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ORIGINAL ARTICLE

Soft silicone foam dressing is more effective than polyurethane film dressing for preventing intraoperatively acquired pressure ulcers in spinal surgery patients: the Border Operating room Spinal Surgery (BOSS) trial in Japan

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Key words
Intraoperatively acquired pressure ulcers; Perioperative nursing; Pressure ulcer prevention; Soft silicone foam dressings; spinal surgery

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Abstract

Preventing intraoperatively acquired pressure ulcers (IAPUs) in patients undergoing spinal surgery in the prone position using a Relton-Hall frame is challenging. We investigated the efficacy of soft silicone foam dressings in preventing IAPUs. A prospective dual-center sham study was conducted among patients undergoing elective spinal surgery in a general hospital and a university hospital in Japan. The incidence of IAPUs that developed when soft silicone foam dressings and polyurethane film dressings were used was compared on two sides in the same patient. IAPUs developed on the chest in 11 of 100 patients (11%). Polyurethane film dressings were associated with a significantly higher rate of IAPUs than soft silicone foam dressings (11 versus 3, $P = 0{\cdot}027$). A multivariate logistic regression analysis revealed that a diastolic blood pressure of <50 mmHg ($P = 0{\cdot}025$, OR 3·74, 95% confidence interval [CI] 1·18–13·08) and the length of surgery (by 1 hour: $P = 0{\cdot}038$, OR 1·61, 95% CI 1·03–2·64) were independently associated with the development of IAPUs. The use of soft silicone foam dressings reduced the risk of IAPUs ($P = 0{\cdot}019$, OR 0·23, 95% CI 0·05–0·79) and was more effective than film dressings for preventing IAPUs in spinal surgery patients.

Introduction

Intraoperatively acquired pressure ulcers

The development of pressure ulcers is a persistent problem, and global efforts to prevent pressure ulcers have been enacted. Consequently, the incidence of pressure ulcers in Japan has decreased from 2·5% (2002) to 1·6% (2013) (1,2). However, the

Key messages

- in the ED and ICU settings, soft silicone foam dressings reduced the incidence of sacral and heel pressure ulcers; however, it is unclear whether the application of soft silicone foam dressings in the operating room is effective in preventing pressure ulcers

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- we conducted a prospective, dual-centre, open-label sham comparison study of patients undergoing elective spinal surgery who were placed in the prone position using a Relton-Hall frame between July 2015 and February 2016
- this is the first sham comparison study between soft silicone foam dressings and film dressings to investigate the effectiveness of soft silicone foam dressings in the prevention of IAPUs in spinal surgery
- IAPUs developed significantly more frequently with polyurethane film dressings than with soft silicone foam dressings (11 versus 3, $P = 0{\cdot}027$)
- a multivariate logistic regression analysis revealed that the length of surgery (by 1 hour: $P = 0{\cdot}038$, OR 1·61, 95% CI, 1·03–2·64) was independently associated with the development of IAPUs, while the use of soft silicone foam dressings significantly reduced the incidence of IAPUs ($P = 0{\cdot}019$, OR 0·23, 95% CI 0·05–0·79)

Figure 1 Relton-Hall frame. The Relton-Hall frame is a device that supports the trunk at four points, thereby avoiding excessive pressure on the abdomen. Additionally, the pads of the Relton-Hall frame tilt medially in order to increase the stable fixation.

incidence of intraoperatively acquired pressure ulcers (IAPUs) still ranges from 5·1% to 17·6% (3,4). The unique environment of the operating room makes preventing IAPUs during surgery more difficult than in other settings. Specifically, surgery patients lie immobile in the same position on the operating table for a prolonged period of time. As such, preventing pressure ulcers during surgery is typically not prioritised by surgeons.

IAPUs and spinal surgery using a Relton-Hall frame

Several studies have reported that the development of IAPUs is associated with surgical procedure (5–8) and positioning (9,10). Among the various positions in the operating room, the incidence of IAPUs is particularly high among patients who are placed in the prone position using a Relton-Hall frame (11) during spinal surgery. In this procedure, careful surgical skill is required to avoid damaging the spinal cord and dura mater; the patient's position is therefore firmly fixed to ensure that the surgery is performed safely. If spinal surgery is performed with the patient in a typical prone position without a Relton-Hall frame, abdominal pressure is increased, and the inferior vena cava is compressed, which leads to substantial bleeding (12). The Relton-Hall frame is a device that supports the trunk at four points, thereby avoiding placing excessive pressure on the abdomen. In addition, the pads of the Relton-Hall frame tilt medially to stabilise the fixation further (Figure 1) (13). Although this frame effectively reduces the risk of intraoperative bleeding (13,14), it often causes the development of IAPUs. Because the contact area of the trunk and pads is small and tilted, the pressure load on the patient and high shear force are applied to the chest and iliac crest, which support the trunk. IAPUs have been reported to develop rapidly when using a Relton-Hall frame (15,16). Thus, methods for preventing IAPUs during spinal surgery using the Relton-Hall frame should be investigated while taking interface pressure and shear force into account.

