

The relation between cumulative stress, peak pressure and daily activity in removable offloading devices and healing of neuropathic diabetic foot ulcers Jaap J. van Netten¹, Jeff G. van Baal¹, Adriaan Bril¹, Sicco A. Bus^{1,2} ¹Dept. of Surgery, Hospital Group Twente, Almelo and Hengelo, the Netherlands. ²Dept. of Rehabilitation, Academic Medical Center, University of Amsterdam, the Netherlands.

Background: Foot ulceration is the most costly complication of diabetes. The gold standard for healing foot ulcers on the plantar side of the foot is offloading by means of a non-removable total contact cast (TCC). Because of known complications with a TCC, removable alternatives have been developed. The relation between cumulative stress, peak pressure and daily activity in these devices and healing of neuropathic diabetic foot ulcers is unknown. **Methods:** A subset of patients (n=31) from a randomized clinical trial concerning three removable offloading devices (bivalved total contact cast [BTCC], MABAL shoe, forefoot offloading shoe [FOS]) was used. Investigated parameters were healing at 12 and 20 weeks, time to healing, cumulative stress at the ulcer location (pressure time integral * daily activity), peak pressure at the ulcer location and peak pressure reduction in comparison to the shoes daily worn before the treatment (measured using the Novel Pedar-X System) and daily activity (measured using a Stepwatch) **Results:** 68% of the ulcers healed within 12 weeks (n=21), 77% healed within 20 weeks (n=24). Mean time to healing of the ulcers that healed within 20 weeks was 8.75 weeks (SD: 3.8; range 3-17 weeks). No significant relation was found between cumulative stress and healing (12 weeks: p=0.767; 20 weeks: p=0.917) or time to healing (Spearman's rho: -0.028). No significant relation was found between peak pressure or peak pressure reduction and healing (12 weeks p=0.966 and p=0.472; 20 weeks: p=0.836 and p=0.907) or time to healing (Spearman's rho: -0.123 and 0.199). No significant relation was found between daily activity and healing (12 weeks: p=0.254; 20 weeks p=0.907) or time to healing (Spearman's rho: 0.054) **Conclusion:** The lack of relation between cumulative stress, peak pressure and daily activity in removable offloading devices and healing or time to healing of plantar neuropathic diabetic foot ulcers is in contrast with relations found in non-removable offloading devices. With mean peak pressure values being around 100 kPa at the ulcer locations, offloading can be regarded to have been adequate in all patients. This implies that other factors play an important role in healing of plantar neuropathic ulcers when patients are treated with removable offloading devices. Adherence can be hypothesized to be a key factor and needs to be taken into account in future studies.