

A sequential randomised controlled trial comparing a dry
Visco-elastic polymer pad and standard operating table
Mattress in the prevention of post-operative pressure sores

J. Nixon^{a,*}, D. McElvenny^b, S. Mason^b, J. Brown^b, S. Bond^c

^a*The Leeds Teaching Hospitals NHS Trust, St James's University
Hospital, Leeds LS9 7TF, UK*

^b*Northern and Yorkshire Clinical Trials and Research Unit, Leeds
LS16 6QB, UK*

^c*Centre for Health Services Research, University of Newcastle
New Castle NE2, 4AA, UK*

Received 1 March 1997; revised 26 October 1997; accepted 27
January 1998

Abstract

Four hundred and forty-six general, vascular and gynaecological surgical patients were recruited to a two centre, double triangular sequential randomised controlled trial to compare the post-operative pressure sore incidence in patients positioned on the standard operating table mattress with those positioned on the dry visco-elastic polymer pad (Action Products, Inc.). Two hundred and twenty two patients were randomised to the experimental group and 224 to the standard mattress. The main endpoint failure rate (a pressure sore) was found to be 11% (22/205) for patients allocated to the dry visco polymer pad and 20% (43/211) for patients allocated to the standard operating table mattress. There was a significant reduction in the odds of developing a pressure sore on the dry visco-elastic polymer pad as compared to the standard, $q = 0.46$ with 95% confidence interval of (0.26, 0.82), $P = 0.010$. The adjusted point estimates of the probability of developing a pressure sore on the dry visco-elastic polymer pad and the standard operating table mattress were 0.11 and 0.21 respectively. © 1998 Elsevier Science Ltd. All rights reserved.

1. Introduction

A literature review of intra-operative pressure sore development suggests a causal relationship between events during surgery and the subsequent development of pressure sores (Bridel, 1992). However, there are few studies (Stotts, 1988; Gendron, 1980; Kemp et al., 1990), and with the exception of Kemp et al. (1990), those available fail to specify research design or include specific factors on pressure sore aetiology.

The extent of intra-operative pressure sore development within the National Health Service (NHS) is unknown, yet many hospital pressure sore prevention policies include strategies for theatres. Recommendations for the intra-operative period are limited to provision of equipment designed for operating tables which do not impinge upon the stability of the patient's position, and hence safety, or anaesthetic and surgical needs.

Products available for use on operating tables include a dry visco-elastic polymer pad, replacement foam mattresses, a liquid displacement cell mattress and silicone fibre overlays. In 1994, none of these product types had been subjected to clinical evaluation by randomised control trial (Bridel, 1993a). Two had been evaluated under laboratory conditions (dry visco-elastic polymer pad and liquid displacement cell mattress) using non-anaesthetized volunteers and both demonstrated reduced interface pressure measurements at key anatomical sites or total body areas in comparison to the conventional operating table mattresses (Moore et al., 1992; Neander and Birkenfeld, 1991).

The dry visco-elastic polymer pad had also been evaluated in a small prospective study (Gendron, 1980). Of the 89 patients positioned on the dry polymer pad 34% were reported as having blanching erythema and 3.3% Stage 2 pressure sores, defined as 'redness, edema and induration at times with epidermal blistering or desquamation'. Interpretation of these results is difficult due to numerous limitations in the reporting of the study. Furthermore, the absence of a control group prevents any conclusion regarding their relative effectiveness in reducing or preventing pressure sores. Justification for the use of equipment in the prevention of intra-operative pressure sores was based upon reported reduced interface measurements (Neander and Birkenfeld, 1991) rather than clinical outcome.

The purpose of this study was to determine the benefits of using an intra-operative pressure reducing support surface. The dry visco-elastic polymer pad was chosen on the basis of previous laboratory evidence suggesting reduced interface pressures (Neander and Birkenfeld, 1991), ease of practical application in direct contact with the skin, intra-operative stability, ease of cleaning and cost.

2. Method

2.1. Aims

The main aim of the study was to compare the post-operative pressure sore incidence in patients positioned on the standard operating table mattress with those positioned on the dry visco-elastic polymer pad.

Secondary objectives were to: investigate the variables which most significantly contribute to post-operative pressure sore incidence and; establish the pre-operative pressure sore prevalence. Findings associated with the primary aim of the study are reported here with other results reported elsewhere.

2.2 Design

Following pilot work (Bridel, 1993b), a sequential double triangular design (Whitehead, 1992) was chosen for this randomised, double blinded, controlled trial of the intra-operative use of a dry visco-elastic polymer pad. Patients were recruited from St Jame's University Hospital, Leeds, and The General Hospital, Hartlepool, if they met the following criteria:

- (a) Scheduled for elective major general, gynaecological or vascular surgery.
- (b) Aged 55 years or over on day of surgery.
- (c) Scheduled to undergo 'major' surgery.
- (d) Position to be supine or lithotomy.

Major surgery was defined as a planned surgical procedure with an average surgical time of 90 min or more. Three sub-specialties within general surgery were not included (liver, urology and breast surgery). Other exclusion criteria included:

- (a) Pressure damage of Grade 2a or above observed pre-operatively
- (b) Ward staff provision of pre-operative alternating pressure mattress
- (c) Dark skin pigmentation which precludes reliable identification of Grade 1 and Grade 2a skin assessments.
- (d) Skin conditions over the sacrum, buttocks or heels which preclude reliable identification of Grade 1 and Grade 2a skin assessments.

