

Original Article

## Skin microclimate on heels: a within-person randomized clinical trial\*

Microclima da pele em calcâneos: ensaio clínico randomizado autocontrolado  
*Microclima de la piel de los talones: ensayo clínico aleatorizado y autocontrolado*

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### Abstract

**Objective:** To evaluate the skin microclimate on the heels of patients hospitalized in an intensive care unit, using multi-layer polyurethane foam with silicone compared to transparent polyurethane film. **Method:** a within-person, parallel, randomized, clinical trial of superiority. Each patient received the experimental intervention (multi-layer polyurethane foam dressing with soft silicone) and the control intervention (transparent polyurethane film dressing), totaling 184 cutaneous sites (92 patients). The study was conducted in a university hospital in Santa Maria, Rio Grande do Sul State, from July 2017 to March 2018. **Results:** No statistically significant difference was identified regarding the temperature of the skin of the heels that developed pressure injuries (PIs), as well as of the heels using transparent polyurethane film between the initial and final assessment. **Conclusion:** The skin microclimate undergoes changes in its values when using dressings for PI prevention.

**Descriptors:** Pressure Ulcer; Microclimate; Skin; Bandages; Clinical Trial

### Resumo

**Objetivo:** avaliar o microclima da pele em calcâneos de pacientes hospitalizados em unidade de tratamento intensivo, usando espuma multicamadas de poliuretano com silicone comparada ao filme transparente de poliuretano. **Método:** ensaio clínico paralelo randomizado autocontrolado de superioridade. Cada paciente recebeu a intervenção experimental (espuma multicamadas de poliuretano com silicone) e a intervenção controle (filme transparente de poliuretano), totalizando 184 sítios cutâneos (92 pacientes). O estudo foi desenvolvido em um hospital

universitário do interior do estado do Rio Grande do Sul, no período de julho de 2017 a março de 2018. **Resultados:** não se identificou diferença estatisticamente significativa quanto à temperatura da pele dos calcâneos que desenvolveram lesão por pressão (LP), bem como dos calcâneos em uso do filme transparente de poliuretano entre a avaliação inicial e final. **Conclusão:** o microclima da pele sofre alterações em seus valores quando em uso de coberturas para prevenção de LP.

**Descritores:** Úlcera por Pressão; Microclima; Pele; Bandagens; Ensaio Clínico

## Resumen

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**Objetivo:** evaluar el microclima de la piel de los talones de pacientes hospitalizados en una unidad de cuidados intensivos, utilizando espuma de poliuretano multicapa con silicona en comparación con película de poliuretano transparente. **Método:** ensayo clínico paralelo, aleatorizado y autocontrolado de superioridad. Cada paciente recibió la intervención experimental (espuma de poliuretano multicapa con silicona) y la intervención de control (película de poliuretano transparente), totalizando 184 sitios de piel (92 pacientes). El estudio se realizó en un hospital universitario del interior del estado de Rio Grande do Sul, de julio de 2017 a marzo de 2018. **Resultados:** no se identificó diferencia estadísticamente significativa en cuanto a la temperatura de la piel de los talones que desarrollaron lesiones por presión (LP), así como los tacones utilizando película de poliuretano transparente entre la evaluación inicial y final. **Conclusión:** el microclima de la piel sufre cambios en sus valores cuando se utilizan fundas para prevenir la IP.

**Descriptores:** Úlcera por Presión; Microclima; Piel; Vendajes; Ensayo Clínico

## Introduction

Pressure injuries (PI) are localized damage to the skin and/or underlying soft tissue, caused by prolonged and/or intense pressure in association with shear<sup>1</sup>, considered a public health problem with high costs for the health system.<sup>2</sup> The identification of PIs is conducted through skin assessment. However, these changes depend on manifestations on the surface, such as the presence of non-blanchable erythema. Thus, it is concerning when the damage emerges from deeper layers – deep tissue pressure injury, because once it becomes evident, it may be more challenging to prevent the injury.<sup>3</sup>

Advancements in knowledge about PIs and their etiology have been remarkable, and skin microclimate has emerged as a prominent factor in this context. In 1970, researchers first mentioned the concept of skin microclimate,<sup>4</sup>

which is now understood as a crucial component in PI prevention.<sup>5</sup> The skin microclimate influences the tolerance of soft tissues to pressure and shear, playing a fundamental role in the development of these injuries.<sup>6</sup>

