









ORIGINAL ARTICLE

Prevention of pressure injury in the operating room: Heels operating room pressure injury trial

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Funding information

Coordenação de Aperfeiçoamento de Pessoal de Nível Superior, Grant/Award Number: 001Fundação de Amparo à Pesquisa do Estado do Rio Grande do SulHospital Universitário de Santa MariaMölnlycke Health Care ABUniversidade Federal de Santa MariaUniversidade Católica Portuguesa / Centro de Investigação Interdisciplinar em Saúde (CIIS) - FCT Financiamento Base UIDB 04279/2020

Abstract

The objective was to evaluate the efficacy of multi-layered silicone foam (intervention) compared with transparent polyurethane film (control) in preventing heel pressure injuries caused by surgical positioning of individuals undergoing elective surgery. It was designed an intra-patient, open, parallel, randomised controlled trial was conducted in a university hospital in southern Brazil, from March 2019 to February 2020, with patients undergoing elective surgeries of cardiac and gastrointestinal specialties. The patients who met the selection criteria constituted, simultaneously, a single group receiving the intervention and active control, through paired analysis of the cutaneous sites (right heel and left heel). The outcome was the occurrence of PI, within the follow-up period was 72 hours. Brazilian Registry of Clinical Trials: RBR-5GKNG5. There was analysis of 135 patients/270 heels, with an overall incidence of 36.7%. The pressure injury incidence was significantly lower in the intervention group (26.7%), compared with the control group ($P = .001$); relative risk of 0.57. In the intervention group, the estimated pressure injury-free time (survival) was 57.5 hours and in the control group, 43.9 hours. It was concluded that Multi-layered silicone foam (intervention) is more efficacious than transparent polyurethane film (control) in the prevention of pressure injuries caused by surgical positioning of individuals undergoing elective surgery.

KEYWORDS

bandages, heel, perioperative nursing, pressure ulcer, randomised controlled trial

1 | INTRODUCTION

Pressure injuries (PI) can be considered an indicator of the quality of health care provided¹ and perioperative

nurses play an important role in patient safety outcomes.² Surgical positioning can cause complications, and PI is the most frequently reported in the literature,³ with incidence ranging from 1.3% to 54.8%,⁴⁻⁶ its development is

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multifactorial and complex.⁷ Furthermore, patients who develop PI during the perioperative period have a higher risk of sepsis, pneumonia, and other adverse events, increasing the risk of mortality.⁸

The heels represent an area susceptible to the appearance of these injuries, due to their anatomical characteristics, such as the curved and accentuated aspect, tending to increase the distortion of soft tissues that interface with the bone. In addition, there is almost no musculoskeletal tissue (highly vascularised) in the site; the subcutaneous tissue and tendon are relatively non-vascularised, with serious impairment of perfusion with the application of pressure.⁹

A systematic literature review indicates that there is a variety of clinical studies on the use of dressings in the prevention of PI, such as hydrocolloids, foams, and films. However, well-constructed randomised clinical trials (RCT) are still scarce.¹⁰

For the prevention of PI in heels, internationally, it is recommended to use multi-layered silicone foam in individuals at high risk of developing PI,¹¹ however, each hospital has its own PI prevention protocol.

International guidelines,¹¹ recommend the use of a prophylactic dressing as an adjunct to heel offloading (Strength of Evidence B1) for individuals at high risk of developing PI in operating rooms, however, each hospital has its own PI prevention protocol.

Several studies suggest that the use multi-layered silicone foam can reduce the incidence of PI, in addition to reducing costs,^{10,12-21} because it has the ability to reduce pressure forces^{22,23} and friction, as well as transferring shear away from critical areas.²² Therefore, multi-layered silicone foam is currently considered the gold standard in the prevention of PI.

Based on the reality of the hospital under study, in which transparent polyurethane film is used in the heels of patients at high risk of developing PI, this was one of the chosen dressings. Moreover, it is effective in the prevention of PI in heels²⁴ and seems to be more cost-effective than other dressings in the prevention of these injuries.^{25,26}

Based on the above, this study aims to evaluate the efficacy of multi-layered silicone foam (intervention) compared with transparent polyurethane film (control) in preventing heel PI caused by surgical positioning of individuals undergoing elective surgery.