Following inclusion in the study patients were randomised to either the standard operating table mattress or the dry visco-elastic polymer pad (torso area and heels). The dry visco-elastic polymer pad was placed in direct contact with the patient's skin. Both heel support for the control group (gamgee pad) and warming mattress provision for both groups (JMW Systems Ltd) was standardised across both research centres.

Randomisation was stratified by centre (Hartlepool, Leeds) and age (55-69 and 70 or over). A telephone randomisation schedule was developed within random permuted blocks of 6, with a run-in of 8, and managed by the Northern and Yorkshire Clinical Trials and Research Unit.

All pre and intra-operative data were recorded by the research nurse, and post-operative data recorded by recovery and ward staff who were blind to the intra-operative mattress allocation. The record pertaining to the intra-operative randomised mattress allocation remained separate from the main data collection proforma to maintain the blind.

2.3 Ethical considerations

Ethical considerations required consultation and compromise in the clinical research sites. The need for informed pre-operative consent and the prospective nature of the data collection dictated the inclusion of elective surgical patients. Of particular importance, from an ethical and professional perspective was that dry visco-elastic polymer pads were in use within the St James's site on an ad hoc basis and this influenced design elements in two ways. Firstly, it was one of the criteria which determined the selection of the double triangular sequential design, as detailed below. Secondly, patients were excluded if pre-operative ward care included the provision of an alternating pressure mattress.

2.4 Statistical design

The trial was designed to detect an absolute difference in the incidence of theatre-generated pressure sores from 10% on the

standard mattress compared to 5% on the dry polymer pad with 90% power at the 5% significance level. Two important issues required consideration in statistical design and informed the choice of the sequential design (Whitehead, 1992) as follows:

- (1) There was a difficulty in determining sample size in advance of the study due to the large degree of uncertainty in the expected incidence of pressure sores in both arms of the trial (Gendron, 1980; Stotts, 1988; Kemp et al., 1990; Bridel, 1993b).
- (2) There was a need to determine the relative effectiveness of the dry visco-elastic polymer pad as quickly as possible because it was already in use as a preventative intervention.

Based on an estimated difference in incidence 10% (standard) to 5% (dry polymer) simulated results indicated that between 500 and 1000 patients would be required. A fixed sample design with the same assumptions would have required a total of 1085 patients to be recruited. Also the double triangular sequential design was specifically chosen so that:

- (1) Inferiority of the dry polymer visco-elastic pad would be distinguishable from a lack of difference between the two mattress types.
- (2) There would be early stopping under the null hypothesis of no difference between the treatments. If no difference existed between the two mattress types, then simulated sample size calculations indicated that the stopping boundary would be reached between 500 and 750 patients.

Independent interim analyses were conducted after recruitment of the first 200 patients and subsequently after every 100 patients recruited. Results were presented to an independent Data Monitoring Committee (DMC) which was responsible for recommending when the trial should be stopped. The DMC and statistician were blind to treatment allocation during the course of this trial.

2.5 Statistical method

Sequential analysis was performed using the odds ratio formulation of the double triangular design with the binary outcome of success and failure as defined in Tables 1 and 2. The null hypothesis was no difference in post-operative pressure sore incidence whether the patients were assigned a dry polymer pad during their operation or a standard foam operating table mattress. Figure 1 illustrates the trial design where Z measures the cumulated evidence of the difference in the incidence of pressure sores on the two treatment arms of the trial, and V indicates the amount of information contained in the data about the treatment effect. The sample statistics, denoted by Z and V were computed and plotted (see Fig. 2) at each interim analysis. q is the odds of developing a pressure sore on a dry polymer pad compared to

Table 1 Skin assessment scale

| Skin Grade | Description of skin |
|------------|------------------------|
| 0 | No skin discolouration |

- 1 Redness to the skin - blanching occurs
- 2a Redness to the skin - non-blanching area
- 2b Superficial damage to epidermis
- 3 Ulceration progressed through the dermis
- 4 Ulceration extended into subcutaneous fat
- 5 Necrosis penetrating the deep fascia and extending to muscle

Adapted from Torrance (1983)

on a standard operating table mattress and is the measure of the difference between the treatments.

Mathematically the effect of the dry visco-elastic polymer pad is given by

$$(\theta) = \frac{PG(1-P_s)}{P_s(1-PG)}$$

Where P_s is the proportion of patients allocated a standard mattress developing a pressure sore and PG is the proportion of patients allocated a dry visco-elastic polymer pad developing a pressure sore, such that

- $(\theta) > 1$ if the dry polymer pad is inferior
- $(\theta) = 1$ if they are equivalent
- $(\theta) < 1$ if the dry polymer pad is superior

The statistics Z and V are given by:

$$Z = \frac{(nsFG - nGFs)}{n}$$

$$V = \frac{nGnsSF}{N^3}$$

Where ns = the number of patients allocated to the standard mattress with endpoint recorded; nG = the number of patients allocated to the dry polymer pad with endpoint recorded; F_s = the number of patients developing a pressure sore on the standard mattress; FG = the number of patients developing a pressure sore on the dry polymer pad; $F = F_s + FG$; $n = ns + nG$ and $S = n - F$.

