

Safety, Effectiveness and Costs of a Novel off-the-shelf Irremovable Device in the Management of Neuropathic Ulceration of the Diabetic Foot - a Prospective Randomized Trial

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Introduction: Although total contact casting (TCC) has been demonstrated to be the gold standard for the off-loading of neuropathic ulceration of diabetic foot, its effective application in the diabetic foot clinics remain scarce because of its complexity and costs. Recently some authors (Boulton and Armstrong, Diabetes Care, 2003, Katz et al. Diabetes Care 2005) suggested the use of removable offloading devices rendered irremovable for the management of neuropathic ulcers of the diabetic foot. We tested the safety, effectiveness and costs of offloading with a novel, off-the-shelf irremovable device in the management of diabetic foot ulceration (DFU). **Patients, Materials and Methods:** we prospectively evaluated off-loading of neuropathic plantar ulcers in 40 diabetic outpatients attending our foot clinic and compared healing rates at the 12-weeks follow-up, number and severity of adverse events, healing time, costs and applicability of the device and patients' satisfaction between those randomly assigned to TCC (Group A) or to the Optima Diab[®] walker (Molliter, Civitanova Marche, I) (Group B). Deep or infected ulcers were excluded. **Results:** No difference between Groups A and B was observed in healing rates at 12 weeks (95 vs 85%), healing time (6.5 ± 4.4 vs 6.7 ± 3.4 weeks), and number of adverse events (6 vs 4). Treatment was significantly less expensive in Group B, which showed a mean reduction of costs of 78% compared with Group A ($p < 0.001$). Practicability was more favourable in Group B, with a reduction of 77 and 58% of the time required for application and removal of the devices, respectively ($p < 0.001$). patients' satisfaction with the treatment was higher in Group B ($p < 0.01$). **Conclusions:** The Optima Diab[®] walker is as safe and effective as TCC in the management of DFU but its lower costs and better applicability may be of help in spreading the practice of off-loading among the centres that manage the diabetic foot