



Comparative study of innovative postoperative wound dressings after total knee arthroplasty

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Purpose : Postoperative wound complications, especially surgical site infections, influence the outcome after total knee arthroplasty. The purpose of our study was to compare four different wound dressings. Following research questions were asked : (1) Which dressing is associated with least wound complications ? (2) Which dressing application is the cheapest ? (3) Which dressing is most comfortable for the patient ?

Methods : 111 patients undergoing a total knee arthroplasty were randomized in 4 groups. Each group received a different dressing with its specific wound management protocol : (1) Zetuvit® with Cosmopor E®, (2) Zetuvit® with Opsite Post-Op Visible®, (3) Aquacel Surgical® and (4) Mepilex Border®. Follow-up evaluations were performed on the fifth postoperative day and included assessment of the wound, status of the wound dressing and the patient's own judgment. Cumulative costs were calculated.

Results : Clinically Mepilex Border®, a silicone dressing, scored the best. No wound complications were seen in this group. The mean number of dressing renewals was 1.9 for the standard dressing which was significantly higher ($p < .0001$) compared to the other dressings. Opsite Post-op Visible® was the cheapest dressing. Mepilex Border® had the best scores for pain, freedom of movement and general comfort.

Conclusions : Mepilex Border® is the most skin-friendly dressing. The number of dressing renewals is a defining factor to calculate the costs. Mepilex Border® appeared to be the best dressing to use after a total knee arthroplasty.

Keywords:

INTRODUCTION

The primary aim of postoperative wound care is optimal wound healing and prevention of wound complications. After a total knee arthroplasty

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– Zetuvit® (Paul Hartmann AG, Heidenheim, Germany).

– Cosmopor E® (Paul Hartmann AG, Heidenheim, Germany).

– Opsite Post-op Visible® (Smith&Nephew Advanced Wound Management, Hull, UK).

– Aquacel Surgical® (ConvaTec Inc., Princeton, USA).

– Mepilex Border® (Mölnlycke Health care, Gothenburg, Sweden).

(TKA), wound exudate leaks from the surgical wound. The ideal wound dressing ought to protect the wound area and allow for sufficient fluid absorption. Wound complications, particularly surgical site infections, lead to prolonged hospital stay and higher costs (3). Several studies have demonstrated that the healing process may be optimized with occlusive wound dressings, which create a moist environment and act as a barrier against microorganisms (4,7,10). Innovative wound dressings (IWDs) were developed combining characteristics of moist wound healing, sufficient absorbing capacity and prevention of surgical site infections.

Several studies already confirmed the advantages of IWDs in comparison to standard wound dressing (4,7,10). In contrast, studies that compare different IWDs with each other are scarce. This study is unique in its comparison of three IWDs, not only with each other but also with a standard wound procedure.

Besides optimal wound care, cost is of major importance. As the IWDs are much more expensive than a standard wound dressing, cost-effectiveness needs to be evaluated. From an economic point of view, following aspects are determinants of cost-effectiveness: price of the dressing, number of dressings needed for one patient, occurrence and cost of wound complications and nursing time needed for wound care. Excellent fluid absorption and retention are important properties of the IWDs, resulting in a decreased number of dressing renewals. Less dressing renewals lead to lower costs, less work for the nurses and a reduced risk of infection.

The purpose of our study was to compare the safety, efficacy and cost of four different wound dressings (three IWDs and one standard). Therefore, the following research questions were evaluated: (1) which dressing has least wound complications, (2) the use of which dressing is the cheapest, and (3) which dressing is perceived as most comfortable by the patient?

MATERIALS AND METHODS

We conducted a consecutive clinical trial comparing three IWDs to the standard wound procedure used at the department of Orthopaedics and Traumatology of Ghent

University Hospital. Sometimes unpleasant wound complications were found with the standard wound procedure. As wound management after surgery is important in preventing wound complications, this trial can teach us whether the choice of wound dressing influences the outcome of TKA. The standard wound procedure consists of Zetuvit® (Paul Hartmann AG, Heidenheim, Germany), an absorbent dressing pad, followed on the first postoperative day by Cosmopor E® (Paul Hartmann AG, Heidenheim, Germany), an absorbent adhesive dressing. The IWDs used in this study were Opsite Post-op Visible® (Smith&Nephew Advanced Wound Management, Hull, UK), a see-through foam dressing with a polyurethane film, Aquacel Surgical® (ConvaTec Inc., Princeton, USA), a hydrofiber dressing with hydrocolloid adhesive layer and Mepilex Border® (Mölnlycke Health care, Gothenburg, Sweden), a foam dressing with an adhesive silicone layer. Of the three IWDs, only Opsite Post-op Visible® was combined with Zetuvit® (Table I).

153 patients undergoing a primary TKA at Ghent University Hospital, were recruited. All patients signed an informed consent and the study design was approved by the Ethics committee of Ghent University in January 2012. The final study population consisted of 111 participants, 70 women and 41 men. The mean age was 63.4 years (range, 23-88 years). Forty-two patients were excluded postoperatively for the following reasons: In four cases a language barrier made communication impossible. Five patients wished to withdraw from the study for personal reasons. In 14 cases the wrong dressing was used or the dressing was applied at the wrong moment. Follow-up assessment was missed in 13 cases because of early hospital discharge (before day 5). Six patients were wrongly recruited as they underwent a revision TKA instead of a primary TKA. Minimum sample size for a statistically significant difference in complication rate was calculated based on the study of Abuzakuk *et al* (2) and found to be at least 13 in each group (alpha 0.05; power 0.95) (Nquery Advisor version 6.01, Statistical Solutions Ltd, Cork, Ireland); In order to account for learning curve and dropouts, it was decided to include at least 25 patients in each group.