It was expected that the mattress effect at each of these interim analyses would be adjusted for the strata used in the randomisation allocation rule. The four other a priori important variables to be accounted for in the event of crossing a stopping boundary were type of operation (vascular, non-vascular), length of operation, proportion of time hypotensive and pre-operative length of stay (Gendron, 1980; Kemp et al., 1990; Stotts, 1988; Bridel, 1993b). The boundaries which were used for an inspection at an interim analysis were adjusted for the limited

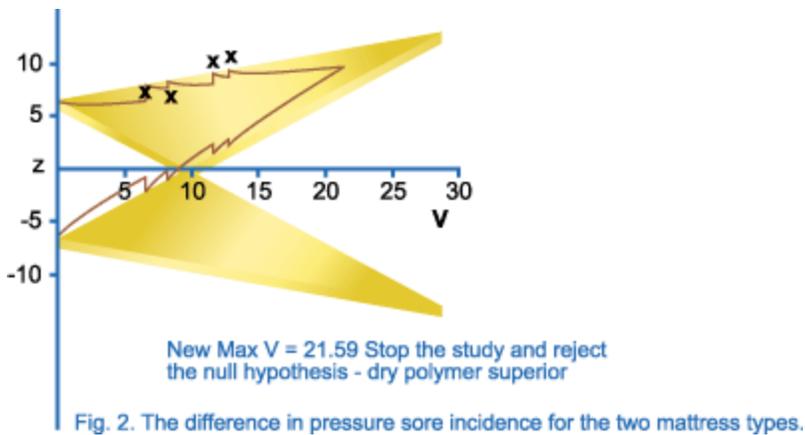
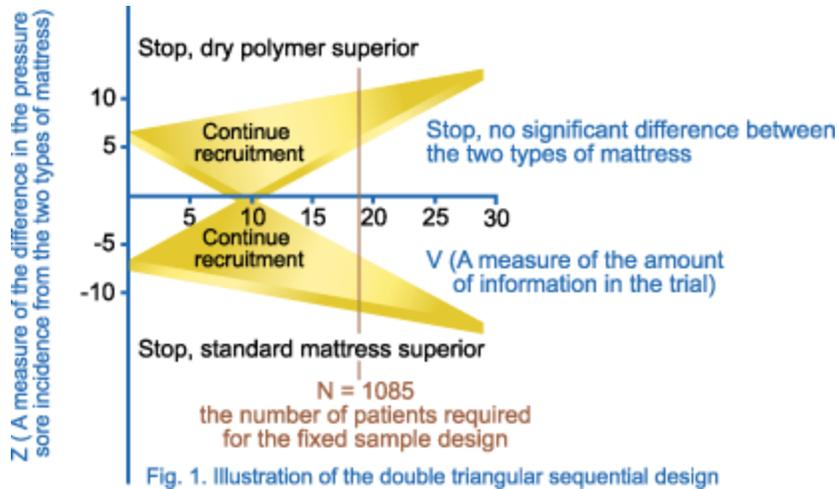
Table 2
Primary endpoint definition

Assessment time

| | | | | |
|-------------------------|---------------------|------------------------|----------------------|---------------|
| Immediate preanesthetic | Immediate (up to 30 | 30 min - 1 h following | Day 1 post operation | Site-specific |
|-------------------------|---------------------|------------------------|----------------------|---------------|

| Skin grade | min) post operation Skin grade | immediate assessment Skin grade | (08.00 - 20.00 h) Skin grade | outcome |
|------------|---|---------------------------------------|---------------------------------|---------|
| 0 | 0 | Any grade | Any grade | Success |
| 0 | ≥ 1 | ≥ 1 | ≥ 1 | Failure |
| 0 | ≥ 1 | ≥ 1 | 0 | Success |
| 0 | ≥ 1 | 0 | Any grade | Success |
| 1 | 0 | Any grade | Any grade | Success |
| 1 | 1 | Any grade | Any grade | Success |
| 1 | $\geq 2a$ | $\geq 2a$ | $\geq 2a$ | Failure |
| 1 | $\geq 2a$ | $\geq 2a$ | 0 or 1 | Success |
| 1 | $\geq 2a$ | 0 or 1 | Any grade | Success |

number of analyses occurring at discrete time points. This adjustment over a series of interim analyses resulted in narrower stopping boundaries which take the form of a 'Christmas tree' shape. The theory of the double triangular sequential design provided a method of calculating adjusted unbiased estimates of the probability of developing a pressure sore on the two types of mattress when a stopping boundary had been crossed.



All statistical analyses for the trial were carried out on 'intention to

treat' basis using the PEST3 and SAS software packages (PEST and SAS). The stratified analysis of treatment effect in this trial was carried out using the overrunning analysis option. The covariate adjustment analysis was carried out using the logistic regression and interactive matrix language procedures in SAS and the overrunning analysis option in PEST3. Terms were only included in the logistic model if their associated chi-square P-value was less than 0.05. Models were chosen by forward stepwise regression and by backward elimination to see if the same statistical model could be established using both methods. These methods involve respectively including the most, and excluding the least, statistically significant terms in the model in a step by step manner. Interactions with treatment were examined as well as main effects.

2.6. Outcome criteria

Skin was assessed using an adapted version of the Torrance scale whereby Stage 2 was subdivided to enable the distinction between intact and broken skin. (Torrance, 1983) as detailed in Table 1. This concurs with debate regarding the classification of pressure sores and the need to distinguish between intact and broken skin (Hitch, 1995; Lyder, 1991). Also included was 'Grade 0' (no discolouration of the skin) to clearly distinguish between assessment of normal skin and missing data.

