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ORIGINAL ARTICLE

# Effectiveness of a low-cost indigenous offloading device to enhance wound healing among people with type 2 diabetes: A pilot study from South India

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## Abstract

**Background** Effective offloading devices are required to treat DFUs. Literature available on the effectiveness of locally made offloading device in treatment of DFUs is less.

**Objective** The aim of the study was to assess and compare the effectiveness of a low-cost indigenous offloading device with an imported offloading device in treating DFUs.

**Methods** A randomized clinical study was conducted in a tertiary care center for diabetes between Apr and Nov 2023. Eligible participants were randomized into group 1 ($n=20$) and group 2 ($n=22$) and were given an imported offloading device and a low-cost indigenously made ankle-length removable offloading device respectively to treat their DFUs. They were followed up at every two weeks till 3rd month or till the end of the wound healing, whichever happened earlier.

**Results** Median age (63 vs. 58 years; $p=.223$), duration of diabetes (15.7 vs. 16.8 years; $p=.158$), and HbA1c% (8.4 vs.9.3%; $p=.803$) of the participants in group 1 and group 2 were similar at baseline. Wound size reduced significantly in both group 1 (5.9 vs. 1.2 $cm^2$; $p<0.001$) and group 2 (3.9 vs. 1.0 $cm^2$; $p<0.001$) from baseline to follow-up, but the difference between the groups was not statistically significant ($p=.074$). Healing time was comparable in both the groups (1 vs. 2; 26.5 vs. 25 median days; $p=.503$).

**Conclusion** The low-cost indigenously made offloading device is found to be equally effective as an imported device in healing of DFUs.

**Keywords** Diabetic foot ulcers · Low cost · Indigenous offloading device · Indian context

## Introduction

Type 2 diabetes is increasing globally, mainly in low- and middle-income countries [1]. India has currently 101.3 million people living with diabetes [2]. Individuals with diabetes have a high risk of developing diabetic foot ulcers (DFUs) due to diabetic neuropathy, PAD, foot deformities, and also several other main factors which include poor foot care practices like barefoot walking and high plantar pressure [3–6]. Evidence also suggests that high pressure due to ill-fitting shoes is a common cause of DFUs [7]. Global prevalence of DFUs was found to be 6.1%, and in Asia, it was 5.5% [8]. Around 19 to 34% of people with diabetes will develop foot ulcer during their lifetime [6]. Global survival rate was found to be 50% at 5 years in people with DFUs [9]. Inappropriate treatment of DFUs further worsens the wound and ends up with lower limb amputation [9]. Hence, DFUs

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