Prevention of IAPUs during spinal surgery using a Relton-Hall frame

While repositioning is typically recommended in order to prevent pressure ulcers (17), it cannot be performed during surgery; it is therefore necessary to develop positioning fixation methods and skin protectants that can prevent IAPUs in a manner that does not hinder surgery. The use of a urethane foam mattress 7–10 cm in thickness has been recommended for the prevention of IAPUs (18,19). Thick urethane foam is highly effective in distributing the interface pressure and preventing pressure ulcers; however, because a thick mattress can destabilise the patient's trunk fixation, a thin mattress must be used instead for spinal surgery. In addition, the length of surgery is strongly associated with the development of IAPUs; sometimes, it takes a long time for spinal surgery, thereby increasing the risk of developing IAPUs. As such, a shorter length of surgery might reduce this risk.

Prophylactic dressings

In recent years, the prophylactic effectiveness of soft silicone foam dressings in intensive care units has been reported (20). Furthermore, several studies found that the application of a polyurethane film dressing and a hydrocolloid dressing in the operating room reduced the risk of developing pressure ulcers during surgery (21,22). We consider prophylactic dressings to be effective in preventing IAPUs in spinal surgery patients in cases where sufficient pressure distribution cannot be achieved using a Relton-Hall frame. However, whether the use of soft silicone foam dressings leads to a reduction in the incidence of reduced pressure ulcers remains to be elucidated, and which types of prophylactic dressing are the most effective in preventing such ulcers is currently unclear.

Preliminary test

To verify the validity of this study, the interface pressure of the Relton-Hall frame was measured for 5 minutes in a healthy

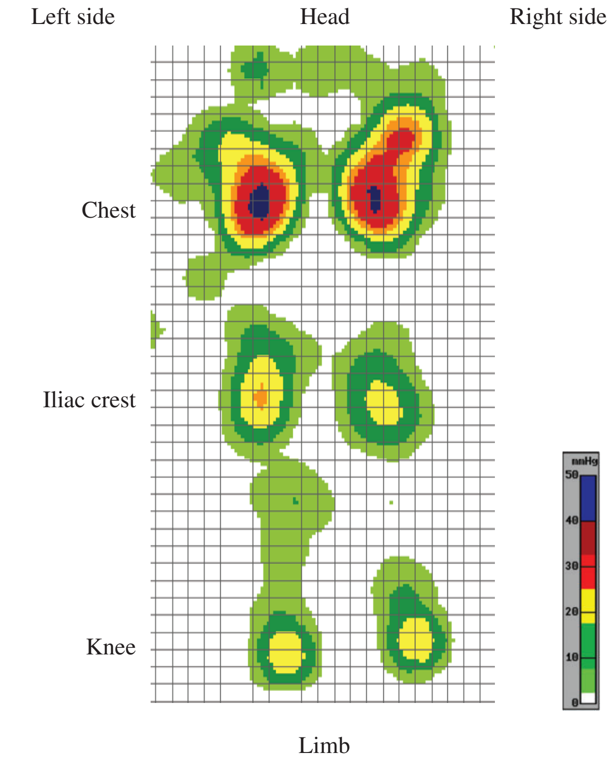

Figure 2 Interface pressure mapping in the prone position using a Relton-Hall frame for the preliminary test. The interface pressure of the left side and right side showed a high degree of similarity. The chest pressures on both the left and right sides were higher than the pressures of the iliac crest.

adult female volunteer using an interface pressure mapping device (Altesta®; Molten Co., Tokyo, Japan). The volunteer was 163 cm in height, and her body weight was 55 kg [body mass index (BMI) 20·7].

The interface pressure was measured three times within 5 minutes, and the peak pressure value was calculated by averaging the data obtained from three measurements. Kumagai *et al.* intraoperatively measured the interface pressure in the iliac region of patients resting on the Relton-Hall frame (23), noting fluctuations within 10 mmHg during surgery. Therefore, we determined that the error of the interface pressures was a maximum 10 mmHg difference between the left and right regions – namely between the left and right chest regions. The peak pressure values on the left and right sides of the chest were 81 and 78 mmHg, respectively, and the peak pressure values on the left and right sides of the iliac crest were 52 and 47 mmHg, respectively. The difference between the peak pressure values of the left and right of the chest was <10 mmHg, as was the difference between the peak pressure values of the left and right sides of the iliac crest. Thus, the interface pressure of the left and right sides of the chest and of the left and right sides of the iliac crest showed a high degree of similarity. The chest pressures on both the left and right sides were higher than the pressures of the iliac crest (Figure 2). In this way, we confirmed the validity of this sham study.

