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An innovative use of limb prosthetic gel to manage Diabetic Foot Pressure

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Background and aims. To avoid abnormal foot loading while maintaining a physiological gait biomechanics does represent a challenge in the management of Diabetic foot ulceration process. To the purpose, the authors investigated a patented silicone-like biomaterial. The study aims at assessing the effectiveness of the proposed material, innovatively arranged within a cotton sock, prior to the launch of the clinical application on Diabetic patients. **Materials and methods.** The patented silicon-like gel (Alps South LLC, Italy) is currently used to manage stress between skin and prosthetic socket of above or below-knee amputees. Under compression, the gel elongates almost linearly in the range 35-400kPa up to 10 times than silicone. A preliminary test was conducted on a healthy volunteer under well controlled conditions, to evaluate a prototype of cotton socks with an internal layer of 1.5mm of gel, and a 3mm gel insole. A calibrated Kistler force platform was used to thoroughly evaluate ground reaction force, and an EMED pressure platform to investigate pressure distribution. The 3mm gel insoles were then supplied to 5 non-Diabetic volunteers with calluses and high peak pressures under the metatarsals. Calluses were removed, and volunteers are going to be re-tested after one month. **Results.** With reference to the propulsion phase, the overall ground reaction force pattern was quite well maintained: the 1.5mm socks only showed a 0.7%b.w. reduction of ant-post force and a 3.3%b.w. increase of vertical force, while reduction was -3.1%b.w. and -7.1%b.w. respectively for the 3mm insoles. Med-lat curves had quite small values (-2.1, 1.1 and -0.1%b.w. at 75% of stance), similar shape, a medial shift when using the gel interface. Especially important, peak pressure in propulsion (range 720-957kPa) was reduced 30-40% by the 1.5mm gel and 59-66% by the 3mm gel. The 5 volunteers, before calluses removal, had peak pressures in the range 474-1188kPa, which, by using the 3mm gel, were reduced 60-72% if greater than 600kPa, and 28-29% if lower. First volunteer already re-tested showed non significant changes in barefoot peak pressures but, extremely interesting, no calluses at all. **Conclusions.** Preliminary tests proved the potential effectiveness of the gel socks in reducing high peak pressures without significantly changing foot biomechanics, and in preventing calluses formation. Feedback from the volunteers, also in terms of usability and eventual side effects, is helping the Manufacturer in preparing sample socks with different gel thickness and arrangement to be delivered to a selected population of Diabetic patients in risk class I, who do not need for specific plantar orthoses to overcome deformities or concurrent pathologies.