

Perfusion, tissue oxygenation and peripheral temperature in the skin of heels of healthy participants exposed to pressure: a quasi-experimental study

Alberto José Gómez-González RN, MSc¹, Juan Carlos Morilla-Herrera RN, MSc, PhD^{1,2,3}, Inmaculada Lupiáñez-Pérez RN, MSc, PhD^{1,2,3}, José Miguel Morales-Asencio RN, MSc, PhD^{1,3}, Silvia García-Mayor RN, MSc, PhD^{1,3}, Álvaro León-Campos RN, MSc, PhD¹, Raquel Marfíl-Gómez RN¹, Marta Aranda-Gallardo RN, MSc, PhD^{3,4}, Ana Belén Moya-Suárez RN, MSc, PhD^{3,4}, Shakira Kaknani-Uttumchandani RN, MSc, PhD^{1,3}

1 Department of nursing, University of Málaga, Faculty of Health Sciences, Málaga, Spain

2 Distrito Sanitario Málaga – Valle del Guadalhorce, Servicio Andaluz de Salud (SAS), Málaga, Spain

3 Instituto de Investigación Biomédica de Málaga (IBIMA), Málaga, Spain

4 Agencia Sanitaria Costa del Sol, Marbella, Spain

Correspondence: Inmaculada Lupiáñez Pérez, Faculty of Health Sciences, C/Arquitecto Francisco Peñalosa, 3, Campus Universitario de Teatinos, 29071 Málaga, Spain. Email: ilupianezperez@gmail.com

Funding information: Spanish Ministry of Industry, Economy and Competitiveness through the Carlos III Health Institute (PI15/02016).

Abstract

Aim: To evaluate the relationship between the pressure exerted on the heel of one foot resting directly on a mattress, versus that exerted on the other heel, protected by a pillow beneath the Achilles tendon area and the changes thus produced in perfusion, oxygenation and temperature in the skin of heels of healthy volunteers lying in a supine position.

Design: Experimental study in a pre-clinical phase, with healthy volunteer participants and intrapeople control. **Methods:** The study was carried out from November 2017 – May 2018. A pressure measurement surface was placed between the participant and the constant lowpressure support surface. Doppler laser devices were used to measure local temperature and perfusion. The degree of oxygenation was determined using an infrared beam close to the pressure zone in each heel. Both feet rested immobile on the bed, in a

natural position, for 2 hr. To ensure intrapeople control, in every case the left heel was raised slightly, compared with the right. Results: Eighteen participants took part in this study. Analysis of the results obtained showed that capillary blood flow was significantly reduced in the heel subjected to pressure, compared with the other heel, while no significant effects on oxygen saturation or temperature were observed. The variables associated with greater oxygen saturation were capillary blood flow, local temperature and pressure exerted. Fatfree mass, fat mass and duration of exposure to pressure were all significantly associated with reduced oxygen saturation. Conclusions: In healthy participants, when the heel is subjected to constant pressure against a constant low-pressure support surface, there is a significant reduction in blood flow, compared with the heel where pressure is relieved. However, there are no significant differences in temperature or tissue oxygenation. Impact: Significant reductions in vascular flow were observed; however, the oxygenation and temperature of the heel tissues remained unchanged. These findings, corroborated in real patients, would advance our understanding and facilitate decision-making on measures to prevent pressure ulcers, such as repositioning or tissue protection. Trial registration: The protocol is registered in ClinicalTrials.gov (NCT02736838).

KEYWORDS: blood gas monitoring, laser doppler flowmetry, non-randomized controlled trials, nursing, pressure ulcer, skin temperature, transcutaneous

Introduction

A pressure ulcer (PU) is a skin lesion provoked by ischaemia, which can cause necrosis in the epidermis, dermis, subcutaneous tissue, muscle, joints and bones. PUs usually appear when the soft tissues are compressed between two planes, such as a bony prominence of the body and an external surface. The control and management of PUs is a challenge for health systems worldwide (NPUAP/EPUAP/PPPIA, 2014; Hanson, Langemo anderson, Thompson, & Hunter, 2010), due to their frequent occurrence and difficult control. The reported prevalence ranges widely and includes values such as 6.2% in Australia (Jull, McCall, Chappell, & Tobin, 2016), 18.1% in Europe (although with considerable differences: values of 18%–23% have been reported in Ireland, Sweden and the UK, but only 8.3% and 12.5% in Italy and Portugal, respectively) (Pancorbo-Hidalgo, García-Fernández, Torra i Bou, Verdú-Soriano, & Soldevilla-Agreda, 2014) and 9.3% in the USA (Van Gilder, Lachenbruch, Algrim-Boyle, & Meyer, 2017).

In Spain, the prevalence varies across the country: reported rates include 7.87% or 8.51% in primary attention clinics and 13.4% in long-term care centres. According to the anatomy affected area, PUs on the heel have been reported in 28.6% of cases (Pancorbo-Hidalgo et al., 2014).

In hospitalized patients, PUs extend the length of hospital stay and increase healthcare costs. In the USA, 60,000 hospital patients die annually from PU-related complications and the average cost of hospital stay for treatment of grade IV PU complications is \$129,248. Hospital stay may be extended by up to three times and in 4% of cases PUs lead to the death of the patient (Brem et al., 2010).

