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Is the use of modern versus conventional wound dressings warranted after primary knee and hip arthroplasty ? Results of a Prospective Comparative Study

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Purpose of the Study: This prospective, open, noncontrolled clinical investigation evaluated the performance of a modern post-operative wound dressing versus conventional dressings used on wounds of patients after undergoing hip or knee replacement.

Methods: The clinical investigation started with a two-week observation phase of conventional wound dressings, followed by an intervention phase where patients were treated with Mepilex[®] Border Post-Op dressings. The primary objective was to evaluate the occurrence of blisters.

Results : There was no blistering in any of the patients in the Mepilex group (n = 49), whereas blistering occurred in 27.3% (n = 3) of patients in the conventional group (n = 11, p < 0.01). The Mepilex dressing was left on for seven days in 70% of patients. There was a significant reduction in the total cost for dressing changes with the Mepilex dressings (p = 0.006).

Conclusion : By using Mepilex dressings, the risk of blistering was negated and the reduced frequency of dressing changes was associated with the reduced overall cost. Therefore, we recommend the use of Mepilex Border Post-Op dressings.

Keywords :

INTRODUCTION

Primary knee and hip replacements are among the most commonly performed orthopaedic and

Acta Orthopædica Belgica, Vol. 81 - 4 - 2015

trauma surgery procedures in Europe (23). Not the least as a result of financial pressures, there has been a trend towards quick post-operative mobilisation of patients, and therefore reduced durations of hospitalisation (21). In view of these factors, it is important to minimise potential deficiencies in treatment to ensure that patients receive high quality of care (16,19,20). Morbidity resulting from skin breakdown can lead to prolonged hospitalisations, wound

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The study was sponsored by Molnlycke Health Care, Gothenburg, Sweden. KZ has received travel expenses from Molnlycke Health Care for presenting the data of this study. The corresponding author declares no other conflict of interest. The other authors do not have any conflict of interest. infections, and the need for further surgery (28-31). Postoperative infection rates following primary hip and knee joint replacement are reported as 0.39 and 1.25% in the literature (4,6,14,25,34,37). One common problem after hip and knee replacement is blistering at the wound site, with reported incidence rates of 13 - 35% (27). A significant factor in this is the friction between skin and dressing caused by joint movement (15). Friction occurs when the dermis separates from the epidermis, and is invariably a result of continued abrasion (10). Other factors affecting the development of post-operative blistering are age-related skin changes, soft tissue oedema following surgery, dressing type, and mode of dressing application (15,27). Damage to the epidermis leaves dermal nerve endings exposed, which is often very unpleasant and painful (27). Exposed dermis can result in superficial wound infections that, in the worst cases, can lead to prosthetic infection (27). Moist wounds are associated with faster healing, fewer infections, and less pain, when compared to dry wounds (12,35). However, a dressing with insufficient absorption capacity may be ineffective in absorbing and retaining wound exudates, enabling the development of moisture-related skin damage (i.e. maceration) and bacterial contamination of the wound, particularly if there is leakage outside the dressing (5).

Often, too little consideration is given to the appropriate selection of post-operative wound dressings. Historically, conventional wound dressings have been used, mostly gauze-based dressings such as woven and non-woven sponges, conforming and non-adherent bandages. These dressings are associated with frequent dressing changes, which can increase the risks of the untoward effects described above. Recent studies suggest that advanced wound dressings, already well-established for the treatment of chronic wounds, are also beneficial for post-operative wound management (*3*,*7*,*12*,*14*). These studies also suggest that the higher cost of such advanced wound dressings is justified.

Mepilex Border Post-Op (Molnlycke Health Care, Gothenburg, Sweden) is a highly conformable self-adherent dressing that absorbs exudate and minimises the risk of maceration. It incorporates Safetac[®], a unique and patented adhesive technology that minimises pain to patients and trauma to wounds and the surrounding skin on dressing re-moval (*11,18,33,36*).