Aim

The aims of this study were as follows:

1. To determine the clinical effectiveness of soft silicone foam dressings in the prevention of IAPUs in patients undergoing spinal surgery under general anaesthesia in the prone position using the Relton-Hall frame.
2. To clarify the different effects of soft silicone foam dressings and polyurethane film dressings in the prevention of IAPUs.

Methods

Study design

This study was designed as a prospective, dual-centre, open-label comparison sham study in which the development of IAPUs was compared based on the split-body values in the same patient. The study was conducted between July 2015 and February 2016 in the operating room of a general hospital and a university hospital in Tokyo, Japan.

This study received approval from the institutional review board of Tokyo Metropolitan Police Hospital (No. 48) and Kyorin University Hospital (H27-049 No. 652). Written informed consent was obtained from each patient. This study was registered as UMIN000021696 (**BOSS trial**) in the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) (http://www.umin.ac.jp/ctr/), which is a public trial registry approved by the International Committee of Medical Journal Editors.

Setting and participants

The Tokyo Metropolitan Police Hospital is a 500-bed acute care hospital in which approximately 5500 surgeries are performed each year. Kyorin University School of Medicine Hospital is a 1000-bed acute care hospital in which approximately 8000 surgeries are performed each year. Both hospitals perform standard procedures for the prevention of IAPUs in accordance with the guidelines of the Japanese Society of Pressure Ulcers (24).

This study included all of the patients who were undergoing elective spinal surgery in the prone position using a Relton-Hall frame. The exclusion criteria were as follows: undergoing emergency surgery, presence of skin disorders or scars in the area to be observed, remarkable spondylosis deformation and age <20 years. We calculated that a sample size of 80 patients would be needed in order to detect a 25% difference in the incidence of pressure ulcers, with an α value of 0·05 and a power of 80%.

Primary endpoint

The primary endpoint of this study was the difference in the IAPU incidence rates when using soft silicone foam dressings versus polyurethane film dressings during surgery. We classified the patients into two groups: the ’with IAPUs group’ and the ‘without IAPUs group’. The relative risk of developing IAPUs was analysed based on the patients’ characteristics and the intraoperative factors.

Demographic data

The following patient characteristics were obtained from the medical records: age, gender, BMI, medical history, Braden scale score (25), American Society of Anesthesiologists (ASA) physical status classification (26), presence of bony prominence, oedema or paralysis and the blood test data, including the haemoglobin and albumin. The following intraoperative factors were obtained from the medical records: surgical procedure, diastolic blood pressure <50 mmHg (yes/no), length of surgery, bleeding amount and core temperature (bladder or rectum). The parameters of the core temperature were the baseline, end and the change between the baseline and the end of surgery. The baseline value was calculated by averaging the data obtained at the start of surgery and at 30 minutes after the start of surgery, and the end was defined as the temperature observed at the end of surgery; the change was calculated by subtracting the baseline from that observed at the end of surgery.

Procedures

Dressing application

One or two days before surgery, the patient was examined for the presence of pressure ulcers or scars and any thoracic deformity. After the induction of anaesthesia, soft silicone foam dressings (Mepilex® border; Molnlycke Healthcare, Tokyo, Japan) were applied to the left side of the chest and iliac crest, while polyurethane film dressings (Opsite flexifix®, control; Smith and Nephew Wound Management KK, Tokyo, Japan) were applied to the right side of the chest and iliac crest. The development of IAPUs was prospectively observed in these four regions (the left and right sides of the chest and the iliac crest) (Figure 3).

Figure 3 Dressing application. Soft silicone foam dressings was applied on left side of the chest and the iliac crest. Polyurethane film dressings was applied on right side of the chest and the iliac crest.

Standard positioning protocol for fixation and the prevention of IAPUs

A standard positioning protocol was used for all of the patients, using a Relton-Hall frame to hold them in the prone position. After the application of the dressings, the patient was moved from the supine position into the prone position on the Relton-Hall frame. We confirmed that the line connecting the spine was straight and that the line connecting the posterior iliac crest and scapula was parallel to the operating table in a fixed position. The trunk width was measured in each patient; this was defined as the length from 4 cm below the axilla to the iliac crest nodules and the distance between the two sides of the iliac crest. The location of the four pads of the Relton-Hall frame was then adjusted.

The urethane foam mattress used was composed of double layers, each 6·0 cm thick (soft nurse yellow pink®; Lack Healthcare Co., Ltd., Tokyo, Japan), in order to reduce the interface pressure. We attempted to redistribute the pressure by placing a piece of urethane foam mattress (cut to 15 × 20 cm in size) on each of the four pads of the Relton-Hall frame before moving the patient into the prone position. Both arms were fixed onto external arm boards. The entirety of each lower limb was placed onto a pressure-distributing mattress on the operating table mattress and fixed in accordance with the physiological curvature. The patient's face was held in place using a Protective Helmet System urethane foam cushion (prone view™; Dupaco Inc., California, USA) (Figure 4). The operating table was not tilted but instead remained flat in this trial. At 30 minutes after the completion of surgery and after shifting the patient back into the supine position, the operating room nurses determined whether or not IAPUs had developed.