The main endpoint for the trial was determined as a success, no pressure sore, or failure pressure sore (Table 2) at any of the five skin sites most likely to incur skin damage (sacrum, left and right buttocks, and left and right heels) (Bridel, 1993c). The primary endpoint was established using the definition of a pressure sore as 'a persistent discolouration of the same skin site on two or more successive days', a definition adapted from those used by previous researchers (Versluysen, 1986; Kemp et al., 1990 Ek et al., 1991; Lyder, 1991). A particular feature of the end point definition was the specificity of persistent worsening of the skin condition from its pre-operative condition to that post-operatively for three successive assessments.

2.7. Reliability

During the 3-month study set-up time training was provided to ward, recovery and intensive care staff

Table 3

Reasons for non entry to trial

| Reason | Number |
|----------------------------|----------------------------------|
| Consent refused | 60 |
| Communication difficulties | 12 |
| Skin | |
| | Dark pigmentation (2) |
| | Skin condition (86) |
| | Pressure sore - 2a or above (74) |

| | |
|---|-----|
| Unknown | 1 |
| Previously included in the study | 6 |
| Pre-operative pressure relieving mattress | 9 |
| Trial management problems | 24 |
| Total | 274 |

involved in the study. The inter-rater reliability of the skin assessment tool was assessed between clinical staff and the research nurses and the research nurses between centres.

Inter-rater reliability and its effect on the validity of the main endpoint was also assessed during the course of the study by independent co-assessment. Completeness of data was subject to nursing staff availability.

3. Results

3.1 Sample

Patients were recruited from November 1994-June 1996 when results reached a stopping boundry in the sequential model. Seven hundred and twenty patients were potentially eligible for inclusion and of these, a final 446 patients were randomised into the trial. Reasons for the high attrition rate are detailed in Table 3. Two hundred and twenty two were randomised to the dry visco-elastic polymer pad group and 224 to the standard mattress. Table 4 reports baseline characteristics and variables thought a priori to effect outcome. At each centre and

Table 4

Baseline variables of treatment and control groups

| Variable | Levels | Dry polymer pad | Standard mattress |
|---|------------------------|-----------------|-------------------|
| | | Total = 222 | Total = 224 |
| Centre | Hartlepool | 66 (30%) | 67 (30%) |
| | Leeds | 156 (70%) | 157 (70%) |
| Age group | 55-69 | 124 (56%) | 128 (57%) |
| | 70+ | 98 (44%) | 96 (43%) |
| Gender | Male | 119 (54%) | 116 (52%) |
| | Female | 101 (45%) | 107 (48%) |
| | Not known (forms lost) | 2 (1%) | 1 (0%) |
| Pre-operative Braden Scale (Braden and Bergstrom, 1988) | 10-14 | 1 (0%) | 0 (0%) |
| | 15-19 | 17 (8%) | 23 (10%) |

| | | | | |
|---|---------------------------|-----------|-----------|--|
| | 20-23 | 202 (91%) | 200 (89%) | |
| | Not known (forms lost) | 2 (1%) | 1 (0%) | |
| Type of surgery | Vascular | 69 (31%) | 70 (31%) | |
| | Non-vascular | 151 (68%) | 153 (68%) | |
| | Unknown (forms lost) | 2 (1%) | 1 (0%) | |
| Length of Operation | Less than 90 min. | 50 (23%) | 40 (18%) | |
| | 90-179 min. | 108 (49%) | 110 (49%) | |
| | 180 min. or longer | 62 (28%) | 73 (33%) | |
| | Unknown (forms lost) | 2 (1%) | 1 (0%) | |
| Length of pre- operative | | | | |
| Hospital stay | 0-1 days | 107 (48%) | 89 (40%) | |
| | 2-4 days | 62 (28%) | 74 (33%) | |
| | 5 days or more | 51 (23%) | 60 (27%) | |
| | Unknown (forms lost) | 2 (1%) | 1 (0%) | |
| Proportion of time Hypotensive during Operation (%) | None | 107 (48%) | 94 (42%) | |
| | 1-24 | 48 (22%) | 56 (25%) | |
| | 25-49 | 26 (12%) | 35 (16%) | |
| | 50-74% | 24 (11%) | 25 (11%) | |
| | 75-100 | 15 (7%) | 13 (6%) | |
| | Unknown (forms lost) | 2 (1%) | 1 (0%) | |

for both age groups, the treatment allocation was evenly balanced and the proportion of patients undergoing vascular surgery on the two types of mattress was similar. There was a tendency for patients assigned to the standard operating table mattress to have slightly longer length of operation, longer pre-operative stay and proportionally more time in a hypotensive state than patients assigned to the dry polymer pad.

3.2 Primary endpoint

The main endpoint was determined for 416 patients, with incomplete data for 30 patients resulting from lost forms (3) and incomplete post-operative skin assessment records (27). Main endpoint failure, a pressure sore was 11% (22/205) for patients allocated to the dry polymer pad and a 20% (43/211) for patients allocated to the standard

operating table mattress (Table 5). (Of note is the low failure rate at Hartlepool 2.3% (3/129) compared with St Jame's 21.6% (62/287).

The median unbiased estimate of treatment effect, based on the odds of developing a pressure sore after being placed on the dry polymer pad during surgery compared with being placed on a standard operating table mattress, was estimated after adjustment for centre and age group. There was a significant reduction of pressure sores on the dry polymer pad as compared to the standard mattress, (θ) = 0.46 with 95% confidence interval of (0.26, 0.82), $P = 0.010$. The adjusted point estimates of the probability of developing a pressure sore on the dry polymer pad and the standard operating table mattress were 0.11 and 0.21 respectively.

