

THE EFFICACY OF REMOVABLE DEVICES TO REDUCE PRESSURE AND HEAL PLANTAR FOOT ULCERS IN DIABETES: A RANDOMIZED CONTROLLED TRIAL

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INTRODUCTION

Adequate pressure relief is required for healing plantar foot ulcers in patients with diabetes mellitus. Guidelines recommend non-removable offloading as primary treatment for these ulcers (Bus et al., 2008). However, in clinical practice removable offloading is more commonly used, mostly for practical reasons.

Compared to non-removable offloading, little is known about the efficacy removable offloading devices to heal plantar foot ulcers, and how healing is associated with plantar pressure reduction (Armstrong et al., 1998).

The aim was to assess the efficacy of three commonly used removable offloading treatment devices on healing of plantar neuropathic foot ulcers in diabetes and to assess the association between peak pressure relief and healing.

METHODS

Sixty patients (48 male, mean age 62.5 years, 87% type 2 diabetes) with a neuropathic non-infected, non-ischemic plantar ulcer in the forefoot were randomized to one of three treatment modalities: a bivalved total contact cast (BTCC), a Mabal cast shoe (MABAL), or a forefoot-offloading shoe (FOS). Patients were stratified according to ulcer size. Patients were followed until healing, or until 12 and 20 weeks, whichever came first. Primary outcome was percentage healing in 12 weeks time. In a subset of 35 patients, dynamic plantar pressure was measured using Pedar-X in both the original shoes of the patient and the offloading device, with peak pressure and peak-pressure-reduction at the ulcer location as outcome parameters.

RESULTS

Foot ulcers were located at the hallux (n = 24), first metatarsal head (n=21), other metatarsal heads (n=13) and toes (n=2). Forty-nine ulcers were small (<2.5 cm²), 11 large (>2.5 cm²) and 41 were Texas 1A (i.e. superficial), 19 Texas 2A (i.e. deep). Significantly more 2A ulcers were treated with BTCC than with FOS.

12-week healing rates according to intention to treat were 58% for BTCC, 60% for MABAL, and 70% for FOS (non-significant between conditions, p=0.70). For 20 weeks, healing rates were 63%, 83%, and 80%, respectively (ns, p=0.31). Time to healing was a mean (SD) 6.8 (3.4) weeks for BTCC, 7.0 (5.3) weeks for MABAL and 9.4 (3.7) weeks for FOS (ns)

No association was found between peak pressure or peak-pressure-reduction and healing of the foot ulcer (p-values range 0.47-0.87). Peak pressure and peak-pressure reduction varied significantly between devices. Peak pressure at the ulcer was 82 kPa for BTCC, 113 kPa for FOS, and 147 kPa for MABAL (p=0.016). Peak pressure reduction compared to the original shoes of the patient was 64% for the BTCC, 47% for FOS, and 34% for MABAL; p=0.061).

DISCUSSION AND CONCLUSIONS

Healing rates were not significantly different between the 3 removable devices. The off-the-shelf FOS condition showed more superficial ulcers, higher healing percentage, and longer time to healing than casting.

BTCC healing rates were substantially lower than previously found for non-removable TCC (~90% healing), while healing rates for the other two devices are comparable for those previously found for similar removable offloading devices.

The lack of association found between peak pressure (reduction) and healing is in contrast to that found in non-removable offloading (Armstrong et al., 1998)

Compared to non-removable offloading, lack of forced adherence may explain the lower healing rates and the lack of association with pressure reduction. This stresses the importance of continuous pressure relief in ulcer healing.

REFERENCES

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 Armstrong DG, et al. J Rehabil Res Dev 35:1-5, 1998