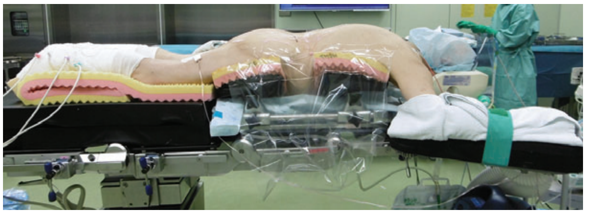

Figure 4 Positioning methods on the Relton-Hall frame. The cut urethane foam mattresses were placed on the Relton-Hall frame pads, and the patient was placed in the prone position on the urethane foam mattresses. Both arms were fixed on external arm boards. The entirety of the lower limbs was placed on a pressure-distributing mattress over the operating table mattress, which was fixed in accordance with the physiological curvature. The face was held by a Protective Helmet System made of urethane foam cushion.

Determination of IAPUs

The IAPUs were classified according to the International NPUAP-EPUAP Pressure Ulcer Classification System. A

Category I pressure ulcer is defined as a site of non-blanchable erythema; a Category II pressure ulcer is defined by the presence of a blister (27). The condition of the skin that had been in contact with the Relton-Hall frame was evaluated by two operating room nurses using the finger pressure method at 30 minutes after the patient was returned to the supine position from the prone position in order to distinguish non-blanchable erythema from blanchable erythema (4). The results were confirmed by agreement between these two nurses. Given that deep tissue injury (DTI) is likely to appear within 1 week after surgery, all of the patients were followed-up by a review of their medical records to ascertain whether or not they had developed any new pressure ulcers on the chest or iliac crest. Patients who developed a pressure ulcer or DTI within 1 week after surgery were classified as having IAPUs.

Measurement and management of the core temperature

The parameters of the core temperature included the baseline temperature, the temperature at the end of surgery and the change in temperature from the baseline to the end of surgery. As mentioned above, the baseline value was calculated by averaging the data obtained at the start of surgery and at 30 minutes after the start of surgery, and the end was defined as the temperature observed at the end of surgery; the change was calculated by subtracting the baseline temperature from that observed at the end of surgery.

During surgery, the patient's bladder or rectal temperature was measured using a temperature probe (BARD® silver TSC tray; Medicon Co., Osaka, Japan; or YSI400; Smith Medical Japan Ltd., Tokyo, Japan) connected to a biological information monitor or a bedside monitoring machine (IntelliVue® MP50; Philips Co., Tokyo, Japan; or BSM-9100; Lifescope J, Nihon Kohden Co., Tokyo, Japan). A warming device (Bair Hugger ™ Temperature Management Unit model 750; 3M Japan Ltd., Tokyo, Japan) with an under-trunk blanket or a lower-trunk blanket at a preset temperature of 43°C was used by the anaesthesiologist to manage the core temperature and prevent hypothermia prior to surgery. The intraoperative warming device (Bair Hugger™) has three temperature settings: high, 43°C; medium, 38°C; and low, 32°C. The initial temperature was set at 43°C to reduce the magnitude of redistribution hypothermia.

Data analyses

The categorical variables associated with the presence or absence of IAPUs on each side were compared using the χ^2 test or Fisher's exact test, while the continuous variables were compared using the unpaired *t*-test or Mann–Whitney *U* test. Variables with *P* values of <0·05 were included in a subsequent multivariate analysis. A multivariate logistic regression analysis was conducted with selected variables. Prior to the analyses, the correlations between the potential independent variables were assessed for multicollinearity. If the correlation coefficients exceeded 0·4, either variable was selected. The statistical analyses were conducted using the JMP® software programme, ver. 10.0.2 (SAS Institute Inc., Tokyo, Japan).

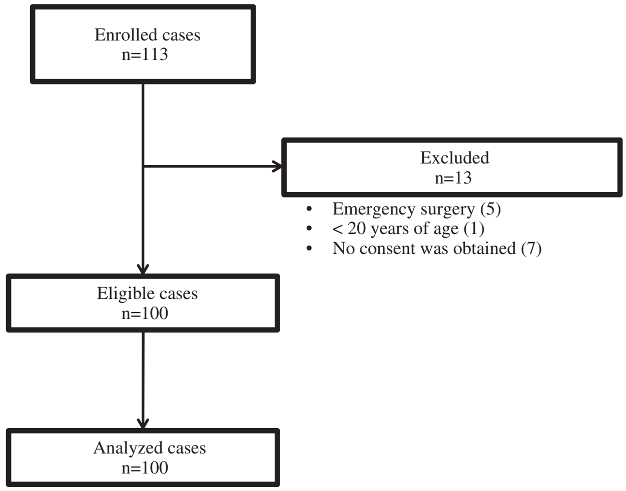

Figure 5 Flow of the participants throughout the study. About 113 patients were assessed for eligibility during the study period. Excluding 13 patients, we analysed the data of the remaining 100 patients.