A sensitivity analysis was carried out assuming that the patients with missing endpoints were in fact failures. The odds of pressure sore development on the dry polymer pad compared to the standard operating table mattress was $q = 0.62$, 95% confidence interval (0.39, 1.00), $P = 0.048$, which is consistent in the sense that the difference in the effects of the two types of mattress is in the same direction as that in the main analysis.

The effect of the variables thought a priori to be important including centre, age, type of surgery, length of operation, length of pre-operative stay in hospital, and proportion of time the patient was in a hypotensive state during surgery, were examined using logistic regression to see if they modified the estimate of the difference in the incidence of pressure sores between the two mattress types. The same model was obtained by using a forward selection and backward elimination.

In order of descending importance, the following variables were significant in modifying the estimate of the difference in the probability of developing a pressure sore on the two mattress types:

- CENT - Centre (Hartlepool = 1, Leeds = 0)
- OPLN - Length of operation in min.
- HYPO - Proportion of time the patient was in a hypotensive state
- STAY - Length of pre-operative stay in hospital in days.

Age and type of surgery were found not to be important in the presence of the other variables. Age was not found to be important even when included in the model of its own.

The model for response with the standard errors of the parameter estimates in parentheses, based on 416 patients with determined endpoints, was given by

$$n = -2.50 - 2.26(\text{CENT}) + 1.26\text{HYPO} + 0.00415\text{OPLN} (0.34) (0.62) (0.49) (0.0016) + 0.0309\text{STAY} (0.015)$$

where the probability that a patient will develop a pressure sore is given by

$$P = 1/(1 + e^{-n})$$

Thus, the probability that a patient will develop a pressure sore, according to the definition of this trial, was higher at Leeds than Hartlepool, increased with the proportion of time in a hypotensive state during their operation, longer length of operation and longer pre-operative hospital stay.

The mean proportion of time in a hypotensive state

Table 5
Trial endpoint by centre and mattress allocation.

| Trial endpoint | Hartlepool | | Leeds | | Total |
|----------------|-----------------|----------|-----------------|----------|-------|
| | Dry polymer pad | Standard | Dry polymer pad | Standard | |
| Failure | 3 | 0 | 19 | 43 | 65 |
| Success | 59 | 67 | 124 | 101 | 351 |
| Undetermined | 4 | 0 | 13 | 13 | 30 |
| Total | 66 | 67 | 156 | 157 | 446 |

for patients in this trial was 19.2%, mean length of operation was 155.2 min., and mean length of pre-operative stay in hospital was 4.7 days. Hence at Hartlepool, the probability of a patient who had these characteristics of developing a pressure sore was $P = 0.02$ and for a similar patient at St Jame's the probability was $P = 0.19$.

The median unbiased estimate of treatment effect after adjustment for centre and the covariates proportion of time hypotensive, length of operation and length of pre-operative stay, was $(\theta) = 0.5$ with a 95% confidence interval (0.27, 0.89), $P = 0.020$. The effect of the dry polymer pad was slightly modified but outcomes remained statistically significantly different. The covariate adjusted value of the mattress effect can be interpreted by imagining a patient with the probability of developing a pressure sore after being placed on a standard mattress for their operation of $P = 0.20$ (the observed incidence). The estimated probability of developing a pressure sore on the dry polymer pad for such a patient is $P = 0.11$ with a 95% confidence interval of (0.07, 0.19).

The covariates which were important in modifying the treatment effect were examined for interaction effect with the mattress. The only interaction which was found to be significant was treatment-centre, $P = 0.012$.

3.3 Grades and sites

The majority of endpoint failures were skin changes from Grade 0 pre-operatively to Grade 1 post-operatively (56/65) with four patients having Grade 0-2a failures and five patients Grade 0-2b failures (1.2%). Failures were observed on a total of 95 skin sites on sacral (39), buttock (40) and heel (16) areas.

Of the 56 Grade 0-1 failures, all remained as either blanching or non-blanching up to day 8. Of the five Grade 2B endpoint failures, only 20 had resolved by day 2. Of the remaining 36, 33 continued to have persistent blanching hyperaemia for varying periods up to day 8 post-

one persisted and deteriorated to 2b. Of the four Grade 2a endpoint failures, two resolved within 24 h to grade 1 which then persisted for varying periods up to day 8, one resolved to 2a within 24 h which persisted to day 8, and two persisted as 2b up to day 8.

Post-operative skin assessments up to day 8 identified a total of 56 patients with Grades 2a/2b at one or more sites, an incidence of 12.5% (56/446), of which 16% (9/56) were related to the trial endpoint (Table 6).

3.4. Reliability and validity

A total of 133 paired assessments were undertaken by 94 nurses for the pre-study inter-rater reliability assessments generating data for 664 skin sites. There was disagreement for 15/664 (2.2%) skin sites, affecting 12/133 (9%) patients. Disagreements were mainly 0-1 (13) with

Table 6

Grade 2 pressure sores observed during post-operative period - immediate to day 8

| | Hartlepool n = 133 | St Jame's n = 310 |
|---------------|--------------------|-------------------|
| Grade 2a | 13 (9.7%) | 22 (7%) |
| Grade 2b | 4 (3%) | 17 (5.5%) |
| Total Grade 2 | 17 (12.8%) | 39 (12.6%) |

only two disagreements for 1-2a. A majority of the disagreements were associated with assessment of heels (10/12 patients).