The overall rationale for this study was to evaluate the clinical performance of Mepilex Border Post-Op in terms of its ability to minimise the risks of blistering and maceration, as well as to examine its impact on the patient, the frequency of dressing changes, and treatment costs.

PATIENTS AND METHODS

This Post-Market Clinical Follow-Up (PMCF) study was conducted in accordance with the principles of the Declaration of Helsinki, ISO standard 14155, and current German regulations.

The investigation was conducted from April 2013 to September 2013 across two sites in Germany. Screened patients were of both sexes, over 45 years of age (with no upper age limit), and were admitted to the hospital and receiving management for hip or knee joint replacement. Patients were included after receiving detailed information from the investigating physician and giving written consent. The main exclusion criteria were patients receiving a prosthesis for fracture or tumour, those with known allergy/hypersensitivity to any of the dressing components, documented skin disease at the time of enrolment (psoriasis, eczema), pre-existing wound at the surgical site prior to surgery, neurological deficits on the operated side (hemiplegia, etc.), and an incision area for which an appropriate dressing size was not available.

Procedures

This investigation was conducted in two phases : one two-week observation phase (OBS) and one subsequent intervention phase (INT). The inclusion and exclusion criteria, skin condition, medication and demographic data of the patients were recorded by investigation personnel during the pre-operative period. The duration of anaesthesia, length of the wound incision, intraoperative antibiotics, and other medication used were recorded. The dressings were applied in the operating theatre by the surgeon, and in the ward by trained investigation personnel in accordance with the Clinical Investigation Plan (CIP). Dressing changes were carried out according to CIP and hygiene regulations of the hospitals.

Standard care was documented during the observation phase. The conventional dressings used in the hospitals were Vliwazell[®], Fixomull[®], Mepore[®], and Cosmopor[®] E. The frequency of dressing changes was according to the standards of the respective hospital.

Mepilex[®] Border Post-Op dressings were applied during the INT phase according to the size of the surgical incision (the following sizes of dressings were available : 10×20 cm, 10×25 cm, and 10×30 cm) and according to the instructions for use supplied by the manufacturers.

The dressing was changed when wound exudate became clearly visible beneath the transparent film (> 50% of the area), or when there were signs of inflammation. If there was no need to change the dressing, it was left on for 7 post-op days.

The parameters (number and frequency of dressing changes, irritation, blistering, skin lesion and maceration, time for dressing changes, resources, and materials needed) were recorded in both OBS and INT phases. Other parameters, only recorded in the INT phase, were patient satisfaction (comfort and overall), and investigation personnell evaluations (ease of dressing application and removal, appropriateness of available dressing sizes, and overall assessment). These parameters were evaluated using a Likert scale (excellent, very good, good, poor). A visual analogue scale (VAS) was used by patients to evaluate pain before, during, and after dressing removal.

The surgical incision was evaluated by the investigation personnel daily until post-op day 7, and the investigator was required to record any unexpected local adverse events, dressing-related or not. Health care resourses, number of dressing changes, and amount of used material data was collected for patients receiving standard treatment and Mepilex Border Post-Op during the 7 investigation days.

Statistics

Analyses were conducted using SAS statistical software (version 9.2, SAS Institute). The descriptive statistics were given and scale variables are presented by mean \pm SD, median, and range. All analyses were conducted on an intention-to-treat (ITT) population, defined as all enrolled patients who received the allocated dressing at least once. The differences between the treatment groups were analysed using the Mann-Whitney U test for continuous and Fisher's exact test for dichotomous variables. Epidemiological differences between the groups were adjusted according to the Cochran-Mantel-Haenszel pooling technique.

Ethics

Research Ethics Committee approval of this clinical investigation was obtained at both participating arthro-

Acta Orthopædica Belgica, Vol. 81 - 4 - 2015

plasty centres before patients were enrolled. Details of the clinical investigation were also registered on clinicaltrials.gov (NCT01841567) before the investigation commenced.