2 | METHOD

This is an intra-patient, parallel, open, randomised clinical trial of superiority, with a 1/1 allocation rate, conducted in a university hospital in southern Brazil, from March 2019 to February 2020. The study population consisted of patients

Key Messages

- pressure injuries were one of the most reported complications related to surgical positioning
- this study aims to evaluate the efficacy of multi-layered silicone foam compared with transparent polyurethane film in preventing heel pressure injuries caused by surgical positioning of individuals undergoing elective surgery
- multi-layered silicone foam is more effective than transparent polyurethane film in the prevention of pressure injuries resulting from surgical positioning in heels of inpatients undergoing elective surgeries
- this study found a pressure injury's global incidence of 36.7%

undergoing elective surgical procedure. Cardiac and gastrointestinal specialties were chosen by convenience.

The cardiac specialty includes the following surgical procedures: myocardial revascularisation surgery, valve plastic or replacement, closure of atrial septal defect, pacemaker implantation, correction of aortic aneurysm, and sternotomy. Gastrointestinal includes esophagoplasty, esophagectomy, gastrectomy, biliodigestive shunt or anastomosis, pancreatectomy, colectomy, hepatectomy, drainage of liver abscess, splenectomy, duodenopancreatectomy, exploratory videolaparotomy. The inclusion criteria defined were:

1. Inpatients in the hospital during the preoperative period of digestive or cardiac elective surgery.
2. Expected postoperative hospitalisation ≥ 48 hours.
3. Age equal to or above 18 years.

Exclusion criteria:

1. Amputation of lower limb.
2. Fracture in one of the lower limbs using skeletal traction or external fixation, plaster, dressing that would prevent access to the heels.
3. Presence of transoperative PI in the heels, before the beginning of the surgical procedure.
4. Impaired verbal communication without companion.
5. Altered level of consciousness and without a companion.

The patients that met the selection criteria constituted, simultaneously, a single group receiving the

intervention and active control, through paired analysis of the cutaneous sites (right and left heels).

Interventions were always applied after surgical positioning and before skin degermation, according to the agreement with the surgical team. The heel was cleaned with 0.9% saline and gauze. The heel was dried with another gauze in order to allow the correct placement of the prophylactic dressings. Intervention group received multi-layered silicone foam (Mepilex Border Heel, Mölnlycke Health Care AB, Sweden). This dressing consists of a soft silicone wound contact layer (Safetac) on a polyurethane film carrier; a flexible, absorbent pad in three layers: a polyurethane foam, a viscose/polyester non-woven spreading layer and a layer with super absorbent polyacrylate fibres; an outer polyurethane film,

which is vapour permeable and waterproof. The multi-layered silicone foam was removed and replaced to visualise the skin to the end of surgical procedure and daily during follow-up period.

Control group received transparent polyurethane film (Advanced, Cremer, brand used at the study site). In order to cover the entire heel region, transparent polyurethane film with 15 cm wide and 10 m long, was cut into strips of 4 cm. Three strips were placed horizontally on the heels, overlapping them around 1 cm. The matrix research project predict measurement of the skin microclimate, therefore, every time these variables were measured, transparent polyurethane film was removed.

In addition to the dressings, the patients received preventive care based on the hospital's PI prevention protocol