A total of 171 coassessments were undertaken in the recovery area (105) and ward (65), generating a total of 851 site comparisons between the main trial assessment and coassessment. Of these there was a discrepancy of 72/851 (8.5%). All discrepant coassessments were only one grade on the skin assessment scale with 68 0/1 and four 1/2a disagreements. The five skin areas had similar levels of disagreements (13-16 assessments). Despite the overall number of discrepancies the number of misclassifications of success or failure which would have resulted had the coassessments been used for determination of the main endpoint rather than the main trial assessments would have been five (three successes would have been failures, one failure would have been a success and one success would have been undetermined). Incorporating these altered endpoints into a sensitivity analysis of the treatment effect results in a median unbiased estimate for $q = 0.50$ with 95% confidence interval (0.29, 0.88), $P = 0.016$. Therefore, the significant difference in the effect of the two mattress types remains.

4. Discussion

The overall endpoint failure rate of 15.6% is consistent with findings from other studies of elective surgical patients which report pressure sore incidence rates ranging from 12-57.4% (Gendron, 1980; Stotts, 1988; Kemp et al., 1990; Marchette et al., 1991; Hoshowsky and Schramm, 1994; Papantonio et al., 1994). The apparently wide variation in incidence can be accounted for by differences in pressure

criteria.

With respect to the endpoint failure rate for the control and experimental groups, two recent studies include the dry polymer pad within a prescribed treatment regime. Hoshowsky and Schramm (1994) reported the results of a trial, comparing standard, foam/gel and dry polymer mattresses. Including only heels, each patient provided their own control. Interpretation is difficult since incidence is calculated using only one immediate post-operative skin assessment, there is no comparison between pre- and post-operative assessments and incidence for each support surface is not detailed, although a statistically significant difference in incidence was reported in favour of the dry polymer pad. Papantonio et al. (1994) in a study of 136 patients, utilized the dry polymer pad intra-operatively for all patients (elective cardiac surgery). They reported an incidence of 27.2% but did not identify exclusion criteria nor distinguish between pre, immediate post-operative and total post-operative period up to day 5.

Results are also consistent with the broader conclusions derived from a systematic review of pressure sore prevention equipment (Effective Health Care, 1995). Using only randomised controlled trials, the review concluded that low technology constant pressure supports reduce pressure sore incidence when compared to standard mattress provision. Whilst the standard operating table mattress is not directly comparable to the standard hospital mattress the principle that a pressure reducing surface reduces patient risk is established.

Skin grades observed were also consistent with findings from other studies of the post-operative period. There was a predominance of persistent blanching hyperaemia, a small number of Grade 2a and 2b sores and a complete absence of severe progressive sores. Continued follow up to day 8 did not identify the delayed appearance of Barton and Barton Type 2 pressure sores (Barton and Barton, 1981; Gendron, 1980; Stotts, 1988; Kemp et al., 1990; Marchette et al., 1991; Hoshowsky and Schramm, 1994; Papantonio et al., 1994). An absence of severe progressive sores reflects the specificity of the exclusion criteria and the short post-operative follow-up (Stotts, 1988). The paucity of post-operative evidence of Barton and Barton Type 2 pressure sores which have previously been identified by case study reports (Gendron, 1980; Vermillion, 1990) suggests these are very rare and their occurrence should prompt local investigation.

However, it is noteworthy that patients with existing skin damage, including signs of potentially irreversible changes (non-blanching hyperaemia) were excluded from the study. There is evidence that patients with existing pressure sores are at greater risk than pressure sore free patients of developing further sores (Berlowitz and Wilking, 1990; Bergstrom and Braden, 1992; Clark and Watts, 1994). The sample is further affected by the exclusion of patients with other skin damage including vascular ulcers to ensure validity.

One criticism which could be leveled at the present study is the inclusion of blanching hyperaemia within the endpoint definition of a post-operative pressure sore. Criticism may be waged on three points - firstly, the large number of post-operative assessors; secondly the reliability of assessment and its effect upon the validity of results; and thirdly, the clinical importance of blanching hyperaemia.

With respect to the first two points, co-assessments quantified the level of disagreement between assessors as 8.5%. However, the sensitivity analysis determined that disagreement affected classification of only five endpoints (2.9%) and did not impact upon the overall difference observed between the two mattresses.

The clinical importance of blanching hyperaemia continues to be a source of debate (Hitch, 1995). Central to this are questions regarding the relationship between the observation of reactive hyperaemia and subsequent skin/tissue loss. This has been the subject of little or no research. Marchette et al. (1991) reported "a significant relationship between the incidence of redness and skin ulcers ($P = 0.00001$)"; however, a number of limitations of the study and published results are apparent including study design (record review), no detail regarding the 'conversion rate' of reddened area to skin loss and an absence of information relating to the statistical methods used.

From a physiological perspective reactive hyperaemia whether blanching or non-blanching in a localised area following a pressure assault is a clear indicator that capillary occlusion has occurred.

From a clinical perspective, pressure sore prevention equipment aims to reduce localised pressure, friction and shear and thereby prevent capillary occlusion. When assessing the immediate effect of a single pressure assault hyperemia provides sensitive clinical evidence of capillary occlusion and the endpoint criteria used in this study clearly distinguishes between transient and persistent skin changes providing an outcome which enables differentiation between the two support surfaces. The validity of the outcome criteria is further supported by the large percentage (69%) of endpoint failure patients whose skin was observed to have changes persistent beyond the endpoint of day 1 post-operatively. Three of the five variables considered of a priori importance reduced the magnitude of the treatment effect.