Background

Various factors can increase the probability of PUs developing: on the one hand, those derived from the limits of mechanical tolerance (internal stress), such as the type, magnitude and duration of the mechanical load (shear and pressure); and on the other hand, individual susceptibility and tolerance (damage threshold), including the individual mechanical properties of tissues, the individual geometry (morphology) of tissues and bones, physiology and individual repair, transport and thermal properties (NPUAP/EPUAP/PPPIA, 2014). There is a strong association between the presence of PUs and the quality of care provided by nursing professionals (Coleman et al., 2013). To reflect this relationship, Coleman et al. (2014) created a conceptual framework incorporating the following factors generally associated with PUs: direct predisposing factors (immobility, skin condition and poor perfusion), indirect predisposing factors (deficient perception and sensory response, diabetes, humidity, poor nutrition and low albumin) and potential indirect predisposing factors (age, medication, pitting oedema, chronic wound, infection, acute illness and elevated body temperature). For the modifiable factors, prevention is of fundamental importance in areas such as evaluating risk factors by means of validated scales, making use of support surfaces, repositioning the patient and maintaining good nutrition and hydration (National Institute for Health & Care Excellence, 2014).

Most PUs are preventable and therefore preventive intervention should be a priority. Nevertheless, many doubts remain in this area. Systematic reviews have highlighted gaps in our knowledge of the intrinsic mechanisms involved in the genesis of PUs and this lack of understanding hampers the development of effective preventive interventions (Chou et al., 2013; Gillespie et al., 2014; Moore & Cowman, 2015).

Acquiring detailed knowledge of the physiopathological mechanisms of the early development of PUs, at the cellular and molecular levels, thus helping us identify new intervention pathways, should be a priority in research (Wang, Pu, Li, Hu, & Jiang, 2016). In this respect, determining the mechanisms by which ischaemia-reperfusion takes place is an area of investigation that currently offers many possibilities (Coleman et al., 2014; Loerakker et al., 2011).

The heel is one of the areas most liable to PUs and so it is important to determine the response to pressure of skin tissue in this area to maximize the effectiveness of preventive interventions. Studies have been undertaken to measure physiopathological parameters of the skin of the heels, in patients with health disorders. In one of these studies, Wong, Stotts, Hopf, Froelicher, and Dowling (2007), Wong, Stotts, Hopf, Dowling, and Froelicher (2011) observed the oxygenation and temperature of the heels of patients with an acute disease. Moreover, Källman et al. (2015) studied the perfusion in the skin and the pressure on the heels in institutionalized patients. Other authors have evaluated capillary blood flow (Goossens & Rithalia, 2008; Rothenberger et al., 2014) and oxygenation (Aliano, Stavrides, & Davenport, 2013) in the heels of healthy participants, resting on various support surfaces. Researchers have also investigated the perfusion in the skin of heels of healthy participants over time and the pressure exerted on the heels, which was then modified to observe the hyperaemic response in the area affected (Mayrovitz & Sims, 2002; Mayrovitz, Sims, Taylor, & Dribin, 2003). Finally, the perfusion on heel skin of healthy participants was compared with that of those at risk of PUs (Abu-Own, Sommerville, Scurr, & Coleridge Smith, 1995).

Despite the considerable investigation that has been conducted in this area, to date no studies have been conducted to simultaneously measure changes in the perfusion, oxygenation and temperature of the skin of the heels of healthy participants, at known levels of constant pressure over time, comparing heels subjected to direct pressure from the support surface used during normal care (constant low-pressure support surface) with heels protected in accordance with standard nursing procedures.

2. The study

2.1 Aim

The aims of this study were to simultaneously evaluate, during a continuous 2-hr period, the changes that occur in blood capillary flow, oxygenation and skin temperature in the heels of healthy volunteers subjected to the pressure exerted by the weight of the foot

directly on a mattress, versus that exerted when the heel is protected by a pillow beneath the Achilles tendon area. Other factors included in the analysis are the patients' sex and anthropometric characteristics associated with peripheral oxygen saturation when the heel is subjected to pressure and peripheral vascular flow in both heels. The details of the study protocol have been published elsewhere (Garcia-Mayor et al., 2018).

2.1.1 Hypothesis

The study evaluated two hypotheses. The first null hypothesis was that there is no association among the oxygenation of the heels subject to direct pressure and the skin temperature, the capillary flux or anthropometric characteristics of healthy volunteers, regardless of being subject to pressure or not. The second null hypothesis was that there were no differences between heels subject to direct pressure and those heels without this condition with respect to oxygenation, skin temperature and blood flow.

2.2 Methodology

2.2.1 Design

A quasi-experimental study with intrapeople control (the participants act as their own control) in a pre-clinical phase, with healthy volunteer participants. TIDieR statement was used to guide the design and completion of the study.

2.2.2 Sample

The study population was composed of healthy volunteers recruited at the Faculty of Health Sciences of the University of Malaga (Spain), where this investigation was conducted. Students from the Faculty were invited to participate as volunteers by members of the research team.

Inclusion criteria

All the participants included in this study aged 18–65 years, signed the informed consent form to participate, had not been diagnosed with any cardiovascular, neurological, digestive, renal, endocrine, gynaecological, haematological, respiratory, infectious, dermatological, autoimmune or osteomuscular disease and presented no functional limitation. In addition, they had observable tissue integrity, no scars or tattoos in the measurement area and had a body mass index (BMI) of 18.5–24.9 kg/m².

Exclusion criteria

Persons who, for any reason, habitually used alpha-beta-blockers, alpha-beta agonists, with direct or indirect vasodilator or vasoconstrictor action of any nature, anticoagulants or topical or systemic steroids or who had a pacemaker or implantable defibrillator or who smoked, consumed large quantities of alcohol (>20 g/day, according to WHO, 2008), who had suffered the amputation of a foot or who were menstruating on the day of measurement were excluded from the study group.