CONSORT 2010 Flow Diagram

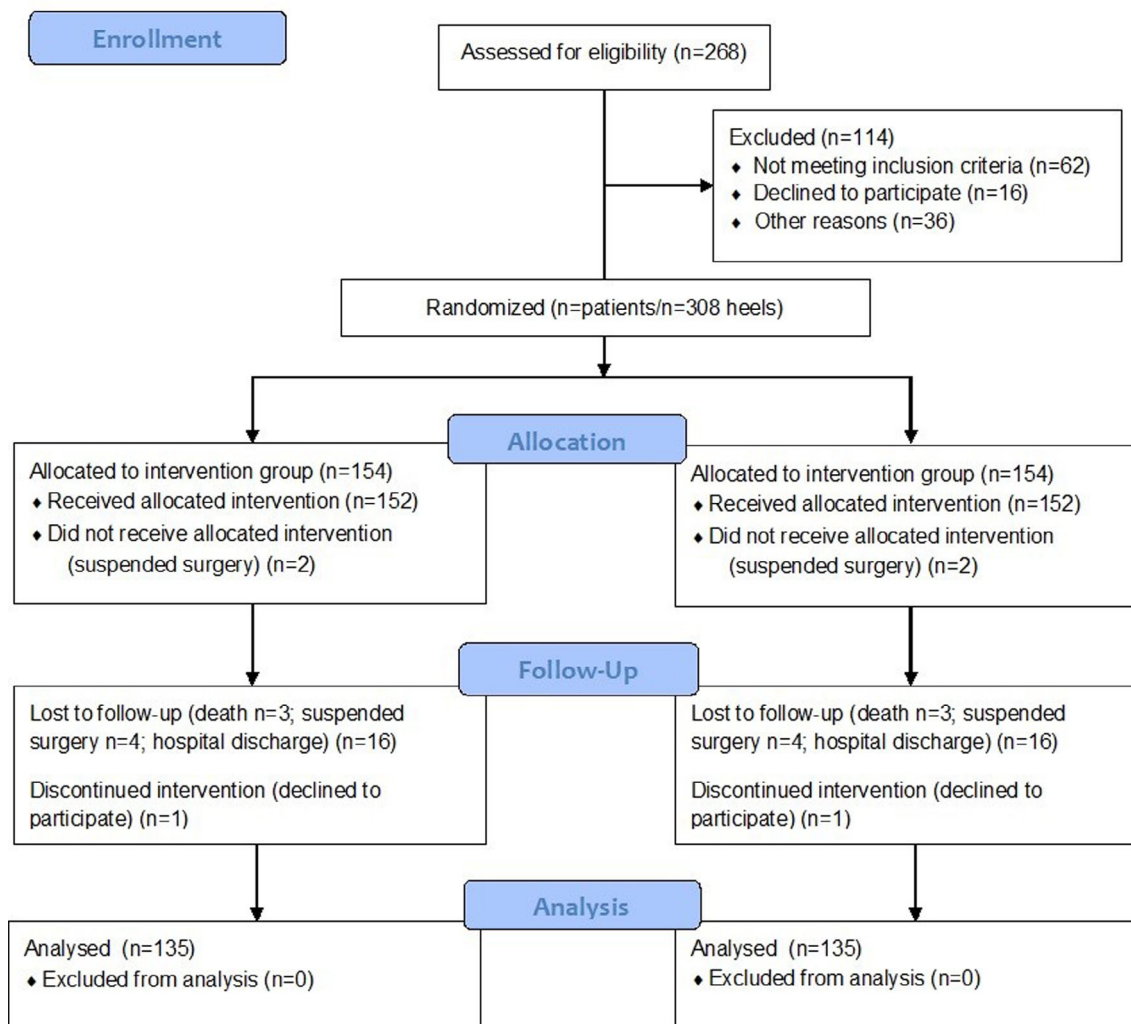


FIGURE 1 Flowchart of study participants' selection—HORPIT. Brazil, 2020

from the health team during post-operative period, including floating heels, daily PI risk evaluation, daily skin inspection, and decubitus change every 2 hours. During the intraoperative period, no additional preventive care was taken, based on the hospital's PI prevention protocol. It stands out that a conventional foam mattress was used on the operating table, without additional pressure-relieving devices for the heels during the surgical time.

The choice of the heels region is justified by being an area of bone prominence particularly vulnerable for the development of PI⁹ and the possibility of performing a self-controlled RCT, eliminating interpersonal factors.²⁷

The G Power 3.1 programme was used to perform the sample calculation, with *t*-test for two independent groups,²⁸ a priori analysis power, considering effect size of 0.6 (superiority RCT), statistical power of 80%, significance level of 99% ($\alpha < .01$), 1/1 allocation ratio, and totaling a sample size of 116 individuals. To this value, 30% was added for possible losses (36 individuals). Thus, the result of the sample calculation was 152 individuals, as the heels were evaluated, this sample was converted into cutaneous sites (304 heels).

Randomisation was performed for each patient, with heels randomised to the control group (transparent polyurethane film) or intervention group (multi-layered silicone foam). For the formation of the groups, a sequence of numbers extracted from a programme available from: <http://stattrek.com/statistics/random-number-generator.aspx> was used, with a minimum number of one and a maximum of two.