P values of <0·05 were considered to indicate statistical significance.

Results

Study participants

A total of 113 patients were assessed for eligibility during the study period. Six patients met the exclusion criteria, and seven patients did not provide their informed consent; thus, 100 patients were ultimately enrolled. We analysed the data of these patients (Figure 5).

Patient characteristics

The mean age (± SD) was 64·6 ± 15·6 years; 67 of the patients (67·0%) were male, and 33 (33·0%) were female. The average BMI of our population was 23·7 ± 3·3. The patients' comorbidities included hypertension ($n = 34$), diabetes ($n = 15$) and congestive heart failure ($n = 2$). The physical status (ASA classification) of the patients was as follows: ASA 1 ($n = 13$), ASA 2 ($n = 81$) and ASA 3 ($n = 6$) (Table 1). The surgical procedures included posterior lumber interbody fusion (PLIF) ($n = 53$), laminectomy ($n = 26$), discectomy ($n = 17$) and other surgeries ($n = 4$). The mean ± SD procedure duration was 2·6 ± 1·2 hours.

IAPU incidence

IAPUs developed in 11 of the 100 patients (11%) within 30 minutes after shifting the patient back into the supine position; 10 patients had Category I IAPUs, and one patient had a Category II IAPU with a blister. The IAPUs developed on the chest in all 11 cases (14 locations) and healed without deterioration before discharge. The number of IAPUs that developed on the side treated with polyurethane film dressings was significantly higher than that on the side treated with soft silicone foam dressings (Table 2). IAPUs developed in 11 locations with

Table 1 Patients characteristics ($n=100$)*

Characteristic	
Age (years, mean ± SD)	64·6 ± 15·6
Gender, *n* (%) (male)	67 (67·0)
Body mass index (mean ± SD)	23·7 ± 3·3
Braden scale score (mean ± SD)	22 ± 2
Hypertension, *n* (%) (yes)	34 (34·0)
Diabetes, *n* (%) (yes)	15 (15·0)
Congestive heart failure, *n* (%) (yes)	2 (2·0)
Haemoglobin level (g/dl ; mean ± SD)	13·6 ± 1·70
Albumin level (g/dl ; mean ± SD)	4·2 ± 0·4
ASA-Physical status classification, *n* (%)	
1	13(13·0)
2	81 (81·0)
3	6 (6·0)

ASA-Physical status classification, American Society of Anesthesiologists physical status classification.
*The data are reported as the mean±SD for continuous variables or *n* (%) for categorical variables.

Table 2 Univariate analysis of perioperative pressure ulcers' location ($n=400$)*

	With pressure ulcers ($n=14$)	Without pressure ulcers ($n=386$)	*P* value
Chest			
Polyurethane film dressings	11 (11·0)	89 (89·0)	
Soft silicone foam dressings	3 (3·0)	97 (97·0)	0·027
Iliac crest			
Polyurethane film dressings	0	100 (100·0)	
Soft silicone foam dressings	0	100 (100·0)	–

*The data are reported as the *n* (%) for categorical variables. Differences were assessed using the chi-square test or Fisher's exact probability test for categorical variables.

polyurethane film dressings and 3 locations with soft silicone foam dressings.

A univariate analysis was conducted for 200 regions of the chest; the iliac crest was excluded because all of the IAPUs developed on the chest. The patients with and without IAPUs were analysed to determine the relative risk of the development of IAPUs. The univariate analyses revealed that 5 variables were significantly associated with the development of IAPUs: diastolic blood pressure of <50 mmHg, dressing, length of surgery, large amount of bleeding and change in the core temperature (Table 3). We excluded the amount of bleeding and change in core temperature from the subsequent analysis because a considerably high correlation was observed between the length of surgery and the amount of bleeding and between the length of surgery and change in core temperature (Pearson's $r=0{\cdot}73$, 0·62, respectively).

The multivariate logistic regression analysis revealed that diastolic blood pressure of <50 mmHg [$P=0{\cdot}025$, odds ratio (OR) 3·74, 95% confidence interval (CI) 1·18–13·08] and length of surgery (by hour: $P=0{\cdot}038$, OR 1·61, 95% CI 1·03–2·64) were independently associated with the

Table 3 Univariate analysis of risk factors associated with perioperative pressure ulcers on the chest ($n=200$)*