The term "microclimate" refers to the temperature and moisture of the skin and the humidity conditions at the skin-surface interface.<sup>6</sup> It can also be defined as the climate in a specific region that differs from the surrounding area – environment. This concept is present in scientific disciplines such as botany, zoology, architecture, and aeronautics. In the context of PI prevention, the microclimate near the skin surface is particularly relevant,<sup>5</sup> as changes in its characteristics increase the risk of developing PIs.<sup>7</sup> Temperature and moisture affect the structure and function of the skin,<sup>5</sup> so maintaining a balanced microclimate is an important component of the ability of the skin and underlying soft tissue to withstand prolonged stress caused by pressure.<sup>7</sup>

The skin of the heels is reported in the literature as one of the areas most affected by PIs,<sup>5,8</sup> which are often severe, difficult to heal, and can present various complications. The main causes are factors such as pressure, shear, and friction. The vulnerability of the heel to pressure damage is also increased by immobility, the patient's skin condition, the presence of previous PIs and/or scar tissue, and suboptimal tissue perfusion.<sup>8</sup>

It is important to highlight that there is a scarcity of high-quality evidence to identify risk factors associated with the development of PIs on the heel. Immobility, diabetes, vascular disease, impaired nutrition, perfusion issues, mechanical ventilation, surgery, and Braden subscales have been identified as potential risk factors for the development of PIs on the heel.<sup>9</sup>

In this perspective, alternative methods need to be put into practice to assess patients at risk of developing PIs. Therefore, the analysis of the microclimate is considered an important strategy in the early assessment of these injuries, as the skin adapts to different temperature and humidity conditions, and extreme variations in these measures negatively affect skin protection.

The specific parameters of the ideal microclimate and possible upper and lower thresholds are still unknown, representing a gap in the scientific knowledge produced.<sup>5</sup>

The introduction of dressings for PI prevention has high levels of evidence;<sup>1</sup> however, it is known that they influence the skin microclimate (temperature and moisture),<sup>5</sup> requiring studies to determine how these two variables positively or negatively influence the risk of developing PIs. Since prophylactic dressings are relatively new additions to prevention actions, some fundamental questions about their effect, particularly from the perspective of the microclimate, remain unanswered.<sup>10</sup>

In this context, this research aims to evaluate the skin microclimate on the heels of hospitalized patients in an intensive care unit, using multi-layer polyurethane foam dressing with soft silicone compared to transparent polyurethane film dressing.

## **Method**

A randomized, open-label, parallel, controlled superiority trial with a 1:1 allocation ratio,<sup>11</sup> guided by the CONSORT tool, was conducted in the intensive care unit (ICU) of a university hospital in Santa Maria, Rio Grande do Sul, Brazil, from July 2017 to March 2018. The controlled approach used in this study allows for the elimination of interference from variable factors between individuals by evaluating symmetrical body sites. The objective is to compare the effectiveness or outcomes between the evaluated sites. This methodology provides a more precise assessment of interventions, minimizing individual influences and highlighting the specific effects of the variables of interest.<sup>11</sup>

The study population consisted of patients hospitalized in the ICU. The study included patients aged 18 years or older, at high risk (scores of 10 to 12) or very high risk (scores of 9 or lower) of developing PIs according to the Braden scale, and with their pair of heels without PIs at the time of the first assessment. Patients with amputation of one lower limb, without access to the heels (e.g., due to plaster cast, wound), or without a legal guardian to consent to the family member's participation

in the first 24 hours of hospitalization were excluded. Patients who met the eligibility criteria formed a single group that received both interventions, one on each heel.

The sample size calculation was performed using Epi Info™ version 7.2, considering a statistical power of 80%, a significance level of 95% ( $\alpha < 0.05$ ), a population size of 227 patients (number of patients admitted to the ICU in 2015), an expected frequency of pressure injury of 40%<sup>12</sup>, and a margin of error of 5 percentage points, totaling 141 individuals. An additional 30% was added to this value for possible losses, totaling 183 individuals.

Thus, the final sample consisted of 184 cutaneous sites, as the heels were evaluated and randomized, the sample was divided by two. In other words, 92 patients were included, totaling 184 cutaneous sites, with 92 heels allocated to the intervention group and 92 to the control group.