RESULTS

Demographic and surgical data

Sixty patients were included in the investigation. 11 were included in the OBS phase and 49 in the INT phase. Of the 49 patients in the INT group, 47 patients were treated with the Mepilex Border Post-Op dressing (2 patients never received the investigational dressing due to pre-operative myocardial infarction and incorrect dressing), and 44 patients completed the study. Of those failing to complete the study, one patient independently removed the dressing, one patient required further surgery after hip dislocation, and one patient experienced severe wound secretion with skin irritation. Participants in the OBS group had a higher mean age of 75.1 (\pm 8.2) years compared to 66.0 (\pm 11.0) years in the INT group (p = 0.028). No significant differences were observed regarding other patient demographic data (Table I).

Blistering and skin status

No blistering was observed in patients of the INT group, whereas 27.3% (n = 3) of OBS group patients developed blisters (p = 0.001). Blistering appeared on one patient after a dressing change on day 3, and on two patients on day 4. Clinically observed skin status and wound conditions were better in the INT group (Table II).

Dressing changes

Our results indicate that the number of dressing changes can be significantly reduced by using the advanced wound dressings, compared to conventional dressings (Table III). No dressing change was required for 70% of patients in the INT group (n = 33) during the first seven days, whereas at least 1 dressing change was performed for all of the patients in the OBS group during that period.

770

Variable	INT-Group	OBS-Group	p-value
	(n = 49)	(n = 11)	
Age			
Mean (± SD)	66.0 (± 11.0)	75.1 (± 8.2)	0.028
Median (range)	69.0 (45.0; 86.0)	74.0 (59.0; 87.0)	
Weight (kg)			
Mean (± SD)	85.3 (± 21.4)	89.2 (± 18.6)	0.44
Median (range)	85.0 (50.0; 150.0)	91.0 (60.0; 115.0)	
Length (cm)			
Mean (± SD)	168.8 (± 10.6)	170.7 (± 12.3)	0.86
Median (range)	165.0 (150.0; 196.0)	168.0 (158.0; 193.0)	
Body Mass Index (kg/m ²)			
Mean (± SD)	30.0 (± 7.7)	30.5 (± 5.5)	0.52
Median (range)	28.5 (18.8; 58.6)	28.7 (23.7; 39.2)	
Type of surgery $(n = 48)$			
Hip arthroplasty (n, %)	26 (54.2%)	5 (45.5%)	0.85
Knee arthroplasty (n, %)	22 (45.8%)	6 (54.5%)	
Duration of anaesthesia (min)			
Mean (± SD)	148.2 (± 39.3)	148.1 (± 40.1)	0.96
Median (range)	148.0 (65.0; 255.0)	123.0 (101.0; 216.0)	
Length of incision (cm)			
Mean (± SD)	17.5 (± 4.5)	16.5 (± 4.8)	0.56
Median (range)	17.0 (10.0; 27.0)	20.0 (10.0; 21.0)	
Antibiotic prophylaxis (n = 48)			
No (n, %)	3 (6.3%)	1 (9.1%)	1.00
Yes(n, %)	45 (93.8%)	10 (90.9%)	

Table I. — Baseline distribution of patient characteristics for both treatment groups (n = 60)

There is a strong correlation between post-operative dressing type and dressing outcome. The OBS group had a considerably higher risk of dressing failure (n = 4), defined as either skin blistering or more than two dressing changes needed within seven days , versus patients in the INT group (n = 4, p = 0.026). The odds ratio for dressing failure was 6.14 for the standard dressing compared to Mepilex Border Post-Op dressing.

Patient and clinician satisfaction

Patient comfort and overall satisfaction with the Mepilex Border Post-Op dressing were rated by the knee arthroplasty patients as good (4.4%) to very good-excellent (96.6%), and by the hip arthroplasty

patients as good (6.4%) to very good - excellent (93.6%).

