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Nanotechnologies for the Management of Pre-ulcerative Conditions in the Diabetic Foot

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Introduction: Autonomic dysfunction is a component of peripheral neuropathy complicating diabetes mellitus. As a consequence of sympathetic denervation the atrophy of sweat glands in the foot and lower limb is a common findings in these patients, who are exposed to a severe anhydrosis which, together with the hyperkeratosis constitute an important risk factor for ulceration. **Aim of the Study:** To test a new tool for the treatment of diabetic anhydrosis [Difoprev[®], LVM Technologies, Bologna - I], based on a biomedical application of nanotechnologies, in a group of neuropathic outpatients. Difoprev[®] is a system constituted by a sock on which nanocapsules containing an hydrating agent are incorporated with electro-chemical methods. Once worn, the nanocapsules transfer themselves on the skin of the patient and release the hydrating agent for all the time the socks are worn. **Patients, Materials and Methods:** 30 neuropathic outpatients with foot anhydrosis attending our foot clinic during 2005 were randomised into two groups: Group A was treated with the application of Difoprev[®], while group B did wear only the socks, without the nanocapsules. Patients were blindly evaluated with a quantitative objective score, hygrometry, Trans-epidermal water loss (TEWL), skin temperature and skin hardness at baseline and after six weeks of continuous treatment. Patients with active or previous ulceration were excluded from the study. **Results:** No difference in any of the parameters considered was observed between the two groups at baseline. While in Group B no difference was observed at the end of the treatment, Group A patients improved significantly ($p < 0.05$) in all of the parameters evaluated, showing both an increase in the skin water content and a reduction in skin hardness, associated with improved local clinical conditions. No adverse events were recorded in both groups during the course of the study. **Conclusion:** Difoprev[®] is a safe and effective treatment for diabetic neuropathic anhydrosis of the foot, and possibly a tool for prevention of neuropathic ulceration of the diabetic foot.