	With pressure ulcers ($n=14$)	Without pressure ulcers ($n=186$)	*P* value
Age (years, mean ± SD)	65·3 ± 13·3	64·5 ± 15·9	0·588
Gender, *n* (%)			
Male	11 (8·2)	123 (91·8)	
Female	3 (4·5)	63 (95·5)	0·340
Body mass index (mean ± SD)	23·8 ± 4·5	23·6 ± 3·1	0·676
Braden scale score (mean ± SD)	22 ± 3	22 ± 2	0·249
Hypertension, *n* (%)			
Yes	6 (8·8)	62 (91·2)	
No	8 (6·1)	124 (93·9)	0·468
Diabetes, *n* (%)			
Yes	4 (13·3)	26 (86·7)	
No	10 (5·9)	160 (94·1)	0·140
Congestive heart failure, *n* (%)			
Yes	0	4 (100·0)	
No	14 (7·1)	182 (92·9)	0·579
Bony prominence, *n* (%)			
Yes	5 (9·3)	49 (90·7)	
No	9 (6·2)	137 (93·8)	0·446
Oedema, *n* (%)			
Yes	0	2 (100·0)	
No	14 (7·1)	184 (92·9)	0·700
Paralysis, *n* (%)			
Yes	0	4 (100·0)	
No	14 (7·1)	182 (92·9)	0·579
Diastolic blood pressure of <50 mmHg, *n* (%)			
Yes	9 (13·2)	59 (86·8)	
No	5 (3·8)	127 (96·2)	0·013
Dressing, *n* (%)			
Polyurethane film dressings	11 (11·0)	89 (89·0)	
Soft silicone foam dressings	3 (3·0)	97 (97·0)	0·027
ASA-Physical status classification, *n* (%)			
1	3 (11·5)	23 (88·5)	
2	11 (6·8)	151 (93·2)	
3	0	12 (100·0)	0·420
Haemoglobin level (g/dl ; mean ± SD)	13·5 ± 1·9	13·6 ± 1·7	0·848
Albumin level (g/dl ; mean ± SD)	4·2 ± 0·3	4·2 ± 0·4	0·498
Length of surgery (hours, mean ± SD)	3·19 ± 1·2	2·54 ± 1·1	0·023
Amount of bleeding (ml, mean ± SD)	427·1 ± 361·9	307·1 ± 555·0	0·024
Core temperature (°C, mean ± SD)			
Baseline	36·4 ± 0·4	36·3 ± 2·0	0·175
End	37·1 ± 0·5	36·7 ± 0·6	0·060
Change	0·7 ± 0·6	0·4 ± 2·0	0·003

ASA-Physical status classification, American Society of Anesthesiologists physical status classification; core temperature, bladder temperature or rectal temperature.
*The data are reported as the mean±SD for continuous variables or *n* (%) for categorical variables. Differences were assessed using the unpaired *t*-test or Mann–Whitney U test for continuous variables and the chi-square test or Fisher's exact probability test for categorical variables.

Table 4 Multivariate analysis of risk factors associated with perioperative pressure ulcers ($n = 200$)

Variable	OR	95% CI	P-value
Dressings			
Soft silicone foam dressings	0·23	0·05–0·79	0·019*
Polyurethane film dressings (ref.)	1·00		
Diastolic blood pressure of <50 mmHg			
Yes	3·74	1·18–13·08	0·025*
No (ref.)	1·00		
Length of surgery (by 1 hours)	1·61	1·03–2·64	0·038*

CI, Confidence interval; $n = 200$, $R^2 = 0{\cdot}15$, $P = 0{\cdot}002$.

development of IAPUs. In contrast, the use of soft silicone foam dressings was found to significantly reduce the risk of IAPUs ($P = 0{\cdot}019$, OR 0·23, 95% CI 0·05–0·79) (Table 4).

Discussion

Structural characteristics of the study

While the assignment of participants to treatment groups was non-randomised, the treatment and control groups were similar with respect to the patient characteristics at the start of the trial. In addition, this was a sham study, which did not require matching in the statistical analysis and had high reliability because the left and right sides were compared in the same patient. Furthermore, the validity of our sham study was confirmed by a preliminary test. We therefore consider that all of the relevant outcomes were measured in a standard, valid and reliable manner.

Application of IAPU-preventative dressings outside of the operating room setting

At present, the effectiveness of prophylactic dressings in preventing pressure ulcers is widely known, and the guidelines recommend their application. Indeed, the NPUAP-EPUAP guidelines of 2009 specifically recommended the use of polyurethane film dressings (28). However, in the revised NPUAP-EPUAP guidelines of 2014, the use of urethane foam dressings is recommended instead (27). This discrepancy in recommendations suggests that further research is needed to clarify which type of prophylactic dressings is most effective for preventing pressure ulcers.

A clinical study reported that dressings reduce friction and shear force, thereby helping to prevent pressure ulcers (29). In recent years, the use of urethane foam dressings has been shown to be effective for preventing pressure ulcer trauma in critically ill patients in an intensive care setting (20).

