Compression textiles and skin irritation: a clinical study

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Introduction

The working principle of many medical devices (e.g. lumbar belts, stockings) is based on their mechanical action on the body. Therefore, their contact with the skin must be considered carefully. Unfortunately, skin irritation is a common phenomenon that becomes a concern, because many patients do not tolerate their medical devices, leading to a poor therapeutic compliance. Exposure to a chemical agent or an allergic reaction are unlikely to occur here as these medical devices are designed to be hypoallergenic, and so we hypothesized that these cutaneous irritations are caused by the mechanical interaction of the skin with the device itself. Skin damage can be related to a prolonged pressure or shear [1, 2]. In addition, several researches have demonstrated how friction is involved in the process of skin abrasion [3].

In a recent survey on textile compression medical devices, users of the French market, we highlighted that, even though 85% were satisfied with medical device efficacy, 57% were not with the comfort and 44% declared skin problems (irritation, redness etc) in particular near the anti-slipping band.

Based on current data in the literature, it seems feasible to quantify the degree of skin damage by clinical criteria but also by certain biophysical measurements. Furthermore, the literature also demonstrates how the contact between the skin and an object is influenced by the mechanical properties of the skin, its roughness and the properties of the material in contact [1].

Thus, we propose a clinical study with the aim of identifying determining factors in the development of skin damage when wearing compression stockings. For this purpose, measurements of mechanical and biophysical parameters will be compared before and after use of two different models of textile compression device in relation to the severity of skin damage induced by the wearing of compression stockings. The aim of this communication is to present the mains results of this clinical study.

Materials and methods

25 patients were recruited at Saint-Etienne University hospital. All patients are compression devices users and have developed skin problems in the past. The study was performed according to the Declaration of Helsinki and was approved by the ethics committee (Comité de Protection des Personnes Sud Est V #21-THUA-01). Prior to participation in the study, all participants provided written informed consent.

The subjects were asked to wear two different brands of compression stockings (one on each leg) and to walk two times 15 min at 5km/h on a treadmill, with a 15 min rest on a chair in between. Immediately after removing the compression devices, the subjects' skin was assessed by a clinician to evaluate the severity of the induced irritation.

Before putting on and after removing the compression stockings, mechanical and biophysical parameters (skin rigidity, skin layers thicknesses, skin temperature, and micro cutaneous blood flow) were acquired at 3 evaluated zones on each leg. Skin replicas of the six evaluated zones were also acquired before experiments to evaluate roughness.

Results

A Kolmogorov- Smirnov test was used to decide between parametric or non-parametric tests. Finally, the comparisons of the different variables according to the conditions before / after walking was performed using a repeated measures analysis of variance (ANOVA). Simple effects were analyzed by a Scheffé post-hoc test. Comparisons of the different variables were analyzed using the Wilcoxon test.

It was evidenced that irritation occurred mainly near the anti-sliding pads. Irritated skins were more compliant, hotter, with thicker epidermis, and a roughness with smaller periodicity in the longitudinal direction, higher in the circumferential one and more plateau than valley. These characteristics are specific of the thigh zone, the two other (popliteal fossa, calf) being significantly different. Results didn't depend on the type of stocking used.

Last, the patient feeling (itching, heat, irritation, compression) did not correlate with irritation level as defined by medical practice.

This clinical study provides valuable insights for clinicians and manufacturers on the mechanical and biophysical factors that contribute to skin irritation when wearing compression stockings, particularly near the anti-sliding pads, and can inform the development of more comfortable and effective devices.

References

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