The data collection tool used was the collector's manual, and the team training began with training on the standard operating procedures (SOPs) necessary for entry into the research field. Afterward, the team was trained for selecting the research participants application of the Braden scale, approaching family members to obtain informed consent, randomization, allocation, and completion of the electronic data collection form, developed in the Epi Info™ version 7.2 program. The team was also trained to use the devices used to collect microclimate variables: an infrared thermometer, a skin analyzer by electrical bioimpedance, and a thermo-hygrometer, as well as the use of interventions.

Daily visits to the ICU were conducted to recruit eligible patients within the first 24 hours of hospitalization. Since all research patients were sedated, the invitation was extended to the family member or legal caregiver in the unit itself, after visiting hours.

A sequence of numbers was generated using the website <http://stattrek.com/statistics/random-number-generator.aspx>, with a minimum number of one and a maximum of two. Subsequently, allocation concealment was

performed so that the researchers responsible for recruitment were unaware of the groups to which the participants could be allocated. For randomization, the numbers were placed inside opaque, sealed envelopes, ordered from 1 to 92 on the outside.

The groups formed were the intervention group (MPFS) and the control group (TPF). The number one was considered the intervention group (IG), and the number two was considered the control group (CG). Randomization was always performed for the right heel. If the number 1 was inside the envelope, the right heel would participate in the IG. If it was the number 2, the right heel would participate in the CG. Thus, the left heel automatically became part of the opposite group. The envelope was opened by a member of the ICU nursing team.

The MPFS was kept for a maximum of five days, as recommended by the manufacturer, and was replaced after this period or whenever necessary. The MPFS was removed from the heel for measurement of the variables and then replaced, as the product technology allows for reuse for more than one application. The TPF allows for a single application, with daily changes due to the need to assess the skin microclimate, but the reasons for changes were recorded, as other reasons were also identified for not keeping the film.

It is important to note that skin microclimate variables were collected on day 1 (baseline) without the use of dressings. Afterward, the dressings were applied to the heels, for which the skin was previously prepared by cleaning with 0.9% saline solution and drying afterward to receive the dressings. All patients included in the study received preventive measures according to the hospital protocol: air mattress, daily assessment of the risk of developing PIs using the Braden scale, repositioning every 2 hours, use of moisturizer on the skin, and keeping the skin dry.

The follow-up period was a maximum of 15 days. Patients were monitored from the time of inclusion until the development of a PI (endpoint) or until discontinuation criteria were met: hospital discharge, transfer to another unit, death, absence of coverage at the time of evaluation, Braden score > 12 within 24 hours. It is noteworthy that the presence of PIs was identified and classified according to international guidelines.<sup>6</sup>

The skin temperature variable was measured using an infrared digital thermometer (62 MAX, Fluke Corporation, Everett, Washington, United States). The distance from the thermometer to the skin was 7 cm, following a similar study conducted in Indonesia.<sup>13</sup> The skin moisture variable was measured using electrical bioimpedance (Skin Analyzer SKN1501, Skin Up Beauty Devices). Both measurements were taken at the center of the heels and the dorsum of the feet (control region for the variables).

The choice of the dorsum of the foot is justified by a study aimed at evaluating the skin temperature of volunteer patients in 25 different body areas, comparing the right side with the left, age groups, and gender. From this study, it was possible to identify that the dorsum of the foot is the body area with a temperature closest to that of the heel.<sup>14</sup>

The ambient temperature and humidity variables were measured using a thermo-hygrometer (model 7663.02.0.00, Cotronic Technology Ltd, China). The temperature and humidity conditions of the environment were controlled and stable at the time of measurement. All devices were calibrated before data collection began.