2.2.3 Data collection

Explanatory variables

The following data on the study participants were obtained: age, sex, height (cm) and weight (kg). Height and weight were determined using an ASIMED mechanical scale fitted with a height gauge and with the participants barefooted and lightly dressed. Data for BMI (kg/m²), fat-free mass (FFM) and fat mass (FM) (kg) were obtained using a BodyComp MF Hexa-AKERN impedance meter. Bioimpedance was measured with the participants immobile, with no contact with any conductive surface and lying in a supine position with the arms and legs slightly separated from the body and the thighs at least 25 cm apart. The participants were dressed, but were asked to remove shoes, socks and metal objects that might alter the conductivity data. The measurements were taken in multifrequency mode (400 μ ARMS, 5–250 kHz) with the electrodes in a tetrapolar arrangement: the emitting electrode was placed on the midline of the flexure of the right wrist, the receiver on the mid-intermolar line of the right foot and the detector electrodes were separated by at least 5 cm from these two electrodes (one on the metacarpophalangeal midline and the other on the metatarsophalangeal midline). Systolic and diastolic blood pressure (mmHg) were measured using an OMRON M6 AC HEM-7322-E sphygmomanometer, with the participant in a seated position.

The pressure exerted on the heels was measured with the XSENSOR PX100:64.160.02 pressure sensor (31.2 × 203.2 cm), with 12.7 mm spatial resolution and 10,240 measurement points. This pressure sensor is composed of two perpendicularly arranged networks of parallel conductive strips, separated by a thin compressible elastomer. The intersection of the two strips forms a capacitive node, determined by the intersecting surface of the two strips and by the separation distance between them and by the separation from the elastomer. When pressure is applied to the node, the elastomer is compressed, the bands approach each other and the capacity increases. This change in

capacity is correlated with pressure via a calibration process. The information supplied by the device is compiled and integrated in the XSENSOR PRO V8 software, which obtains the average pressure on the heel (in mmHg) every 15 min, over a total period of 2 hr.

Outcome variables

The perfusion and temperature data for the skin on the heels were collected with two Doppler laser units (MoorVMS-LDF2). In this non-invasive method, the laser light is transmitted by fibre optics to the tissue (depth: 1 mm) and the light scattered by the tissue is received by a photodetector. During this measurement, the participant's feet were covered with an opaque sheet so that the photosensitivity of the device would not alter the results. The oxygenation measurements were obtained by transcutaneous oximetry using two near infrared units (MoorVMS-NIRS).

The Doppler and the near infrared laser information were collected and integrated into the MoorVMS-PC V4.0 software, where the perfusion, temperature and mean oxygen saturation (SaO₂) data for each heel were obtained every 15 min, over a total period of 2 hr, measured in arbitrary units (AU) (a relative unit of measurement that describes the ratio of perfusion to a predetermined reference measurement for the device used), namely °C and % respectively. The evaluators were trained by members of the research team and by technicians of the Laser Doppler device company.

2.2.4 Intervention

The intervention was carried out at the Faculty of Health Sciences of the University of Malaga (Spain) between November 2017 and May 2018. To ensure maximum control of the study conditions, the following measurement protocol was applied. The room where the intervention took place was maintained at a temperature of 26°C, to ensure that the tissue temperature values were always obtained under the same conditions.

In every case, the participant lay in a supine position on a constant low-pressure support surface, resting on an articulated bed at 0° elevation, with a pillow, simulating the clinical situation commonly found in homes, nursing clinics and hospitals. The pressure measuring surface was interposed between the participant and the mattress.

The measurement devices were then placed close to both heels: the Doppler laser unit was focused on the tuberosity of the calcaneus and the near infrared laser device on the midline between the heel-bone and the external malleolus (Figure 1). Both feet rested on

the bed in a natural position, immobile, for 2 hr. To ensure that one of the heels supported as little pressure as possible, the left leg was slightly raised by a pillow beneath the Achilles tendon area, as is standard clinical practice in many hospital units. The sensor for the right heel was surrounded by a viscoelastic pad to protect the skin.

2.2.5 Experimental validity, reliability and rigour

In this pre-clinical phase, reaction thresholds were obtained for the physiological parameters of healthy participants, following the uninterrupted exertion of pressure on the heels for 2 hr. In addition, perfusion data were obtained, using validated, reliable instruments, meeting the ISO 13845:2003 standard and presenting the following parameters: bandwidth: high pass 20 Hz; low pass 3 kHz, 15 kHz, 22 kHz; flux smoothing time constants: 0.1 s, 0.5 s, 1.0 s, 3.0 s and unfiltered, with automatic gain control and zeroing; oxygenation range 0%–99%, accuracy $\pm 3\%$; temperature range 5–50°C, accuracy $\pm 0.3^\circ\text{C}$; pressure range 5.25–99.76 mmHg, accuracy $\pm 10\%$. The anthropometric data (BMI, FFM and FM) were obtained using impedance tomography. All measurements were obtained by the same two people, trained for this study and following a strict protocol. For the analyses over time, the first 30 min of data for each of the variables measured were rejected, to avoid artefacts produced by the adjustment of the foot to the surface as the participant adopted a supine position.

2.2.6 Ethical considerations

The trial was reviewed and approved by the corresponding Ethics and Health Research Committee of the University. The ethical standards of the Declaration of Helsinki were upheld at all times and all the study data were obtained in accordance with the principles set out in current legislation on the protection of personal data. The databases were stored in computers dedicated exclusively to this project. All the participants who participated in the study gave signed informed consent, after receiving a complete explanation of the study.

2.2.7 | Data analysis

Descriptive and exploratory analysis: descriptive statistics of the variables were obtained, with measures of central tendency and dispersion or percentages, according to the nature of each variable; in every case, the normality of the distribution was evaluated using the

Kolmogorov–Smirnov test and the asymmetry and kurtosis of the distributions and histograms were also determined.

