

Clinical efficacy of therapeutic footwear with a rigid rocker sole in the prevention of recurrence in patients with diabetes mellitus and diabetic polineuropathy: A randomized clinical trial, Lopez-Moral, et. al. *PLoS One*, 14(7), July 11, 2019

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Level of Evidence: 4

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The authors of this study begin by reviewing various significant statistics regarding diabetic foot ulcers (DFUs) including: lifetime incidence (19% - 34%), 2.5 times higher risk of death than those without DFU history, mortality rate of 70% 5 year after amputation, and an annual cost of \$176 billion for the treatment of diabetic foot complications. With this inspiration in mind, the principal aim of the study was to analyze in an intention-to-treat analysis of the clinical efficacy of a rigid rocker sole in the reduction of the recurrence rate of plantar ulcers in patients with diabetic feet.

This study was conducted in a randomized and controlled parallel (1:1) clinical trial of diabetic patients from June 2016 to December 2017. Patients who met inclusion criteria were then followed for 6 months or until the development of a recurrence event. Clinical examinations included debridement of high-risk points of the forefoot, as well as evaluation of the insoles and therapeutic footwear. Patient group assignments were random and both groups were to wear therapeutic footwear with the following general characteristics: high toe box, enough width to accommodate toe deformities such as claw or hammertoes, wide heel, and laces or buckles for fasteners. Soles of the shoe were either semi-rigid rocker (control) or rigid rocker (experimental).

The primary outcome measure was ulcer recurrence defined by the International Working Group and Infectious Disease Society of America as a full-thickness wound involving the foot or ankle. Patient compliance was evaluated via questionnaire at each consultation and those who had greater than 60% compliance were included in the statistical sub-analysis. 51 patients were included in this study, with 25 patients randomly selected in the control group and 26 patients randomly selected into the experimental group. Of the 51 patients, 29 patients completed the 6-month follow-up without any DFU recurrence. Based on the results, the median follow-up time was 26 weeks.

As the authors discuss their final results, they found that the experimental rigid rocker sole recurrence rate of 23% was similar to a previous study of 27.7%. The authors also were open regarding the limitations to their study. Their sample size was reduced, all of the patients were considered low activity, and plantar pressure was not specifically analyzed. In conclusion, the authors strongly recommend the use of rigid rocker sole therapeutic footwear for reducing the recurrence rate of DFUs for those who have a history of ulcers in the plantar aspect of the foot, those with a foot deformity, and those who have undergone minor amputations.



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