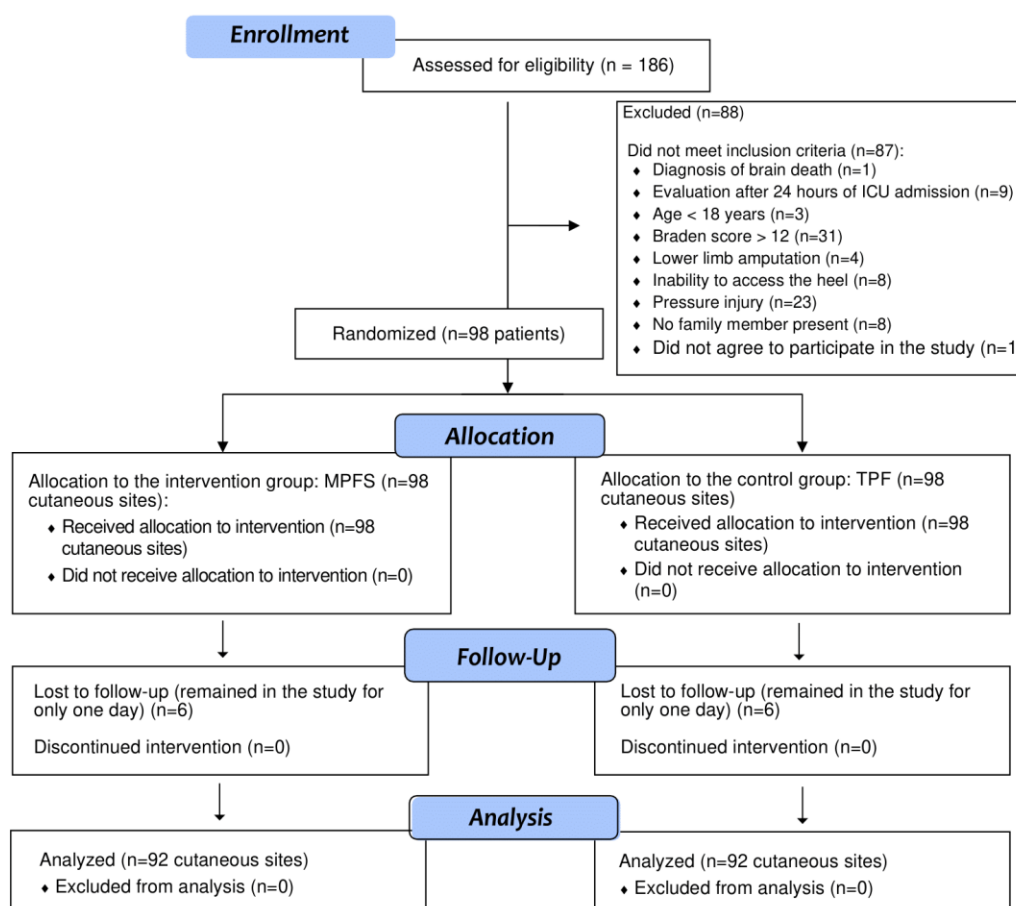
A descriptive analysis of the qualitative variables was performed using absolute frequency (n) and relative frequency (%), while quantitative variables were analyzed using measures of central tendency (mean or median) and dispersion (standard deviation - SD or interquartile range - IQR). The Shapiro-Wilk test was used to assess the normality of the quantitative data. For variables between the baseline (first measurement, without the use of dressings) and end (last measurement) groups, the Wilcoxon test was performed (paired data, non-normal distribution).

To analyze the outcome variables between the groups with and without the development of PIs, the Student's t-test was performed (for data with a normal distribution) or the Mann-Whitney U test (for data without a normal distribution). To analyze the correlation between quantitative variables, the Spearman correlation was used (in the absence of a normal distribution). A very high correlation was considered when r values were between 0.90 and 1.00; high from 0.70 to 0.90; moderate from 0.50 to 0.70; low from 0.30 to 0.50; and insignificant from 0.00 to 0.30.<sup>15</sup> The significance level was set at 5%.

The research was conducted in accordance with the ethical standards required by Resolutions 466/2012, 510/2016, and 580/2018 of the Ministry of Health. This study was approved by the Ethics Committee of the Federal University of Santa Maria under Opinion number: 1,966,620 and Certificate of Presentation for Ethical Consideration (CAAE) 63998117.9.0000.5346. It was also approved by the Brazilian Clinical Trials Registry (ReBEC) under registration RBR-4s8qjx.

## Results

In total, 186 patients were considered eligible for the study. However, 88 patients were excluded, resulting in 98 patients being randomized. At the end of the analysis, 92 patients (184 heels) were included, as illustrated in Figure 1.