For the draw, the number one¹ was considered intervention group (IG) and two,² control group (CG). Randomisation of number two² was always performed for the right heel. Therefore, before starting data collection, the number sequence was extracted in the aforementioned programme, and these numbers were placed inside opaque and sealed envelopes, ordered outside from 001 to 152. The envelopes were opened in the presence of a member of the nursing or health team at the research site, in order to avoid violation of randomisation.²⁸

The collection team consisted of 10 people: three nurses who were postgraduate students (master's or doctorate), one nurse, and six nursing undergraduate students. All collectors received theoretical and practical training before the beginning of data collection. The training was based on the collecting handbook developed for the purpose.

Data collection was performed through an electronic form elaborated using the Epi Info programme and mobile device. Patients were evaluated preoperatively for eligibility. Those who met the selection criteria participated in the informed consent process. After signing the Informed Consent Form, preoperative and intraoperative data were collected before the beginning of surgery. Then, the

interventions were randomised and applied. The patient was re-evaluated at the end of the surgical procedure and the follow-up extended daily up to 72 hours after (immediate postoperative, first postoperative day, second postoperative day). Both dressings were kept on the heels during the follow-up period.

The outcome (presence of PI) was identified and classified according to international guidelines,^{11,29} which constituted the follow-up period defined, since PI resulting from surgical positioning can occur up to 48 or 72 hours postoperatively.³⁰

The data were analysed with the aid of the Statistical Package for the Social Sciences (SPSS) software version 21. Categorical variables were expressed by absolute and relative frequencies, and continuous variables were presented as mean and SD or median and interquartile interval (IQ). To evaluate the normality distribution of continuous variables, the Shapiro–Wilk test was applied.

To evaluate the outcome (development of PI), its incidence in each group (intervention and active control) and the relative risk were calculated. The incidences of each group were compared using the Chi-square test. A Kaplan–Meyer test (survival analysis) was performed in order to evaluate the estimate of PI-free time between the groups

TABLE 1 Distribution of sociodemographic and clinical characteristics—HORPIT, Brazil, 2020, n = 135

Variable	n (%)
Gender	
Female	47 (34.8%)
Male	88 (65.2%)
Self-reported race	
White	101 (74.8%)
Brown	22 (16.3%)
Black	12 (8.9%)
Specialty	
Cardiac	91 (67.4%)
Gastrointestinal	44 (32.6%)
ASA score	
I	1 (0.7%)
II	18 (13.3%)
III	102 (75.6%)
IV	14 (10.4%)
Variable	Mean ± SD (Min–Max)
Age (years)	59.5 ± 12.9 (18–82)
Surgery length (hours)	4.6 ± 1.3 (0.5–8.2)
Time in the surgical room (hours)	6.4 ± 1.6 (1.7–9.7)

Abbreviations: ASA, American society of anaesthesiologists; Max, maximal value; Min, minimal value.

TABLE 2 Incidence and classification of the pressure injuries—HORPIT, Brazil, 2020, n = 270

Variable	Intervention (n = 135)		Control (n = 135)	
	n	%	n	%
Presence of pressure injury	36	26.7	63	46.7

Variable	Intervention (n = 36)		Control (n = 63)	
	n	%	n	%
Classification of the pressure injuries				
Pressure injury stage 1	33	91.6	59	93.6
Pressure injury stage 2	1	2.8	1	1.6
Deep tissue pressure injury	2	5.6	3	4.8

(intervention and active control). A significance level of 5% was considered. The analysis was performed per protocol, and only those individuals who completed the follow-up were included. A protocol analysis was used to assess the effects of interventions under ideal or experimental conditions.³¹

This study was approved by the Ethics Committee at the Federal University of Santa Maria with Certificate of Presentation for Ethical Evaluation (CAAE) 77103617.6.0000.5346. Furthermore, the study was registered on the platform of the Brazilian Registry of Clinical Trials (ReBEC), being approved under identifier RBR-5GKNG5.

3 | RESULTS

The evaluation for eligibility included 268 patients, of whom 114 did not meet the selection criteria. Therefore, 154 patients/308 heels were randomised, of whom 154 heels were allocated to each group (intervention or control). After excluding 16 lost to follow-up and one discontinued intervention in each group, 135 heels were analysed in the IG and 135 in the CG—Figure 1.