Bivariate analyses were performed by applying Student's t test for independent and paired samples, when a normal distribution was observed. Otherwise, the Wilcoxon and Mann–Whitney U non-parametric tests were used. ANOVA was used for quantitative–qualitative relationships, with measures of central robustness (the Welch and Brown–Forsythe tests) in cases of non-homoscedasticity (which was determined using the Levene test). The Kruskal–Wallis analysis of multiple comparisons was performed for non-parametric distributions and correlational analysis was applied using Pearson's r and Spearman's rho for the quantitative variables. Generalized linear models were created to analyse variations in mean flow, SaO₂, temperature and pressure, in both heels. The Mauchly sphericity test

and the Greenhouse–Geisser correction were applied in the absence of sphericity and the partial eta-squared (η^2) value was determined. The standard error of measurement (SEM) was calculated using the formula $SEM = SD * \sqrt{1 - ICC}$, where ICC is the intra-cluster correlation coefficient. The minimal detectable change (MDC) (the minimal amount of change that a measurement must show to be greater than within-participant variability and measurement error) was estimated using the formula: $SMD * 1.96 * \sqrt{2}$.

Multivariable analysis: multivariable linear regression analysis was conducted according to the nature of the variable, to determine factors associated with the modification of the variables of interest. The explanatory variables were those for which bivariate analysis revealed a significant association ($p < .05$). The outcome variables were those related to the main objective of the study. Post hoc analyses were carried out to evaluate the power of the results of the multivariable regression. All analyses were performed assuming a 95% confidence interval, with SPSS V25 statistical software (IBM Corp., 2017).

3. Results

Of the 18 participants who participated in the study (measurement equivalent: 2,160 min), 55.6% were women and 44.4% were men, with an average age of 23.56 years. All had a normal anthropometric profile (Table 1). Figure 2 shows the flowchart of participation. Mean FFM values were 16.34 kg higher for men than for women, while mean FM values were 4.47 kg lower. In both cases, the difference was statistically significant (Mann–Whitney U test; $p < .01$). However, with respect to BMI, there were no significant differences between the sexes (Mann–Whitney U test; $p = .198$). It was also observed no

significant difference between the results for men and women as concerns systolic and diastolic blood pressure (Mann–Whitney test; $p = .154$ and $p = .688$, respectively).

The comparative analysis showed that, given a statistically significant ($p < .01$) difference in pressure between the heels, capillary blood flow was significantly lower in the heel under direct pressure (28 AU at 75 min; $p = .002$). For SaO₂ and tissue temperature, the differences between the heels were minimal and non-significant ($p = .499$ and $p = .445$ respectively), although they were somewhat higher in the heel under pressure (Figure 3). Table 2 shows the SEM and the MDC values obtained for each of the outcome variables. Significant correlations were obtained ($p < .01$) for the here outcome variables with the heel under direct pressure: flow-SaO₂ ($r = .345$), flow-temperature ($r = .396$) and SaO₂-temperature ($r = .447$). With respect to SaO₂ in the skin of the heel under direct pressure, the linear regression model obtained a goodness of fit of 26% ($p < .01$). In this model, the most influential explanatory variables of the outcome variable were capillary blood flow, temperature, pressure exerted, FFM, FM and time elapsed, all of which were statistically significant ($p < .01$). Increases in flow, temperature and pressure were all associated with greater SaO₂. Among the anthropometric variables, increases in SaO₂ were measured in participants with better FFM and FM. The model showed that the passage of time was associated with a significant decrease in SaO₂ (Table 3). Post hoc power analysis yielded a power of 99.86% for these results. For the heel without direct pressure, this same model was replicated, obtaining a poor fit ($R^2 = 0.12$), with temperature, flux and FM as the explanatory variables with significant association. Two different linear regression models were evaluated for capillary flow and temperature as outcome variables. In any case was a good fit obtained for the explanatory of SaO₂, pressure exerted, capillary blood flow, temperature, FFM, FM or duration of exposure to pressure.

4. Discussion

The aim of this study was to evaluate, simultaneously, the changes that take place in capillary blood flow, SaO₂ and skin temperature, in healthy volunteers when one heel is subjected to the pressure exerted by the weight of the foot resting directly on a constant low-pressure support surface, versus that exerted on the other heel, protected by a pillow beneath the Achilles tendon area. At all times the skin of the heels subjected to direct pressure was at a higher temperature than when the pressure was relieved. Moreover, with a greater duration of exposure to pressure, the temperature rose (for both heels).

Corroborating the findings reported by Lachenbruch, Tzen, Brienza, Karg, and Lachenbruch (2015), our results show that increased skin temperature in the heel is related to increased capillary blood flow (hyperaemia) in the area, although the latter authors did not study the heel, but rather the sacral area of healthy participants. To our knowledge, no previous studies have been undertaken to measure skin temperature when the heel is exposed to pressure with healthy participants. Further research is needed to determine whether in real clinical settings this increase in tissue temperature is associated with an increased risk of patients developing PUs.

For both heels, the values for SaO₂ decreased over time, despite the healthy status of all the participants. Although this outcome has been reported previously (Aliano et al., 2013), we reinforce this observation with objective pressure data, measurements over a longer period and a larger sample size. According to our results, the SaO₂ was greater in the skin of the heels under direct pressure than when the pressure was relieved. This finding needs to be confirmed in a clinical setting and with longer measurement times, since the outcome may vary with prolonged hypoperfusion. In addition, the results obtained with the regression model suggest that other factors, such as FFM, FM and time elapsed, should also be taken into account for the heel under pressure. On the other hand, the heel without direct pressure did not obtain a good fit in the regression model, although these results need to be confirmed in the clinical setting.

Two of the variables analysed in our study and which are known to influence tissue oxygenation – capillary blood flow and the duration of immobility – were included in the conceptual model proposed by Coleman et al. (2014), an association which suggests that SaO₂ may be related to the genesis of PUs. In the latter model, body temperature is a potential indirect predisposing factor. In our case, changes in tissue temperature are associated with changes in SaO₂. Accordingly, this parameter may be relevant to the control and/or prevention of PUs.