**Figure 1** - Flowchart of participant selection according to the CONSORT statement for non-pharmacological interventions. Santa Maria, RS, Brazil, 2018

The average age of the participants was 58.3 years. Most of the research participants were male (n=52; 56.5%) and self-identified as white (n=81; 88.0%). Of the 184 cutaneous sites (heels) evaluated, 20 developed PIs, but there was no significant difference (p=0.052) in heel temperature between the first (baseline) and the last measurement (end). However, a difference in moisture (p=0.001) of the heel was found between the first and last measurements – Table 1.

**Table 1** – Comparison of microclimate variables (temperature and humidity) of heel skin between the first and last measurements. Santa Maria, RS, Brazil, 2018. n=184

Skin Microclimate Variables	First measurement ( <i>baseline</i> )	Last measurement ( <i>end</i> )	p-value <sup>†</sup>
	Median (IQR*)	Median (IQR*)	
Heel Temperature (°C)	29.8 (3.8)	30.7 (3.1)	0.006
Heel Moisture (%)	16.2 (10.4)	29.5 (18.4)	<0.001

Note: \* IQR = interquartile range, † Wilcoxon test. p-value significant at a 5% significance level

When evaluating the microclimate variables of the skin on heels that did not develop PIs, an average temperature of 30.6°C (95% CI 30.1-31.1) and a moisture level of 28.9% (95% CI 26.1-31.7) were identified. Furthermore, there was a significant difference in temperature (p=0.025) and moisture (p<0.001) between the baseline and end measurements. The same was observed in the intervention group (MPFS). Regarding the skin microclimate of the heels that developed PIs, an average temperature of 31.9°C (95% CI 31.0-32.8) and a moisture level of 34.3% (24.6-44.1) were observed. No significant difference (p=0.052) was identified in skin temperature between the baseline and end measurements, the same was observed in the control group (TPF) – Table 2.

**Table 2** – Relationship between skin microclimate variables and the development of pressure injuries. Santa Maria, RS, Brazil, 2018. n=184

Skin microclimate variables	Intervention group (MPFS*)	Control group (TPF†)
	Median (IQR‡)	Median (IQR)
Heel temperature on day 1 (baseline) (°C)	29.6 (3.8)	29.9 (3.7)
Heel temperature on the last day (end) (°C)	30.7 (3.1)	30.8 (3.1)
p-value§	0.038	0.080
Heel moisture on day 1 (baseline) (%)	16.5 (10.8)	15.8 (10.2)
Heel moisture on the last day (end) (%)	25.2 (15.1)	33.8 (20.4)
p-value§	<0.001	<0.001
Skin microclimate variables	Developed PIs <sup>  </sup> (n=20)	Did not develop PIs (n=164)
	Median (IQR)	Median (IQR)
Heel temperature on day 1 (baseline) (°C)	29.7 (5.1)	29.8 (6.7)
Heel temperature on the last day (end) (°C)	32.0 (2.6)	31.0 (5.2)
p-value§	0.052	0.025
Heel moisture on day 1 (baseline) (%)	10.8 (2.3)	11.5 (8.2)
Heel moisture on the last day (end) (%)	31.9 (43.5)	23.5 (25.7)
p-value§	0.001	<0.001

Note: \* MPFS = multi-layer polyurethane foam with soft silicone, † TPF = transparent polyurethane film, ‡ IQR = interquartile range, § Wilcoxon test. p-value significant at a 5% significance level. || PIs = pressure injuries

Table 3 presents the univariate analysis performed between the risk factors and the development of PIs, with no difference between the groups. However, even though there was no statistically significant difference, there is a trend of relationship between ambient temperature (p=0.081) and ambient humidity (p=0.095) with the development of PIs.

