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Clinical study



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# Behavior of provisional pressure-reducing materials in diabetic foot

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#### **KEYWORDS**

Diabetic foot; Hyperpressures; Pressure reduction; Wools **Abstract** *Objective:* The main aim of this work is to assess the behavior of felts of latex foam, wool, wool on latex and 10 mm polyurethane foam as provisional pressure-reducing materials compared to foot hyperpressures. Secondary aims are to determine how Body Mass Index and Physical activity impact the pressure-reducing capacity of these materials. The research hypothesis sets out that there are statistically significant differences between the pressure-reducing capacity of the different materials and that they are impacted by Body Mass Index and Physical Activity.

*Research design and methods*: This study was descriptive, correlational and experimental. The sample was comprised of 32 subjects, 64 feet aged between 19 and 76 years, with plantar hyperpressures of different etiologies. The pressure was assessed using the platform pressures.

*Results:* The results revealed an effective reduction of pressures for all materials; this was more durable for polyurethane.

*Conclusions:* It was concluded that pressure-reducing materials are effective on the reduction of hyperpressures but there are differences between them as to duration of the effect.

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1. Introduction

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Diabetic foot remains one of the most significant complications of Diabetes Mellitus. It causes a high number of leg amputations, a high degree of disability, in addition to an increase in the number and cost of hospital admissions [1-5].

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Sole hyper-pressures in the foot at risk are reported as one of the causes of onset of difficult to resolve lesions. Currently, there has been major progress over the use of increasingly effective dressings and scarring methods (negative pressure therapy, growth factors, protease modulators, etc.). However, the use of provisional pressure reduction materials has only been partially studied [6]. The use of pressure reductions as the main thrust of ulcer treatment of neuropathic or neuroischemic origin is highly beneficial; reducing the hyperpressure in the area leads to modifications to the histology of the lesions, which change from a chronic inflammatory state to a much more favorable condition [7–9]. The reduction in pressure has the basic aim of distributing the load over a broader area, so that the hyperpressure peaks over certain points are reduced [10].

There are other studies that evaluate the effectiveness of the felts, in particular wool felts [11,12].

For this reason, a global study of provisional pressure reduction materials as a more generalized technique for the reduction of hyperpressures, in addition to the impact of the variables Body Mass Index (hereinafter BMI) and Physical Activity on these, is especially noteworthy.

#### 2. Research design and methods

This study was descriptive, correlational and experimental [13]. The sample was comprised of 32 subjects, that is 64 feet, with ages between 19 and 76 years. Each foot or case was considered separately. The software G-Power 3.1.0 (University of Kiel, Kiel, Germany) was used to calculate sample size. For an alpha error of 0.05, a power of 95% and a mean effect size, the minimum number of cases necessary is 34. The pressure reduction material are wools of latex foam, wool, wool on latex and 10 mm-thick polyurethane foam.

#### 2.1. Inclusion criteria

All participants presented type II diabetes. History of plantar ulceration of the foot (increase in pressure) [14–17] or present some kind of prior amputation (predisposes the increase in pressure and restructuring of the foot loads) [16,18–20] or present areas of plantar callus (hyperpressure) [21].

### 2.2. Exclusion criteria

Have previously received treatment for the plantar hyperpressures: plantar orthesis, foot surgery, shoe therapy, etc. [22,23].

Sample subjects are patients from the Podiatry Clinical Area and Podiatry degree students from University of Seville, who comply with the inclusion criteria and voluntarily agree to take part in the study. This study was authorized by the site's management.

The pressures platform Rss-Scan<sup>®</sup> (Beringen, Belgium) was used to assess plantar pressure. This was calibrated for each subject, using the patient's weight before each test session. Individuals walked barefoot on the platform to familiarize themselves with the system and to guarantee as natural a gait as possible [24]. Subsequently, three barefoot steps for each subject were recorded on the platform, which was quantified in  $N/m^2$  [25–27]. The mean maximum pressure was calculated for each one of the 10 areas into which the program splits the foot (the five metatarsals, the first toe, minor toes, mid foot, internal and external heel area). Once the area of maximum pressures was identified, the pressure reduction material was positioned. The man walks barefoot on the platform with the material. High pressure area is considered greater tan 294,000 N/m<sup>2</sup>. It was covered the sole of the foot and leaving the area of maximum pressure without support. The cut out was corresponded to the size of the overhead area. The diameter of the cut out will depend on the extent of the affected area.

The pressure reduction was prepared by covering the entire foot and leaving the maximum area of pressure without support; this was fixed onto the sole of the foot and reinforced with a cohesive bandage (Fig. 1). The original thickness is the same in all materials. Therefore, it cannot be withdrawn by the patient and the edge effect (increased pressure on margins) was reduced [28]. The bath is not allowed in 72 h. Subjects confirmed verbally that had performed the same activity with each material. After inserting the pressure reduction, the pressure was measured.

After 72 h, three new measurements of the plantar pressures with the subject barefoot were taken to obtain the mean for each one of the pressure reduction area [29]. The reduction in thickness of the material close to the pressure reduction area was reduced by three points. The subject used the same shoe throughout the study so that the conditions were homogeneous. This process was repeated with all pressure reduction materials (wools of latex foam, two presentations of wools presented as 5 mm and one of 10 mm, wool on latex and 10 mm-thick polyurethane foam). All measurements follow the same procedure.

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