Relton-Hall frame and prophylactic dressings

Application of prophylactic dressings in the operating room

Few reports have examined the effects of the application of prophylactic dressings in the operating room. Kohta *et al.* conducted a case–control study of the application of prophylactic dressings on various sites for patients who underwent surgery under general anaesthesia and were deemed to be at a high risk of developing IAPUs (21). They also investigated the risk factors for IAPUs in an age- and gender-matched cohort. The risk factors were the use of dressings ($P = 0{\cdot}001$, OR 0·06, 95% CI 0·01–0·34), the prone position ($P = 0{\cdot}01$, OR 8·79, 95% CI 1·63–47·40), length of surgery ($P = 0{\cdot}003$, OR 1·68, 95% CI 1·19–2·39) and low BMI ($P = 0{\cdot}02$, OR 0·77, 95% CI 0·58–0·95). Polyurethane film dressing and hydrocolloid dressing reduced the risk of IAPUs. However, the authors did not discuss the differences in the efficacy of these dressings in detail.

Imanishi *et al.* reported the effects of the application of polyurethane film dressings on the sacrum in the prevention of IAPUs in patients undergoing surgery in the lithotomy position (22). They also investigated the risk factors for IAPUs, which were found to include length of surgery ($P = 0{\cdot}043$, OR 3·94, 95% CI 1·04–14·93) and the use of polyurethane film dressings ($P = 0{\cdot}032$, OR 0·41, 95% CI 0·18–1·08). Brindle *et al.* examined the effects of the use of soft silicone foam dressings in preventing pressure ulcers among patients undergoing cardiovascular surgery of the sacrum in the supine position. However, the type of dressing used did not significantly influence the incidence of pressure ulcers.

Prophylactic dressings

Clark *et al.* reported that prophylactic dressings may be able to both redistribute pressure and protect the skin from the effects of shear force and friction (30). We agree with this hypothesis in part. Shear force is not reduced by the support surface, and the application of prophylactic dressings is needed to protect against its effects. Although Clark *et al.* hypothesised that prophylactic dressings might play a role in redistributing pressure, we are of the opinion that prophylactic dressings only have limited ability to redistribute pressure.

This study demonstrated that in a situation in which the interface pressure is somewhat suitably distributed, soft silicone foam dressings are effective in preventing IAPUs in patients undergoing surgery in the prone position using a Relton-Hall frame. We therefore consider that soft silicone foam dressings can be effective in preventing IAPUs under certain conditions.

Hypothesis

The use of prophylactic dressings, including soft silicone foam dressings, will help prevent the development of IAPUs under certain conditions.

Applicable conditions and sites

Heel

We consider pressure at the heel to be a good indication for prophylactic dressing. Santamaria, Torra and Forni (20,31,32) investigated the effects of prophylactic dressings on the heel.

Sacrum

Although a number of studies have examined the effects of prophylactic dressings on the sacrum, the findings are controversial. However, these differences can be explained by our hypothesis that positive effects are only achieved under certain circumstances. Imanishi *et al.* reported the effects of prophylactic dressings in the prevention of IAPUs of the sacrum in patients undergoing surgery in the lithotomy position (22). The use of prophylactic dressings significantly influenced the incidence of IAPUs. Based on their results, we consider the interface pressure during surgery in the lithotomy position to be higher than that in the supine position. This is a specific setting in which it is not possible to fully redistribute the pressure at the support surfaces. Furthermore, the operating table is often tilted during urology surgery, with the head-side down, which results in the application of shear force to the sacrum. These factors and settings make prophylactic dressings useful for preventing IAPUs.

In contrast, Brindle *et al.* reported that soft silicone foam dressings had no significant impact on the development of pressure ulcers (33). Based on their findings, we can make the following inference: pressure redistribution is easy to perform when the patient is in the supine position, where there is a large area of contact between the operating table and the patient's trunk. When cardiovascular surgery is performed in this position, the operating table is not tilted nor is the head-side facing downwards; therefore, no shear force is applied to the sacrum. In such cases, the effects of the support surface alone are sufficient to prevent IAPUs.

Chest: prone position using a Relton-Hall frame

When surgery is performed in the prone position using a Relton-Hall frame, it is difficult to obtain pressure redistribution on the chest. All of IAPUs developed on the chest, with no IAPUs of the iliac crest noted. In this preliminary test, the interface pressures at the chest were higher than those at the iliac crest because the interface pressure at the iliac crest was redistributed by the support surface when the entire limb was placed on the operating table. This caused IAPUs to develop at the chest, where the interface pressure was moderately high and where there was a high level of shear force. Under these circumstances, prophylactic dressings were effective in preventing IAPUs. In contrast, at sites where it was possible to achieve sufficient pressure redistribution without the dressings, such as iliac sites, the effects of the prophylactic dressings was masked by the effect of the support surface. Furthermore, the pads of the Relton-Hall frame tilt medially, and shear force subsequently occurs. Soft silicone foam dressings also can help reduce shear force and thereby prevent IAPUs.

Applicable conditions

In summary, the conditions under which prophylactic dressings are effective are as follows: situations in which the support surface cannot fully achieve pressure redistribution (i.e., at locations where the interface pressure is high, such as the pads of a Relton-Hall frame and the heel); situations involving high levels of shear force, such as tilted operating tables; cases in which the duration of mechanical loads is shortened; and cases in which the interface pressure occurs over a small surface area (i.e., the pads of a Relton-Hall frame, the heel).