**Table 3** – Univariate analysis of risk factors for pressure injury development. Santa Maria, RS, Brazil, 2018. n=184

Note: \* PIs = Pressure injuries

Risk factor	Developed PIs* (n=20)	Did not develop PIs* (n=164)	p-value <sup>‡</sup>
	Median (IQR) <sup>†</sup>	Median (IQR) <sup>†</sup>	
Heel temperature on day 1 (baseline) (°C)	29.7 (5.1)	29.8 (6.7)	0.603
Heel temperature on the last day (end) (°C)	32.0 (2.6)	31.0 (5.2)	0.169
Difference between heel temperature on day 1 and last day (°C)	2.1 (4.6)	0.6 (5.1)	0.322
Heel moisture on day 1 (baseline) (%)	10.8 (2.3)	11.5 (8.2)	0.477
Heel moisture on the last day (end) (%)	31.9 (43.5)	23.5 (25.7)	0.351
Difference between heel moisture on day 1 and last day (%)	15.7 (42.0)	9.5 (23.8)	0.197
Ambient temperature (°C)	24.4 (1.2)	23.8 (1.4)	0.081
Ambient humidity (%)	57.0 (9.7)	60.0 (8.7)	0.095
Body temperature (°C)	36.7 (1.1)	36.8 (0.8)	0.308

Risk factor	Developed PIs* (n=20)	Did not develop PIs* (n=164)	p-value <sup>  </sup>
	Mean±SD <sup>§</sup>	Mean±SD <sup>§</sup>	
Difference between heel temperature and control region (dorsum of the foot) (°C)	0,8±2,8	0,9±1,8	0.868
Difference between heel moisture and control region (dorsum of the foot) (°C)	6.9 (9.5)	5.2 (9.9)	0.496

† IQR = interquartile range, ‡ Mann-Whitney test. p-value significant at 5% level. § SD = standard deviation, || Student's t-test. p-value significant at a 5% significance level

Table 4 shows the correlation between the microclimate variables regarding the heels and the dorsum of the foot. A strong positive correlation ( $r=0.876$ ;  $p<0.001$ ) was

observed between the skin temperature on the heels and the temperature of the dorsum of the foot.

**Table 4** – Univariate analysis of risk factors for pressure injury development. Santa Maria, RS, Brazil, 2018. n=184

Variables	Heels				Dorsum of the foot			
	Temperature		Moisture		Temperature		Moisture	
	r*	p-value <sup>†</sup>	R	p-value <sup>†</sup>	R	p-value <sup>†</sup>	r*	p-value <sup>†</sup>
Ambient temperature	0.042	0.567	0.048	0.518	-0.027	0.720	-0.140	0.059
Ambient humidity	0.110	0.137	0.168‡	0.022	0.061	0.411	0.175‡	0.018
Body temperature	0.019	0.799	- 0.171‡	0.021	0.026	0.724	0.130	0.078
Heel temperature	1	-	-0.001	0.990	0.876‡	<0.001	0.103	0.165
Heel moisture			1	-	-0.065	0.380	0.255‡	<0.001
Dorsum of the foot temperature					1	-	0.063	0.399
Dorsum of the foot moisture							1	-

Note: \* r = correlation coefficient, <sup>†</sup> Spearman's correlation test, ‡ p-value significant at a 5% significance level

## Discussion

In recent years, changes in skin microclimate and their relationship with the development of PIs have been highlighted. It is observed that preventive dressings induce some physical occlusion to the skin and, therefore, may interfere with microclimate conditions, as heat can be accumulated between the dressing and the covered skin. Changes in skin temperature and moisture are almost inevitable in critically ill patients in clinical settings, and such conditions must be managed to protect tissues. Although the concept of

microclimate and its effects on the risks of PIs are gaining increasing attention from clinicians and researchers, knowledge is still in its early stages.<sup>5</sup>

Prolonged pressure causes an increase in skin temperature and erythema in the heel area.<sup>16</sup> It is observed that extremes in skin temperature and moisture seem to potentiate the effects of pressure, shear, and friction. This suggests that the goal of managing the microclimate should be related to avoiding extremes of skin temperature or moisture.<sup>5-6</sup>

When skin moisture increases, it contributes to maceration and skin breakdown, as the stratum corneum becomes weaker, leading to skin damage as the tissue becomes more vulnerable to external forces.<sup>13,17</sup> Skin can be considered a viscoelastic material, so its physical characteristics can influence skin friction behavior through changes in skin elasticity, as well as the amount of adipose and muscle tissue under the dermal layer.<sup>18</sup>

The human body temperature adapts when exposed to temperature changes caused by internal or external factors. To maintain a constant temperature, vasodilation or vasoconstriction is triggered to protect the normal integrity of the skin. A systematic review examined the evidence on the effect of skin temperature on tissue degradation, and the results indicate a clear correlation between elevated skin temperature and harmful effects on the skin, both short and long term.<sup>19</sup> The findings of this review support continuous monitoring of skin temperature in patients at risk of PI, as it may contribute to early detection of PIs, allowing for immediate treatment to prevent worsening.