According to our model, moreover, in a healthy participant the level of FFM and FM is significantly associated with the changes that occur in the SaO₂ of the skin of the heels. Therefore, the appearance of a PU in this area will depend, to a greater or lesser extent, on the FFM and FM of the person affected. This model accounts for 26% of the changes observed in the SaO₂ of the skin of the heels. In view of the scant attention paid to this question in previous research, it would seem to warrant more detailed consideration.

With respect to tissue perfusion, our results are comparable with those obtained by Rothenberger et al. (2014) and Mayrovitz et al. (2003), who also observed that the tissue

perfusion of heels subjected to direct pressure on a constant low-pressure support surface was at all times lower than in heels where the pressure was relieved. However, no other study has observed that this capillary blood flow changes very little over time. This stability might be part of a compensatory physiological process in healthy people, for whom more time under direct pressure would have to elapse before the perfusion became significantly compromised.

The logical continuation to this study would be to address the clinical phase, i.e., to obtain the same measurements in a real clinical situation, with patients admitted to acute care hospitals and nursing residences, since it is these participants who are at greatest risk of deterioration to skin integrity (Jull et al., 2016; Pancorbo-Hidalgo et al., 2014; Van Gilder et al., 2017). Such an analysis of the clinical phase would enable us to determine the stage at which the physiological values studied become strongly associated with the appearance of PUs. This knowledge would, in turn, enhance decision-making and help prevent the appearance of this condition.

4.1 Limitations

This study was conducted under conditions of maximum experimentality and with healthy participants. Aspects such as age or health status of the participants in the study limit the extension of these results to that population that usually suffer PUs. Therefore, its external validity may be limited, and the findings reported need to be corroborated in a real clinical setting. However, due to the complexity of the measurement procedure described, it would be a difficult matter to reproduce the experimental conditions in clinical practice. In this respect, further advances are required in the design of measurement devices, to make them more accessible in practical situations. Nevertheless, the values obtained in healthy people can be used as a reference background to compare measurements in people with health conditions.

5. Conclusions

According to the data analysis, both null hypotheses have been refuted. In heels subjected to continuous pressure for 2 hr, tissue perfusion decreased significantly, with respect to heel tissues relieved of this pressure. However, no significant differences were observed in local temperature or oxygenation during this period. In healthy participants, compensatory mechanisms seem to play a major role, helping the maintenance of the homeostasis. Continuing this present study to a clinical phase, conducted in hospitals and

nursing residences, would strengthen its external validity and help establishing the most suitable stage of treatment for applying measures to prevent the occurrence of PUs in the heel and thus reduce their incidence.

Acknowledgements

This study has been possible thanks to the participation of the volunteer participants and the Faculty of Health Sciences of the University of Malaga, which have given their laboratories for the realization of this field work.

Conflict of interest

No conflict of interest has been declared by the authors.

Author contributions

AJGG, JCMH, ILP, SGM, RMG, ALC, JMMA, ABMS, MAG, SKU: Made substantial contributions to conception and design, acquisition of data and analysis and interpretation of data; AJGG, JCMH, ILP, JMMA: Involved in drafting the manuscript and revising it critically for important intellectual content; AJGG, JCMH, ILP, SGM, RMG, ALC, JMMA, ABMS, MAG, SKU: Gave final approval of the version to be published. Each author participated sufficiently in the work to take public responsibility for appropriate portions of the content; AJGG, JCMH, ILP, SGM, RMG, ALC, JMMA, ABMS, MAG, SKU: Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

ORCID

Alberto José Gómez-González <https://orcid.org/0000-0002-9560-7213>

José Miguel Morales-Asencio <https://orcid.org/0000-0001-7911-7487>

Silvia García-Mayor <https://orcid.org/0000-0002-3913-3850>

Álvaro León-Campos <https://orcid.org/0000-0002-1468-3012>

REFERENCES

- Abu-Own, A., Sommerville, K., Scurr, J. H., & Coleridge Smith, P. D. (1995). Effects of compression and type of bed surface on the microcirculation of the heel. *European Journal of Vascular and Endovascular Surgery: The Official Journal of the European Society for Vascular Surgery*, 9(3), 327–334. [https://doi.org/10.1016/S1078-5884\(05\)80139-X](https://doi.org/10.1016/S1078-5884(05)80139-X)
- Aliano, K. A., Stavrides, S., & Davenport, T. (2013). The use of hemoglobin saturation ratio as a means of measuring tissue perfusion in the development of heel pressure sores. *Surgical Technology International*, 23, 69–71.
- Brem, H., Maggi, J., Nierman, D., Rolnitzky, L., Bell, D., Rennert, R., Vladeck, B. (2010). High cost of stage IV pressure ulcers. *American Journal of Surgery*, 200(4), 473–477. <https://doi.org/10.1016/j.amjsurg.2009.12.021>
- Chou, R., Dana, T., Bougatsos, C., Blazina, I., Starmer, A. J., Reitel, K., & Buckley, D. I. (2013). Pressure ulcer risk assessment and prevention: A systematic comparative effectiveness review. *Annals of Internal Medicine*, 159(1), 28–38. <https://doi.org/10.7326/0003-4819-159-1-201307020-00006>
- Coleman, S., Gorecki, C., Nelson, E. A., Closs, S. J., Defloor, T., Halfens, R., Nixon, J. (2013). Patient risk factors for pressure ulcer development: Systematic review. *International Journal of Nursing Studies*, 50(7), 974–1003. <https://doi.org/10.1016/j.ijnurstu.2012.11.019>
- Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Nelson, E. A. (2014). A new pressure ulcer conceptual framework. *Journal of Advanced Nursing*, 70(10), 2222–2234. <https://doi.org/10.1111/jan.12405>
- NPUAP/EPUAP/PPPIA (2014). National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and treatment of pressure ulcers: Clinical practice guideline. In E. Haesler (Ed.), *Prevention and treatment of pressure ulcers: Clinical practice guideline as already indicated* (pp. 38– 59). Osborne Park Western Australia: Cambridge Media.
- García-Mayor, S., Morilla-Herrera, J. C., Lupiáñez-Pérez, I., Kaknani Uttumchandani, S., León Campos, Á., Aranda-Gallardo, M., ... Morales-Asencio, J. M. (2018). Peripheral perfusion and oxygenation in areas of risk of skin integrity