Satisfaction with the Mepilex Border Post-Op dressing was rated by the clinicians (physicians and nurses) from good (7.9%) to very good-excellent (92.1%) for the hip joints and from good (9.4%) to very good - excellent (90.6%) for the knee joints.

Application and removal of Mepilex Border Post-Op dressings was considered painless by almost all patients.

Economic outcomes

The mean cost of dressing changes during the 7 days was reduced from \notin 43.10 in the OBS group to \notin 28.00 in the INT group (p = 0.0062) (Table IV).

Variable	INT-Group	OBS-Group	p-value
	(n = 47)	(n = 11)	
Blisters (n, %)	0 (0)	27.3 (3)	< 0.001
Skin stripping (n, %)	0 (0)	9.1 (1)	0.16
Oedema (n, %)	38.6 (17)	54.5 (6)	0.11

Table II. — Skin status outcome for both treatment groups (n = 60)

Table III. — Number of dressing changes outcome for both treatment groups (n = 60)

Variables	INT-Group	OBS-Group	p-value
	(n = 47)	(n = 11)	
Number of dressing changes			
Mean (± SD)	0.66 (± 1.273)	2.00 (± 0.77)	0.0004

Table IV. — Number of dressing changes and healthcare resources outcomes for both treatment groups (n = 60)

Variables	INT-Group	OBS-Group	p-value
	(n = 47)	(n = 11)	
Number of dressing changes			
Mean (± SD)	0.66 (± 1.273)	2.00 (± 0.77)	0.0004
Time, min.			
Mean (± SD)	2.54 (± 1.45)	4.3 (± 1.03)	0.003
Material Cost, €			
Mean (± SD)	25.1 (± 10.2)	34.3 (± 17.7)	0.3252
Personnel Cost, €			
Mean (± SD)	2.93 (± 1.97)	8.87 (± 3.52)	< 0.001
Total Costs, €			
Mean (± SD)	28.0 (± 11.4)	43.1 (± 19.4)	0.0062

By using the Mepilex Border Post-Op dressings, a significant reduction (33%) in personnel costs for dressing changes was observed. This was partly due to the mean time per dressing change being significantly greater in the OBS group (4.3 minutes) versus the INT group (2.54 minutes, p = 0.003).

DISCUSSION

Given that post-operative wounds resulting from knee or hip arthroplasty often heal without any problems, wound management is often not a priority in the operating theatres. Consequently, surgeons may not give sufficient consideration to the appropriate selection of a post-operative dressing. However, by choosing the most suitable wound dressing, it is possible to prevent skin breakdown from occurring in a simple surgical wound. Consideration must be given to the cost-effectiveness of each dressing, time and ease of application, transferability to the wards, and most importantly, agreement from staff and patients (*32*). Choosing a more expensive, advanced dressings (compared to conventional simple self-adhesive gauze-based dressings such as woven and non-woven sponges) appears to have more clinical and cost-related advantages.

There are numerous known contributing factors in the aetiology of skin breakdown following knee and hip replacement surgery (9,26). Extrinsic factors are gentle surgical technique (1,10,26), type of wound closure (17), use of anticoagulants (13), and tourniquet application time (8). PRIMARY KNEE AND HIP ARTHROPLASTY

In 2012, Ousey *et al* used a two-stage Delphi survey of international experts to form a consensus on how skin blistering and other wound complications can be avoided with effective post-operative wound management (24). Experts agreed that the initial wound dressing should ideally be left on as long as possible, at least seven days, provided there are no signs of excessive wound secretion or infection. The dressing should fit easily over the wound, be easy to apply and remove, able to accommodate wound swelling, and cause minimal pain on removal.