Prophylactic dressings are expected to be ineffective in preventing IAPUs under the following conditions: when the redistribution support surface device works well, interface pressure loaded over a large area (i.e., the back or sacrum in patients undergoing surgery in the supine position) or extremely high interface pressure.

Which dressing was most effective in preventing pressure ulcers?

Polyurethane film dressings can prevent shear force and friction (34), as can the multi-layered silicone foam structure of soft silicone foam dressings (35,36). Hydrocolloid dressings can protect the skin from shear force and friction but do not reduce the interface pressure (37). To our knowledge, no other studies have so far compared the effectiveness of the prophylactic use of soft silicon foam dressings and polyurethane film dressing in the prevention of IAPUs in surgery with a Relton-Hall frame.

This study showed that soft silicone foam dressings were more effective than polyurethane film dressings for preventing the development IAPUs in patients undergoing spinal surgery in the prone position using a Relton-Hall frame. On the side where soft silicone foam dressings were used, the odds ratio of IAPUs was less than one-quarter of that on the side where polyurethane film dressings were used (Table 4). Polyurethane film dressings are currently the best low-friction film dressing available (38). We concluded that soft silicone foam dressing reduced the development of IAPUs more effectively than polyurethane film dressings, even when surgery was performed in the prone position with the use of a Relton-Hall frame because the cushion was capable of reducing both shear force and friction.

Risk and prevention for IAPUs in statistical analysis

Length of surgery and diastolic blood pressure of <50 mmHg were independently associated with an increased risk of IAPUs. In contrast, the use of soft silicone foam dressings significantly reduced the incidence of IAPUs in this study. In previous studies, it was reported that the risk factors for IAPUs included a length of surgery (39,40), large amount of bleeding (41), hypotension (42), hypothermia (43,44) and hyperthermia (45,46).

The length of surgery

The development of IAPUs was associated with the length of surgery, with a prolonged length of surgery associated with a higher incidence of IAPUs. Pressure ulcers develop in relation to the interface pressure and the loading time (47); as such, the length of surgery and positioning are often risk factors for the development of IAPUs. In this study (as well as in previous studies), the length of surgery was significantly associated with the development of IAPUs. Reducing the length of surgery is the most effective way of preventing IAPUs. However, the length of surgery cannot be reduced, practically speaking, because of the difficulty of the procedure. Furthermore, the prolonged length of surgery, the greater the amount of bleeding, which also influences the risk of developing IAPUs.

Hyperthermia and hypotension

We previously reported that hyperthermia was an independent risk factor for the development of IAPUs in neurosurgery performed in the park-bench position (45,46). There has also been recent discussion that microclimate control may play a key role in preventing pressure ulcers (48).

However, in this study, the core temperature did not increase in the latter half of the procedure. Hyperthermia did not occur when spinal surgery was performed in the prone position using a Relton-Hall frame because of the large space between the abdomen and the operating table. Thus, there is a larger area of exposed skin in comparison to neurosurgery. From the aspect of hyperthermia, the Relton-Hall frame is likely to help prevent IAPUs.

In this study, diastolic blood pressure <50 mmHg was significantly associated with the incidence of IAPUs. Spinal surgery using a Relton-Hall frame can result in an increased amount of bleeding. As a result, the blood pressure and cardiac function are reduced (12,14). Decreased blood flow to the soft tissue subsequently leads to the development of pressure ulcers.

Limitation of prophylactic dressings

Despite using prophylactic dressing in this study, the length of surgery and diastolic blood pressure <50 mmHg were extracted as risk factors of IAPUs. Under these circumstances, the preventive effect of the dressing was small; this was considered to be a limitation of the prophylactic dressing.

Limitations of this study

This study has several limitations. First, the treatment intervention and data collection were performed by the same operating room nurse because it was an open-label study. However, it is unlikely that the results reflected the intention of the data collector because the study involved bilateral side comparisons in the same patient. Second, the effects of the soft silicone foam dressings on IAPUs in other positions were unclear because this study was performed with a Relton-Hall frame in only two institutions. Further research is needed to investigate the effects of these dressings in other surgical positions and with other surgical procedures at other institutions.

Conclusion

Soft silicone foam dressings were found to be clinically effective in preventing IAPUs in patients undergoing spinal surgery under general anaesthesia in the prone position using a Relton-Hall frame. The novel finding of this study was that soft silicone foam dressings had a greater prophylactic effect against the development of IAPUs in spinal surgery patients than polyurethane film dressings. The application of prophylactic dressings in the operating room to prevent the development of IAPUs is only needed when surgery is performed in a position that involves the loading of shear force. With regards to the clinical implications, our results suggest that applying soft silicone foam dressings during surgery may help prevent the development of IAPUs and reduce the interface pressure at the support surface without affecting positional fixation or the surgical procedure.

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