- impairment exposed to pressure patterns. A phase I trial (POTER Study). *Journal of Advanced Nursing*, 74(2), 465–471. <https://doi.org/10.1111/jan.13414>
- Gillespie, B. M., Chaboyer, W. P., McInnes, E., Kent, B., Whitty, J. A., & Thalib, L. (2014). Repositioning for pressure ulcer prevention in adults. *The Cochrane Database of Systematic Reviews*, 4, CD009958. <https://doi.org/10.1002/14651858.CD009958.pub2>
 - Goossens, R. H. M., & Rithalia, S. V. S. (2008). Physiological response of the heel tissue on pressure relief between three alternating pressure air mattresses. *Journal of Tissue Viability*, 17(1), 10–14. <https://doi.org/10.1016/j.jtv.2007.09.001>
 - Hanson, D., Langemo, D. K., Anderson, J., Thompson, P., & Hunter, S. (2010). Friction and shear considerations in pressure ulcer development. *Advances in Skin & Wound Care*, 23(1), 21–24. <https://doi.org/10.1097/01.ASW.0000363489.38996.13>
 - IBM Corp. (2017). *IBM SPSS Statistics for Windows, Version 25.0*. Armonk, NY: IBM Corp.
 - Jull, A., McCall, E., Chappell, M., & Tobin, S. (2016). Measuring hospital-acquired pressure injuries: A surveillance programme for monitoring performance improvement and estimating annual prevalence. *International Journal of Nursing Studies*, 58, 71–79. <https://doi.org/10.1016/j.ijnurstu.2016.02.005>
 - Källman, U., Engström, M., Bergstrand, S., Ek, A.-C., Fredrikson, M., Lindberg, L. G., & Lindgren, M. (2015). The effects of different lying positions on interface pressure, skin temperature and tissue blood flow in nursing home residents. *Biological Research for Nursing*, 17(2), 142–151. <https://doi.org/10.1177/1099800414540515>
 - Lachenbruch, C., Tzen, Y. T., Brienza, D., Karg, P. E., & Lachenbruch, P. A. (2015). Relative contributions of interface pressure, shear stress and temperature on ischemic-induced, skin-reactive hyperemia in healthy volunteers: A repeated measures laboratory study. *Ostomy/ Wound Management*, 61(2), 16–25.
 - Loerakker, S., Manders, E., Strijkers, G. J., Nicolay, K., Baaijens, F. P. T., Bader, D. L., & Oomens, C. W. J. (2011). The effects of deformation, ischemia and reperfusion on the development of muscle damage during prolonged loading. *Journal of Applied Physiology* (Bethesda, Md.: 1985), 111(4), 1168–1177. <https://doi.org/10.1152/jappphysiol.00389.2011>

- Mayrovitz, H. N., & Sims, N. (2002). Effects of different cyclic pressurization and relief patterns on heel skin blood perfusion. *Advances in Skin & Wound Care*, 15(4), 158–164. <https://doi.org/10.1097/00129334-200207000-00006>
- Mayrovitz, H. N., Sims, N., Taylor, M. C., & Dribin, L. (2003). Effects of support surface relief pressures on heel skin blood perfusion. *Advances in Skin & Wound Care*, 16(3), 141–145. <https://doi.org/10.1097/00129334-200305000-00012>
- Moore, Z. E. H., & Cowman, S. (2015). Repositioning for treating pressure ulcers. *The Cochrane Database of Systematic Reviews*, 1, CD006898. <https://doi.org/10.1002/14651858.CD006898.pub4>
- National Institute for Health and Care Excellence. (2014). Pressure ulcers: prevention and management. Clinical guideline [CG179]. Retrieved from <https://www.nice.org.uk/guidance/cg179>
- Pancorbo-Hidalgo, P. L., García-Fernández, F. P., Torra i Bou, J.-E., Verdú-Soriano, J. & Soldevilla-Agreda, J. J., (2014). Epidemiología de las úlceras por presión en España en 2013: 4.o Estudio Nacional de Prevalencia. *Gerokomos*, 25(4), 162–170. <https://doi.org/10.4321/S1134-928X2014000400006>
- Rothenberger, J., Krauss, S., Held, M., Bender, D., Schaller, H.-E., Rahmanian-Schwarz, A., ... Jaminet, P. (2014). A quantitative analysis of microcirculation in sore-prone pressure areas on conventional and pressure relief hospital mattresses using laser Doppler flowmetry and tissue spectrophotometry. *Journal of Tissue Viability*, 23(4), 129–136. <https://doi.org/10.1016/j.jtv.2014.05.001>
- VanGilder, C., Lachenbruch, C., Algrim-Boyle, C., & Meyer, S. (2017). The International Pressure Ulcer Prevalence™ Survey: 2006–2015: A 10-Year pressure injury prevalence and demographic trend analysis by care setting. *Journal of Wound, Ostomy and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society*, 44(1), 20–28. <https://doi.org/10.1097/WON.00000000000000292>
- Wang, Y., Pu, L., Li, Z., Hu, X., & Jiang, L. (2016). Hypoxia-inducible factor-1 α gene expression and apoptosis in ischemia-reperfusion injury: A rat model of early-stage pressure ulcer. *Nursing Research*, 65(1), 35–46. <https://doi.org/10.1097/NNR.0000000000000132>