Table 1 describes the sociodemographic and clinical characteristics of the research participants. Most of the participants were male (n = 88; 65.2%), white (n = 101; 74.8%), with a mean age of 59.5 years. Regarding the surgical specialty, 91 (67.4%) individuals underwent cardiac surgery and 44 (32.6%) gastrointestinal one. Regarding the assessment of the risk of surgical death, most individuals obtained an American Society of Anaesthesiologists (ASA) III score (n = 102; 75.6%). The mean surgery length was 4.6 hours and the mean time in the operating room, 6.4 hours.

Table 2 presents data on the development of PI. Of the 135 participants, 70 (51.9%) developed PI, of whom 29 (21.5%) had PI in both heels and 41 (30.4%) in only one. Among the 270 skin sites analysed, 99 developed PI,

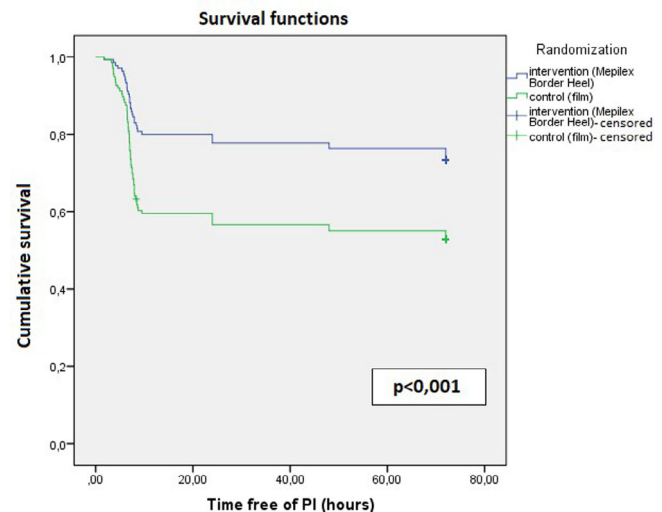


FIGURE 2 Survival analysis of Kaplan-Meier—HORPIT, Brazil, 2020, n = 270. Logrank test. *P*-value at a significance level of 5%

resulting in a global incidence of 36.7%. The incidence of PI was different ($P = .001$) between the IG (26.7%) and the CG (46.7%), with a relative risk of 0.57.

Survival analysis was performed using the Kaplan-Meier method, analysing PI-free time (survival) in each group (intervention and control)—Figure 2.

In the IG (multilayer multi-layered silicone foam), the estimated PI-free time (survival) was 57.5 hours (95% CI 53.0-62.0) and in the CG (transparent polyurethane film), 43.9 hours (95% CI 38.5-49.4). Furthermore, there is a significant difference between the intervention and CGs ($P < .001$), that is, the PI-free time in the IG is higher than in the CG.

4 | DISCUSSION

Pressure injuries in the heels region have as main cause tissue deformations due to exposure to pressure, friction,

and shear. Associated with this, the morphological and mechanical properties of the skin are influenced by several factors, including age, health status, and associated diseases.⁹

Atypical foot anatomies characterised by heavy-weight foot, sharp posterior calcaneus, and thin soft tissue padding are theoretically more prone to heel ulcers.³² During surgery, the feet do not remain in an upright position, but in external rotation. It is known that skin strains with the foot in external rotation (abducted) are significantly greater than when the foot was upright.^{33,34} The participants of this study were mostly male, white, and with a mean age of 59.5 years. The majority underwent cardiac specialty surgery and presented an ASA Score III for risk of surgical death. The mean surgery length identified was 4.6 hours, and the mean length of stay in the operating room was 6.4 hours.

A similar study that aimed to evaluate the clinical efficacy of using multi-layered silicone foam compared with polyurethane film in the prevention of PI in the intraoperative period of the spine showed some similar results. The age of the individuals was 64 years, 67% were male, 81% had ASA score II, and the mean procedure length was 2.6 hours.³⁵

During the intraoperative period, the most common complication of surgical patients is the PI development mainly classified as stages 1 and 2, which can be observed immediately after surgery.³⁶ These data corroborate the findings of this study, in which 51.9% of the participants developed PI in at least one of the heels and mostly stage 1.