The relationship between proportion of time hypotensive and increased length of surgery to treatment effect support the pathophysiology literature which suggests that there are threshold values for pressure and time which are threshold values for pressure and time which are dependent upon auto-regulatory processes at an individual level (Bridel, 1993d). The maintenance of capillary flow and the 'critical closing pressure' is determined on an individual basis by an interplay of forces between intravascular pressure, muscle contraction and elastic forces of the blood vessel wall and externally applied pressure (Lippold and Winton, 1979). Auto-regulatory processes affecting capillary flow are evident (Frantz et al., 1993) and related to systemic blood pressure (Schubert, 1991). The results illustrate that if internal factors increase the risk of capillary occlusion, the potential benefit of reducing external pressure is modified (or reduced).

Time is important in two ways: firstly, there is evidence of low/reduced blood flow in response to external pressure and associated diminished tissue oxygenation (Bader, 1990; Frantz et al., 1993; Xakellis et al., 1991), with suggested risk of gradual development of ischaemic conditions. Secondly, if complete occlusion or ischaemia occurs time becomes important in determining the extent of tissue

damage (Kosiak, 1961).

A relationship between length of stay and pressure sore incidence has been reported (Norton et al., 1962; Stotts, 1988) and some debate exists as to whether length of stay reflects morbidity and intrinsic risk or hospitalization and continuous exposure to extrinsic factors such as high pressures (Versluisen, 1986) or both.

With respect to age, results are inconsistent with much of the literature which clearly links increasing age to increased pressure sore prevalence and incidence (Barbenel et al., 1977; Waterlow, 1988; Bergstrom and Braden, 1992; Papantonio et al. 1994), although similar results are reported by Kemp et al. (1990). An important consideration is that sampling was purposive in relation to both age (55 years) and surgery (major) and results suggest that potential age related differences in risk are less important in such a homogenous group than the morbidity associated with individual circumstance.

In relation to type of surgery, case study (Gendron, 1980; Vermillion, 1990) and audit data, rather than research evidence led to the inclusion of this as a variable of a priori importance requiring consideration. There was a perception of increased risk amongst vascular surgical patients, indeed a difference in the overall post-operative pressure sore incidence was observed - vascular 25.6% and other 14.6%.

Unexplained are the differences between centres and the low failure rate at Hartlepool (3/129). The differences observed in the immediate post-operative period (trial endpoint) are not mirrored in the continued post-operative follow up to day 8; indeed a greater proportion of Hartlepool patients were observed to have Grade 2 pressure sores during their post-operative recovery (Table 6). It is unclear whether patient characteristics (hypotensive episodes, length of surgery and Braden Scores), measurable practices (pre-operative length of stay, post-operative mattress) and/or unmeasured practice (positioning/repositioning) account for variation within the immediate post-operative period, and is an area requiring further investigation.

4. Conclusions

In this randomised controlled study of 446 vascular, general and gynaecology patients, the use of a dry visco-elastic polymer pad intra-operatively reduced the probability of pressure sore development by half. Although the effect was slightly modified by the variables centre, proportion of time hypotensive, length of surgery and pre-operative length of stay, the effect of the dry visco-elastic polymer pad remained statistically significant. Similarly, in sensitivity analyses accounting for skin assessment variation and undetermined endpoints the effect of the dry visco-elastic pad in reducing post-operative pressure sore incidence remained statistically significant. It is noteworthy that the majority of endpoint failures were persistent blanching hyperaemia, but that 69% of these patients were observed to have persistent skin changes beyond the peri-operative period and this furthers the debate regarding the clinical importance of this outcome. The minimal cost of the dry visco-elastic polymer pads in comparison to the cost of pressure sore treatment and the personal cost to patients, in relation

practice.

Acknowledgements

This trial was supported by a grant from the Northern and Yorkshire Regional Health Authority. The authors would like to extend their thanks to ward, theatre and anaesthetic recovery staff at Hartlepool and St Jame's for their invaluable and dedicated support. Trial management and data analysis was supported by an independent Data Monitoring Committee and Professor John Whitehead of Reading University. Also to members of the research team including: Angela Phillips and Jackie Bainbridge (Northern and Yorkshire Clinical Trials and Research Unit); Susanne Coleman and Lisa Hope (Nursing Research and Practice Development Unit, St. Jame's) and: Darren McVitie and Alison Briscoe (Surgical Division, Hartlepool). This work was undertaken by The Leeds Teaching Hospitals NHS Trust who received funding from the NHS Executive; the views expressed in this publication are those of the authors and not necessarily those of the NHS Executive.