In the current study, no patients in the INT group experienced blistering, which we attribute to the Safetac adhesive technology and superior flexibility of the Mepilex Border Post-Op compared to conventional post-operative wound dressings. Reduced flexibility of the dressing leads to increased shear forces along the dermal/epidermal barrier and is, in addition to post-operative oedema, one of the main causes of blistering (3). In a randomised, controlled trial, Ravenscroft et al observed a reduction in blistering from 22.5% using a conventional wound dressing to 2.4% with a more advanced regime (27). In the prospective, controlled trial by Hooper et al, blistering was also significantly reduced (from 20% to 4%) by using modern versus conventional wound dressings (Mepore) (16).

Permeability of the wound dressing plays an important role, since increased moisture in the area around the wound can lead to skin maceration and blistering (9). Simple wound dressings with gauze, and self-adhesive dressings with cotton pads absorb the moisture from the wound and often dry it out completely (2). By using film dressings that are permeable to water vapour, the balance of moisture in the wound can be maintained more effectively (2). Moreover, bacteria can rapidly penetrate a dressing that is moist on the outside (7). In contrast, semi-occlusive film dressings are impermeable to bacteria (9).

By using a transparent film, the skin around the wound can be examined closely at any time without changing the dressing, meaning that irritation and signs of infection can be identified at an early stage (9). The Mepilex[®]-Border Post-Op contains highly absorbent fibres, which can absorb post-

operative wound exudates more effectively than conventional cotton padding or gauze dressings. We can therefore assume that post-operative bleeding from the wound can be better controlled, reducing blood encrustation on the edges of the wound that can become stuck to the dressing. This, in addition to the dressing's patented Safetac[®] technology, which is designed to prevent the dressing from sticking to the wound, is presumably the reason for the low level of pain experienced during dressing changes.

Frequent post-operative dressing changes are regarded as a risk factor for exogenous bacterial contamination, and therefore superficial wound infection (9). McGuiness *et al* also showed that cellular wound healing is interrupted for approximately three to four hours after a dressing change, as a result of the decreased skin temperature (22,38).

Although the cost of the Mepilex Border Post Op dressing is considerably higher than that of a standard dressing, overall dressing costs were reduced by around 35% owing to the reduced time required to change the dressing and the longer wear time. Improved absorption of wound moisture reduces prolonged wound exudation. It can be assumed that mechanical irritation of the skin caused by dressing changes can be reduced when fewer dressing changes are required. The reduction of blistering and skin damage, which require subsequent treatment, further offset the cost of the dressings. We did not document these costs further in this investigation. However, treatment costs are known to increase as a result of post-operative skin breakdown, particularly if additional dressing changes are required, more analgesics and antibiotics are used, and periods of hospitalisation are longer or readmission to hospital is required (9).

The limitation of this investigation might be the relatively low sample size in both groups, as blistering was the primary endpoint. Blinding of the patients was not possible owing to the investigative design, and this might have exaggerated the effect of the new dressing on subjective parameters like satisfaction and pain. We deliberately did not conduct a prospective, randomised trial, as the primary aim of this PMCF study was to document both the real treatment situations in the respective hospitals and the effects of the new dressings. In the OBS group, the dressings were changed when the practitioner or patient considered it necessary. It could therefore be the case that dressings were changed too early or left on too long.

Wound drainage was used for almost all patients in the first two to three days post-op, so we were not able to draw any conclusions in terms of the effectiveness of the new type of dressing without drainage.

Further studies should focus on orthopedic patients with difficult acute wound situations, for example in revision arthroplasty.

CONCLUSION

This investigation shows that the use of advanced modern wound dressings on the post-operative wounds of patients who have undergone primary hip and knee arthroplasty is reasonable and justified. The risk of blistering was reduced even further in our investigation with the Mepilex Border Post-Op dressing than in other reported investigations comparing modern advanced wound dressings and conventional wound dressings. The dressing was generally rated as very good by patients and practitioners alike, and it contributed to a reduction in the direct costs of wound treatment overall.

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