- WHO (Ed.). (2008). Alcohol y atención primaria de la salud: Informaciones clínicas básicas para la identificación y el manejo de riesgos y problemas. Washington, DC: Organización Panamericana de la Salud.
- Wong, V. K., Stotts, N. A., Hopf, H. W., Dowling, G. A., & Froelicher, E. S. (2011). Changes in heel skin temperature under pressure in hip surgery patients. *Advances in Skin & Wound Care*, 24(12), 562–570. <https://doi.org/10.1097/01.ASW.0000408466.88880.f8>
- Wong, V. K., Stotts, N. A., Hopf, H. W., Froelicher, E. S., & Dowling, G. A. (2007). How heel oxygenation changes under pressure. *Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society*, 15(6), 786–794. <https://doi.org/10.1111/j.1524-475X.2007.00309.x>

TABLES AND FIGURES

Figure 1: placement of laser Doppler and infrared units

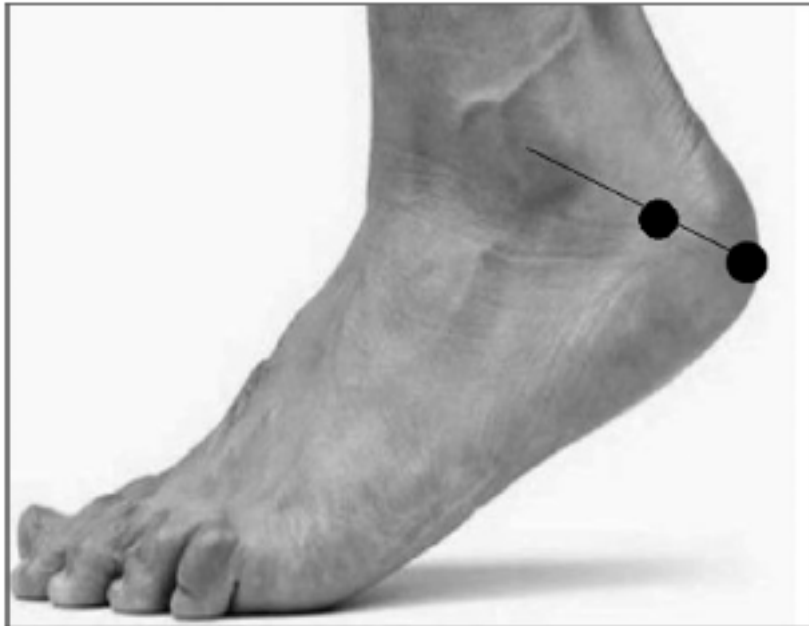


Table 1: participant's characteristics

| Participants' characteristics | Mean or frequency |
|---------------------------------|-------------------|
| Age (mean and SD) | 23.56 (5.27) |
| Gender | |
| Male | 8 (44.4%) |
| Female | 10 (55.6%) |
| BMI (kg/m ²) | 22.23 (1.62) |
| FFM (kg) | 48.12 (9.59) |
| FM (kg) | 15.05 (4.35) |
| Systolic blood pressure (mmHg) | 108.83 (10.98) |
| Diastolic blood pressure (mmHg) | 64.89 (7.54) |

Abbreviations: SD, standard deviation.

Figure 2: flow diagram

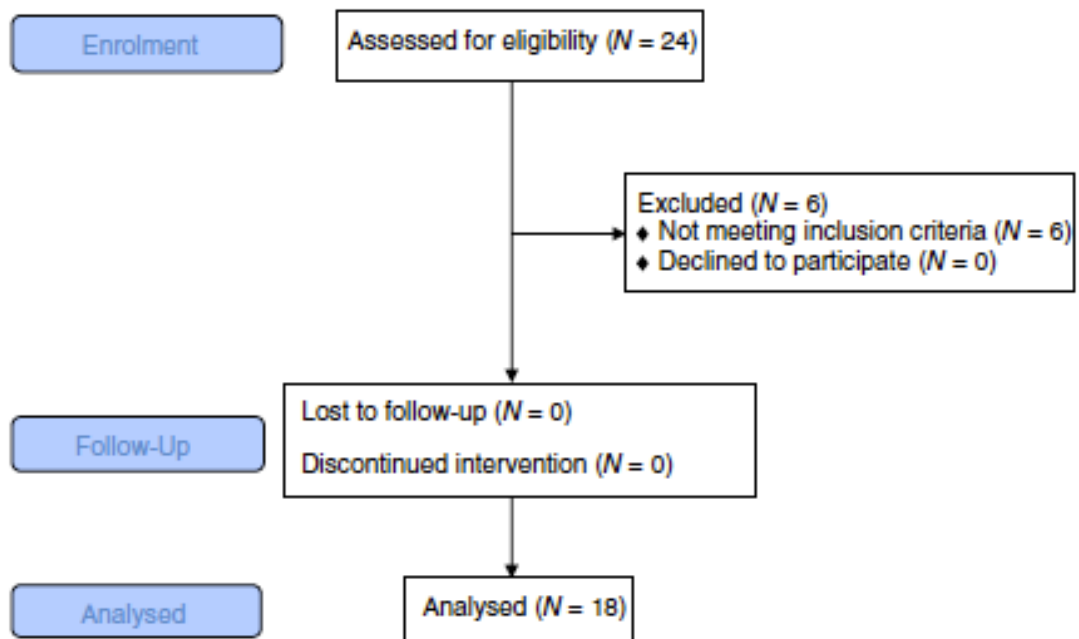


Figure 3: distribution of tissue flow, oxygen saturation, temperature and pressure in both heels