References

- Bader, D.L., 1990. The recovery characteristics of soft tissue following repeated loading. *Journal of Rehabilitation Research and Development* 27 (2), 141-150.
- Barbenel, J.C., Jordan, M.M., Nicol, S.M., Clark, M.O., 1977. Incidence of pressure sores in the Greater Glasgow Health Board area. *Lancet* 2, 548-550.
- Barton, A., Barton, M., 1981. *The Management and Prevention of Pressure Sores*, Faber, London.
- Bergstrom, N., Braden, B., 1992. A prospective study of pressure sore risk among institutionalised elderly. *Journal of the American Geriatrics Society* 40 (8), 747-758.
- Berlowitz, D.R., Wilking, S.V., 1990. The short-term outcome of pressure sores. *Journal of the American Geriatrics Society* 38 (7), 748-752.
- Braden, B.J., Bergstrom, N., 1989. Clinical utility of The Braden Scale for predicting pressure sore risk. *Decubitus* 2 (3), 44-46; 50-51.
- Bridel, J., 1992. Pressure sores and intra-operative risk. *Nursing Standard* 7 (5), 28-31.
- Bridel, J., 1993a. Pressure sore risk in operating theatres. *Nursing Standard* 7 (Tissue Viability Suppl.), (32), 4-10.
- Bridel, J., 1993b. The epidemiology of pressure sores. *Nursing Standard* 7 (42), 25-30.
- Bridel, J., 1993c. The aetiology of pressure sores. *Journal of Wound Care* 2(4), 230-238.
- Clark, M., Watts, S., 1994. The incidence of pressure sores within a National Health Service Trust hospital during 1991. *Journal of Advanced Nursing* 20, 33-36.
- Effective Health Care, 1995. The prevention and management of pressure sores: How effective are pressure relieving interventions and risk assessment for the prevention and treatment of pressure sores? *Effective Health Care* 2 (1).
- Ek, A.C., Unosson, M., Larsson, J., Von Schneck, H., Bjurulf, P., 1991. The development and healing of pressure sores related to the nutritional state. *Clinical Nutrition* 10, 245-250.

Frantz, R., Akellis, G.C., Arteaga, M., 1993. The effects of prolonged pressure on skin blood flow in elderly patients at risk for pressure ulcers. *Decubitus* 6 (6), 16-20.

Gendron, F., 1980. Burns occurring during lengthy surgical procedures. *Journal of Clinical Engineering* 51 (1), 19-26.

Hitch, S., 1995 NHS Executive Nursing Directorate - Strategy for Major Clinical Guidelines - Prevention and Management of Pressure Sores: A Literary Review. *Journal of Tissue Viability* 5 (1), 3-24.

Hoshowsky, V.M., Schramm, C.A., 1994. Intra-operative pressure prevention: an analysis of bedding materials. *Research in Nursing and Health* 17 (5), 333-339.

Kemp, M.G., Keighley, J.K., Smith, D.W., Morreale, B., 1990. Factors which contribute to pressure sores in surgical patients. *Research in Nursing and Health* 13 (5), 293-301.

Kosiak, M., 1961. Etiology of decubitus ulcers. *Archives of Physical Medicine and Rehabilitation* 42, 19-29.

Lippold, O.C.J., Winton, F.R., 1979. *Human Physiology*, 7th ed. Churchill Livingstone, Edinburgh.

Lyder, C., 1991. Conceptualisation of the stage 1 pressure ulcer. *Journal of Enterostomal Nursing* 18 (5), 162-165.

Marchette, L., Arnelli, I., Redick, E., 1991. Skin ulcers of elderly surgical patients in critical care units. *Dimensions of Critical Care Nursing* 10 (6), 321-329.

Moore, E., Rithalia, S., Gonsalkorale, M., 1992. Assessment of the Charnwood Operating Table and Hospital Trolley Mattresses. *Journal of Tissue Viability* 2 (2), 71-72.

Neander, K-D., Birkenfeld, R., 1991. Decubitus prophylaxis in the operating theatre? *Journal of Tissue Viability* 1 (3), 71-74.

Norton, D., McLaren, R., Exton-Smith, A.N., 1962. *An Investigation of Geriatric Nursing Problems in Hospital*. Churchill Livingstone, Edinburgh.

Papantonio, C.T., Wallop, J.M., Kolodner, K.B., 1994. Sacral ulcers following cardiac surgery: incidence and risks. *Advances in Wound Care* 7 (2), 24-36.

PEST Planning and Evaluation of Sequential Trial Software, University of Reading.

SAS Statistical Analysis Software, SAS Institute Inc.

Schubert, V., 1991. Hypotension as a risk factor for the development of pressure sores in elderly subjects. *Age and Aging* 20 (4), 255-261.

Stotts, N.A., 1988. Predicting pressure ulcer development in surgical patients. *Heart Lung* 17 (6), 641-647.

Torrance, C., 1983. *Pressure sores: Aetiology, Treatment and Prevention*. Croom Helm, London.

Vermillion, C., 1990. Operating room acquired pressure ulcers. *Decubitus* 3 (1), 26-30.

Versluysen, M., 1986. How elderly patients with femoral fracture develop pressure sores in hospital. *British Medical Journal* 292, 1311-1313.

Waterlow, J., 1988. The Waterlow card for the prevention and management of pressure sores: towards a pocket policy. *Care Science and Practice* 6 (1), 8-12.

Whitehead, J., 1992. *The Design and Analysis of Sequential Clinical Trials*, 2nd ed. Ellis Horwood, Chichester.

Xakellis, G.C., Frantz, R.A., Arteaga, M., Meletious, S., 1991. A comparison of changes in the transcutaneous oxygen tension and capillary blood flow in the skin with increasing compressive weights.

American Journal of Physical Medicine and Rehabilitation 70 (4), 172-177.

ACTION and AKTON are registered trademarks of Action Products, Inc.®

Copyright 2005, Action Products, Inc.. Any concerns, send e-mail to service@actionproducts.com.