Shear is considered one of the main risk factors for the development of ischemic PI. However, microclimate variables – skin temperature and humidity – have been shown to be coadjutants in detecting the risk of PI, since localized changes in skin temperature can suggest changes in temperature in deeper regions.<sup>20</sup>

The thermal response of the skin surface to a cooling stress was calculated for deep tissue inflammation and deep tissue ischemia, and then compared to the computerized temperature of healthy tissue skin. In this context, an increase in intra-subject temperature between 0.25°C and 0.9°C was associated with inflammatory processes, considering that a decrease in intra-subject temperature between -0.2°C and -0.5°C was associated with local ischemia. In both cases – inflammation and ischemia – the differences in intra-subject temperature were within a fraction of 1°C.<sup>21</sup>

In this study, there was a significant increase in temperature and moisture of the patients' heels between the first assessment (baseline) and the last assessment (end), and there was a significant difference for all items in the multi-layer polyurethane foam with soft silicone. In the TPF, there was no significant difference in temperature, maintaining the difference for humidity.

Therefore, the findings suggest that the foam managed skin temperature ( $p=0.006$ ), as seen in patients who did not develop PIs ( $p=0.025$ ), where there was a significant increase in temperature. However, for the heels treated with the TPF, there was no difference between baseline and end ( $p=0.080$ ). When evaluating the baseline and end temperatures between the heels that developed PI, the difference was not significant ( $p=0.052$ ). Therefore, there is an indication that the foam may have managed the temperature in the presence of PI. However, in this study, it was not possible to establish a relationship between these variables.

A study that evaluated skin responses to the application of dressings with and without pressure on the heel and sacral regions suggests that the dressing contributes to skin protection and does not cause additional irritation or skin changes during pressure. It is known that an increase in the skin's surface temperature and the hydration of the stratum corneum are associated with an increased risk of PI. However, the dressing may counteract these undesirable effects at the skin-dressing interface by providing additional reduction of friction (and shear) on the external surface of the dressing in contact with the support surface and within the internal materials of the dressing.<sup>16</sup>

Researchers<sup>22</sup> conducted a study using thermal imaging as a complement to visual skin assessment techniques in newly admitted ICU patients. One of the findings of this study clearly identified an area of inflammation on the left heel, with a temperature increase of  $+2.0^{\circ}\text{C}$  compared to the adjacent normal skin. This thermal change observed at admission evolved into a Deep Tissue PI on day 4. Therefore, skin temperature changes can be used to identify the risk of developing superficial PIs of the skin<sup>13</sup> and deep PIs.<sup>22</sup>

Therefore, the establishment of clinical parameters regarding the variables – temperature and moisture – should be instituted. Thus, a study aimed to identify the skin temperature in different body areas of individuals hospitalized in a surgical unit, with no risk of developing PIs, with an average ambient temperature and humidity of

23.9°C and 63.4%, respectively. The results suggest that the temperature of these individuals' heels correlates with the ambient temperature and humidity, with an average heel temperature of 28.0°C in adults.<sup>23</sup>

In this study, when evaluating the 20 heels that developed PIs, no significant difference was identified between the temperature on the first day (29.7°C) and the last day (32.0°C) – ( $p=0.006$ ). However, when evaluating the 164 heels that did not develop PIs, a statistically significant difference was observed between the temperature on the first day (29.8°C) and the last day (31.0°C) – ( $p=0.025$ ).

A study conducted at a hospital in Japan, aiming to assess whether the microclimate is an independent risk factor for the development of PIs, through continuous measurements of skin temperature, perspiration, and interface pressure, concludes that the change in skin temperature to a higher level is an important risk factor for the development of PIs.<sup>17</sup>

Regarding humidity, which provides parameters of skin hydration, measured through bioelectrical impedance, there was a significant difference between the first and last day, with a greater variation in moisture in the group that developed PIs.

