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The efficacy of removable casting devices to offload and heal plantar foot ulcers in diabetes: a multicenter randomized controlled trial Sicco A. Bus[1,2], Jaap J. van Netten[1], Anke Kottink[1], Marieke Hutten[1], Erik Manning[1], Max Spraul[3], Sjef van Baal[1] [1]Dept. of Surgery, Hospital Group Twente, Almelo and Hengelo, the Netherlands. [2]Dept. of Rehabilitation, Academic Medical Center, University of Amsterdam, the Netherlands. [3]Dept. of Internal Medicine, Mathias Spital, Rheine, Germany

Background: Adequate mechanical pressure relief is required for healing neuropathic plantar diabetic foot ulcers. Guidelines recommend non-removable offloading, but removable offloading is more commonly used, mostly for practical reasons. Little is known about the efficacy of removable (casting) devices to heal plantar foot ulcers.
Methods: 60 diabetic patients (48 male, mean age 62.5 years, 87% type 2) with non-infected, non-ischemic neuropathic plantar forefoot ulcers were randomized to either a bivalved total contact cast (BTCC), Mabal cast shoe (MABAL), or a forefoot offloading shoe (FOS). Patients were stratified to ulcer size and followed until healing or until 20 weeks. Peak pressure at the ulcer site while walking in the device and daily stride count were measured, and adherence to using the device was assessed by patient reporting. **Results:** Ulcers were mostly located at the metatarsal heads (n=34) or hallux (n=24), 49 were classified as small (<2.5 cm^2), 41 as University of Texas grade 1A (other 19 as grade 2A). 12-week healing rates according to intention-to-treat were 58% for BTCC, 60% for MABAL, and 70% for FOS (ns, p=0.70); 20-week healing rates were 63%, 83%, and 80%, respectively (ns, p=0.31). Mean peak pressure at the ulcer site was 81 (SD 55) kPa for BTCC, 176 (80) kPa for MABAL, and 107 (52) kPa for FOS (significant, p=0.005); mean daily stride count was 4150 (SD 1626), 3514 (1380), and 4447 (3190), respectively (ns, p=0.71). Percentage of visits that patients reported to have worn the device <50% of time during the last two weeks was 27% for BTCC, 7% for MABAL, and 5% for FOS (significant, p=0.029). **Conclusions**: Healing rates were not significantly different between the 3 removable devices, and for MABAL and FOS comparable to rates previously found for similar type removable devices. The BTCC showed the lowest pressures and highest non-adherence of all devices, and a much higher stride count and substantially lower healing rates than previously found for non-removable TCC (~90% healing, 300 daily strides). Exposure to high levels of repetitive stress by lack of forced adherence and high activity level may explain these differences in healing rates, and stresses the importance of continuous pressure relief in healing of plantar foot ulcer