for data analyses. Subjects randomized to mild-compression diabetic socks demonstrated significant decreases in calf and ankle circumferences at the end of treatment as compared to baseline. LE circulation did not diminish throughout the study with no significant decreases in ABI, TBI or SPP for either group.

### Conclusions

Results of this RCT suggest that mild compression diabetic socks may be effectively and safely used in patients with diabetes and LE edema.

### References

1. Eberth-Willershausen W, Marshall M

Correspondence: Stephanie C. Wu, Center for Lower Extremity Ambulatory Research (CLEAR), Dr. William M. Scholl College of Podiatric Medicine at Rosalind Franklin University of Medicine and Science, North Chicago, IL, USA.  
E-mail: stephanie.wu@rosalindfranklin.edu

Acknowledgments: the study was also partially supported by grant number 2T35DK074390 from the National Institute of Diabetes and Digestive and Kidney Disease. The content is solely the responsibility of the authors and does not represent the official views of the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health.

Funding: the study was funded by a grant from Sigvaris Inc (Peachtree City, GA) the manufacturer of the mild-compression socks. The sponsor played no role in the conduct of the study, the analysis of the data, nor the drafting of this manuscript.

Conflict of interest: the authors declare no potential conflict of interest.

Conference presentation: results from the study were previously published in abstract form in: Diabetes 2015;64(S1):A37. doi: 10.2337/db15-1-38.

This work is licensed under a Creative Commons Attribution 4.0 License (by-nc 4.0).

©Copyright S.C. Wu et al., 2017  
Licensee PAGEPress, Italy  
Veins and Lymphatics 2017; 6:6637  
doi:10.4081/vl.2017.6637

[Prevalence, risk factors and complications of peripheral venous diseases in the Munich population]. Hautarzt 1984;35:68-77.

2. Yu GV, Schubert EK, Khoury WE. The Jones compression bandage. Review and clinical applications. J Am Podiatr Med Assoc 2002;92:221-31.
3. Chantelau E. [Symptom veiled by polyneuropathy. Swollen foot in diabetes mellitus]. MMW Fortschr Med 2006;148:46-7.
4. Messerli FH. Vasodilatory edema: a common side effect of antihypertensive therapy. Am J Hypertens 2001;14:978-9.
5. Mudaliar S, Chang AR, Henry RR. Thiazolidinediones, peripheral edema, and type 2 diabetes: incidence, pathophysiology, and clinical implications. Endocr Pract 2003;9:406-16.
6. Brodovicz KG, McNaughton K, Uemura N, et al. Reliability and feasibility of methods to quantitatively assess peripheral edema. Clin Med Res

- 2009;7:21-31.
7. Armstrong DG, Nguyen HC. Improvement in healing with aggressive edema reduction after debridement of foot infection in persons with diabetes. *Arch Surg* 2000;135:1405-9.
  8. Gardner AMN, Fox RH. The return of blood to the heart: venous pumps in health and disease. London: John Libbey; 1989.
  9. Gaskell P, Parrott JCW. The effect of a mechanical venous pump on the circulation of the feet in the presence of arterial obstruction. *Surg Gyn Obst* 1978;146:583-92.
  10. Akbari CM, LoGerfo FW. Diabetes and peripheral vascular disease. *J Vasc Surg* 1999;30:373-84.
  11. Banga JD. Lower extremity arterial disease in diabetes mellitus. *Diab Rev Int* 1994;3:6-11.
  12. Dinh T, Scovell S, Veves A. Peripheral arterial disease and diabetes: a clinical update. *Int J Low Extrem Wounds* 2009;8:75-81.
  13. Eneroth M, Persson BM. Amputation for occlusive arterial disease, a prospective multicenter study of 177 amputees. *Int Orthop* 1992;16:383-7.
  14. Pawlaczyk K, Gabriel M, Urbanek T, et al. Effects of intermittent pneumatic compression on reduction of postoperative lower extremity edema and normalization of foot microcirculation flow in patients undergoing arterial revascularization. *Med Sci Monit* 2015;21:3986-92.
  15. Park DJ, Han SK, Kim WK. Is the foot elevation the optimal position for wound healing of a diabetic foot? *J Plast Reconstr Aesthet Surg* 2010;63:561-4.
  16. Wu SC, Crews RT, Najafi B, et al. Safety and efficacy of mild compression (18-25 mm Hg) therapy in patients with diabetes and lower extremity edema. *J Diabetes Sci Technol* 2012;6:641-7.

Non commercial use only