

**Effectiveness and Safety of Using a Digital Silicone Padding in the Primary Prevention of Neuropathic Lesions in the Forefoot of Diabetic Patients**

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**Background:** In diabetic subjects with complications from peripheral neuropathy the hyperpressure areas, in the absence of protective sensation, can rapidly lead to ulcerative lesions. Partial digital silicone orthoses could provide an innovative and functional therapeutic solution in the management of pre-ulcerative areas of the forefoot in neuropathic diabetic patients. We clinically tested this hypothesis.

**Methods:** Digital off-loading silicone padding (Podikon 10 and 22, Podolife, Rubano, I) were prepared for 89 neuropathic patients with deformities and localised hyperkeratosis in the forefoot. After 3 months and in basal conditions the number of areas of hyperkeratosis was evaluated together with the hardness of the skin, the number of active lesions and any adverse events associated with use of the orthosis. The patients were compared with 78 randomised controls undergoing standard therapy. In a sub group of 10 patients a static and dynamic biomechanical evaluation was also carried out with a computerised podobarometric platform (Ecosystem, Ecosanit, Anghiari - I).

**Results:** Both the number of lesions and the prevalence of hyperkeratosis and skin hardness were significantly lower ( $p < 0.01$ ) in the group treated with the silicone orthoses than in the control group. No adverse events were reported during the 3 months of observation. The podobarometric analysis highlighted a significant ( $p < 0.001$ ) reduction of peak pressure in the areas undergoing orthotic correction.

**Conclusions:** Silicone padding is effective and safe in the prevention of lesions in neuropathic patients at high risk of ulceration and significantly reduces the incidence of new lesions in the three month follow-up period compared to standard treatment.