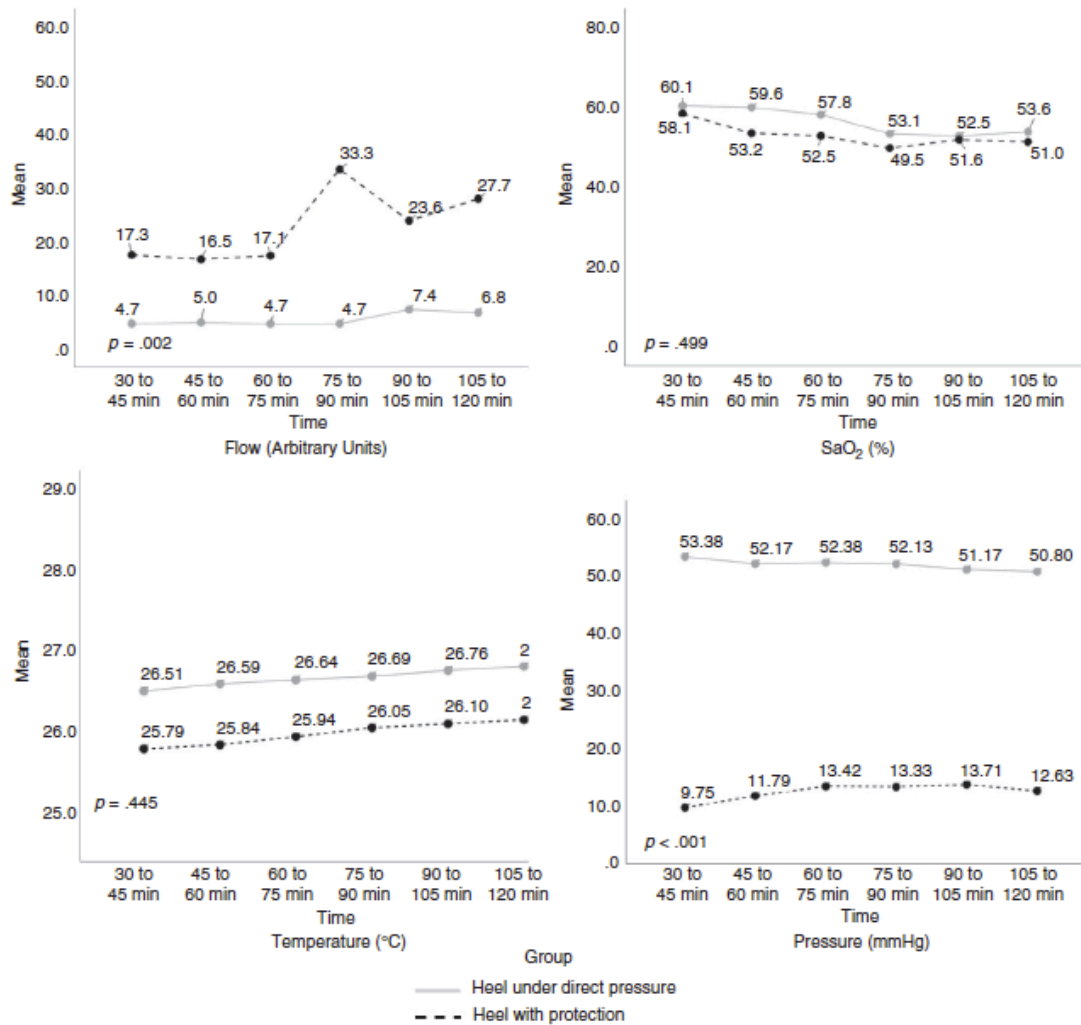


Table 2: standard error of measurement and minimum detectable change of variables Flux, SaO₂ and Temperature

| | SEM | CI 95% | MDC (95%) |
|-------------------------|------|-------------|-----------|
| Flux-1 (AU) | 1.14 | 3.31-7.77 | 3.15 |
| Flux-2 (AU) | 7.97 | 6.23-37.49 | 22.10 |
| SaO ₂ -1 (%) | 3.45 | 50.37-63.93 | 9.58 |
| SaO ₂ -2 (%) | 4.87 | 49.92-62.01 | 13.50 |
| Temp-1 (°C) | 0.25 | 26.14-27.13 | 0.70 |
| Temp-2 (°C) | 0.27 | 25.42-26.48 | 0.75 |

Note: 1, Heel under direct pressure;2, Heel with protection. Abbreviations: SEM, standard error of measurement, MDC, Minimum detectable change, variations of within- participant scores over time

Table 3: Linear regression model of the oxygen saturation in the heel under direct pressure

| | B | Std. error | t | p | CI 95% | | VIF |
|---------------------------------------|--------|------------|--------|-------|--------|--------------------------------|-------|
| | | | | | Lower | Upper | |
| Temp-1 | 1.643 | 0.286 | 5.752 | <0.01 | 1.081 | 2.205 | 1.071 |
| Flux-1 | 0.622 | 0.177 | 3.517 | <0.01 | 0.274 | 0.971 | 1.217 |
| Press-1 | 0.120 | 0.050 | 2.373 | 0.018 | 0.020 | 0.219 | 1.109 |
| FFM | -0.274 | 0.085 | -3.221 | <0.01 | -0.107 | -0.049 | 1.247 |
| FM | -0.883 | 0.028 | -4.730 | <0.01 | -0.515 | -0.241 | 1.229 |
| Time | -0.119 | 0.310 | -4.219 | <0.01 | -0.063 | -0.166 | 1.054 |
| Outcome Variable: SaO ₂ -1 | | | | | | R ² = 0.26; p < .01 | |

Note: 1, Heel under direct pressure.