The assessment of skin moisture in humans through bioimpedance or bioelectrical impedance is an effective method that does not cause pain. The pathophysiological changes that occur with the skin in PIs can be verified by alterations in bioimpedance. Thus, the use of a device that assesses bioelectrical impedance can prove to be useful clinical information regarding the prevention of PIs.<sup>24</sup>

In a study conducted by German researchers, 20 healthy women were evaluated following a 90- and 150-minute immobilization protocol in a supine position. The following variables were assessed: skin temperature, hydration of the stratum corneum, transepidermal water loss, and erythema in the sacral and heel regions. There was an increase in skin surface temperature and erythema in the skin of the sacral and heel regions. The hydration of the stratum corneum and transepidermal water loss increased in the heel, but not in the sacral region.<sup>25</sup>

Skin temperature assessed through infrared thermography in the buttock region of healthy women, in a supine position, with and without the use of additional coverings for PI prevention, showed that after one hour lying in the Fowler's position, there was a considerable heat trapping ( $\sim 3^{\circ}\text{C}$  rise) between the skin and the support surface.<sup>10</sup>

Considering the microclimate variables as risk factors, there was no statistically significant difference; however, there is a trend towards an increase in ambient temperature ( $p=0.081$ ) and a decrease in ambient humidity ( $p=0.095$ ) being associated with the development of PIs. Regarding the heels, there is a positive correlation of moisture with the ambient humidity and a negative correlation between heel moisture and body temperature.

With extreme ambient temperatures, core temperature requires a higher metabolic demand for oxygen. Thus, the skin and soft tissues under pressure suffer a reduction in blood and oxygen supply.<sup>6</sup>

A similar study suggests that the increase in body temperature is significantly higher in patients with PIs ( $p=0.042$ ).<sup>13</sup> Another study reveals that it was not possible to measure skin moisture due to high humidity (60-80%) and high temperature ( $\pm 30^{\circ}\text{C}$ ) in the unit.<sup>17</sup>

Regarding the dorsum of the foot, there is a positive correlation between the dorsum temperature and the heel temperature. Therefore, based on this result, it is suggested that if over time the dorsum temperature remains within certain parameters while the heel temperature changes, this situation may be considered a warning sign for the development of PIs. The periumbilical region was used as a control in a study conducted at a hospital in Indonesia, which aimed to evaluate the microclimate and the development of PIs and superficial skin changes. The study indicates that skin temperature monitoring can be performed by comparing it to another control region.<sup>13</sup>

The evidence found in this study suggests that the skin temperature and heel moisture can be useful as clinical parameters to establish preventive care, as they undergo changes in their values when using coverings. However, it is necessary to establish values for these variables considered within the normal range, which are identified in this study as baseline values, without the use of coverings.

The research presents limitations such as the absence of blinding and the verification of variables over a very broad time frame, which may influence the results.

The findings of this study suggest changes in the variables of skin temperature and moisture in critically ill patients using coverings. It presents results that can contribute to the construction of clinical parameters for skin microclimate values, based on the evidence found, contributing to the management of clinical practice. Furthermore, the importance of classifying Stage I PIs and suspected deep tissue injury in individuals with dark skin pigmentation is highlighted. This is because the evaluation of skin temperature, subepidermal humidity, change in tissue consistency, and presence of skin pain, rather than the identification of erythema, is a recommendation of the Guideline for the prevention and treatment of pressure injuries from the European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel, and Pan Pacific Pressure Injury Alliance.<sup>9</sup>

## **Conclusion**

This study provides an understanding of skin microclimate variations, specifically regarding temperature and humidity, when using coverings for PI prevention. The use of different dressings is associated with modifications in cutaneous microclimate, highlighting a trend towards increased skin humidity in certain scenarios.

There was no significant difference in the skin temperatures of the heels that developed PIs. Regarding the comparison of microclimate variables, a difference in temperature and moisture was found between baseline and end in the intervention group (MPFS); however, no significant difference in skin temperature was identified between baseline and end in the control group (FTP), although there was a significant difference in moisture.

From these findings, there arises a concern about the real interpretation of cutaneous microclimate management. The lack of evidence defining "normal" ranges for skin temperature and moisture drives the use of the dorsum of the foot as a comparative point for such evaluations. Therefore, there is a pressing need for a systematic review to establish these clinical parameters of cutaneous microclimate, especially in ICU and other inpatient settings.

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