Surgical patients have an incidence ranging from 1.3% to 54.8%.⁴⁻⁶ The high incidence of PI found in this study may be related to the prolonged surgery length^{30,37-41} and the ASA surgical risk score III or IV.⁴²

The incidence of PI was different ($P = .001$) between the IG—multi-layered silicone foam (26.7%) and the CG—transparent polyurethane film (46.7%), with a relative risk of 0.57, indicating that the CG has a 57% higher risk of developing PI than the IG. Regarding the classification of PI, both groups had a higher incidence of PI stage 1.

These findings corroborate the results of another Brazilian study, which indicates an incidence of PI of 20.6% in patients undergoing cardiac surgery, with the majority of lesions (98.6%) classified as stage 1 and the most affected cutaneous site was the heel.³⁶ Another study also identified that the number of PI on the side treated with polyurethane film dressings was significantly higher than on the side treated with multi-layered silicone foam dressing ($P = .027$).³⁵

It is noteworthy that the use of additional dressings in the prevention of PI is an important recommendation,¹¹ which may reduce the risk of these injuries. In Australian

long-term institutions, the use of polyurethane foam in the sacral and heel region (intervention) was compared with clinical guidelines (control) in the prevention of PI for 4 weeks in 228 residents, suggesting a relative risk reduction of 80% in residents who used the dressings.²⁰

Furthermore, reinforcing this recommendation, a cohort study evaluated critically ill patients at high risk of developing PI, and 150 patients received intervention (multilayer polyurethane foam) in the heels at admission to the emergency room and another group constituted the control ($n = 221$), receiving usual care for the prevention of PI. The authors concluded that multilayer polyurethane foam was effective in preventing PI in heels acquired in the intensive care unit.⁴³

In addition, some studies have evaluated coverage from a biomechanical perspective. These studies concluded that Mepilex Border Heel dressing reduce the superficial and deep tissue loads near the calcaneal bone, providing an important biomechanical protective effect.⁴⁴⁻⁴⁶

However, there are few studies conducted in the intraoperative period⁵ and this scenario presents specific risk factors, in addition to the time on the operating table and ASA surgical risk score: hypothermia^{30,36,47,48} or hyperthermia⁴¹; haemorrhage^{30,36}; sweating⁴¹; general anaesthesia^{30,36}; surgical position³⁰ mainly supine^{37,49}, or prone³⁶; among others.

This study presents as a result that, in the IG, the estimates PI-free time (survival) was 57.5 hours (95% CI 53.0–62.0) and in the CG, 43.9 hours (95% CI 38.5–49.4), $P < .001$. A non-randomised self-controlled clinical trial compared the transparent polyurethane film associated with clinical guidelines (intervention) to only clinical guidelines (control) in the prevention of PI in heels of 100 ICU patients. There was a difference in the incidence of PI between the groups, and in the IG, the PI-free time was 19.2 days.²⁴

The results of this study show that the group that received transparent polyurethane film has a 57% higher risk of developing PI than the group that received multi-layered silicone foam. The same occurred in a study conducted in a university hospital in Japan, with 100 patients undergoing spinal surgery in prone position, which compared the efficacy of foam dressings with soft silicone applied to the chest and iliac crest on the left side of the body with polyurethane film dressings applied in the same skin sites on the right side. The authors identified that the use of silicone foam dressings reduced the risk of PI and was more effective than polyurethane film.³⁵

The limitation of this study is the absence of blinding of the researchers, which can lead to differential biases that affect one study group more than another. Despite that, the findings of this study contribute to evidence-based health practice, providing support for clinical

nursing practice, in addition to supporting international recommendations for the prevention of PI.

It is concluded that the CG presented a 57% higher risk of developing PI than the IG, in addition to showing shorter PI-free time. Therefore, multi-layered silicone foam (intervention) is more effective than transparent polyurethane film (control) in the prevention of PI resulting from surgical positioning in heels of inpatients undergoing elective surgeries. Further studies evaluating devices and dressings in the prevention of PI in different surgical specialties are suggested.

CONFLICT OF INTEREST


We declare that there is no conflict of interest.

DATA AVAILABILITY STATEMENT


Research data are not shared.

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How to cite this article: Eberhardt TD, de Lima SBS, de Avila Soares RS, et al. Prevention of pressure injury in the operating room: Heels operating room pressure injury trial. *Int Wound J*. 2021;18:359-366. <https://doi.org/10.1111/iwj.13538>