For the sake of logistic organisation, the study population was randomized into 4 consecutively operated groups. Because each wound dressing requires a different wound management protocol (Table I), classic randomisation was not feasible. The recommendations for the specific dressing were followed accurately. Each dressing was used consecutively over a period of time until 25 patients were treated. The next week the subsequent wound dressing was introduced. If more patients

Table I. — Wound management protocol and sample size per group

| | Wound care immediately after TKA | Wound care first postoperative day* | Follow-up | Sample size |
|---------|---|-------------------------------------|-----------|-------------|
| Group 1 | Zetuvit [®] , absorbent dressing pad | Cosmopor E [®] | Day 5 | n = 31 |
| Group 2 | Zetuvit [®] , absorbent dressing pad | Opsite Post-op Visible [®] | Day 5 | n = 25 |
| Group 3 | Aquacel Surgical [®] | / | Day 5 | n = 29 |
| Group 4 | Mepilex Border [®] | / | Day 5 | n = 26 |

* In all four groups the compression bandage (Velpeau's bandage) was removed on day 1.

were planned for TKA during the week the twenty-fifth patient was reached, these patients were included in the previous group for logistical reasons. The recruitment of patients started in March 2012 and was finalised on January 2013. The surgical technique was a standard internationally accepted surgical technique including anterior longitudinal mid-line or medial incision, use of tourniquet and wound suture in flexion.

The nursing staff recorded the number of dressing changes before day 5 as well as the reason for dressing renewal. Recording the number of dressing changes was important to gain an objective insight into the dressings' fluid handling capacity. On the fifth postoperative day the wound was assessed and the dressing was evaluated using an evaluation form including following items :

Wound complications

Five wound complications were checked : (1) Blistering, (2) Stripping, (3) Maceration, (4) Sensitivity reaction and irritation and (5) Infection. The four dressings were compared with regard to occurrence and frequency of wound complications and mean number of dressing changes. Pictures of the wounds were taken in case of doubt.

Costs

To calculate the costs of the dressing material the retail price of each specific dressing (10 × 25 cm or 9 × 25 cm) in Belgium in March 2013 was multiplied by the mean number of used dressings. In the first two groups (Cosmopor E[®] and Opsite Post-op Visible[®]) the dressing was not applied immediately after surgery but on the first day after surgery. In those two groups, the extra costs of the Zetuvit[®] pad, which was used to cover the wound immediately after surgery, was added.

The total cost of postoperative wound management is defined by the sum of the cost of the dressing material and the cost of the dressing renewals (total cost wound

management = cost dressing material + cost dressing renewal). To determine the cost of a dressing renewal, it's important to take into account the cost of extra material used for wound cleansing as well as the cost of extra nursing time needed for the renewal. Because it is difficult to determine the exact cost of a dressing renewal, especially the extra nursing time, a graph (Fig. 2) was designed.

Assessment by the patient

Since patient reported outcomes are now considered the most valuable outcome measures, patients were asked to score their observations regarding : (1) pain perceived while removing the dressing on a scale from 0, meaning no pain, to 10, meaning worst pain imaginable, by means of a Visual Analogue Scale (VAS). (2) Overall comfort of the dressing, (3) freedom of movement and (4) disagreeable sensation (itchiness, discomfort, irritation) of the dressing on a VAS scale from 1, worst score, to 5, best score.

Statistical analysis

To determine differences between the 4 groups, chi-square tests were used for categorical variables and Kruskal-Wallis tests for continuous variables. All statistical analyses were performed using SPSS Version 20.0 (SPSS Inc, Chicago, IL, USA). Statistical significance was established as $p > 0.05$.

RESULTS

Wound complications (Table II)

No wound complications were found in the Mepilex Border[®] group (Table II). Blisters were found in the Aquacel Surgical[®] group (6.9%) and in the Opsite Post-op Visible (4%) group. Infection

Table II. — Listing and comparison of wound complications in the different groups

| | Cosmopor E® | Opsite Post-op Visible® | Aquacel Surgical® | Mepilex Border® | Chi-Square |
|-----------------------------------|-------------|-------------------------|-------------------|-----------------|------------|
| Blistering (%) | – | 4% | 6.9% | – | p = 0.738 |
| Maceration (%) | – | – | 3.4% | – | P = 0.626 |
| Infection (%) | – | – | – | – | – |
| Irritation/Redness (%) | 12.9% | 4% | – | – | P = 0.012 |
| Stripping (%) | – | – | – | – | – |
| Number of dressing changes (Mean) | 1.9 | 0.28 | 0.66 | 0.27 | p < 0.0001 |

and stripping were not seen. The incidence of irritation and redness was highest (12.9%) in the Cosmopor E® group (p = 0.012).

Cosmopor E® was renewed most often during the first 5 days after surgery with a mean number of dressing changes of 1.9. The IWDs were changed significantly less frequently (p < .0001) with a mean of 0.27 for Mepilex Border®, 0.28 for Opsite Post-op Visible® and 0.66 for Aquacel Surgical®.

Mepilex Border® caused least (0%) wound complications.

Costs (Table III)

The material of the control group, Cosmopor E®, was the cheapest (5.00 euro). The price of Opsite Post-op Visible® (5.71 euro) was comparable to Cosmopor E® and was the cheapest of the IWDs. The cost of the dressing material approximately doubled for the Mepilex Border® group (10.49 euro) and was 6 times higher for the Aquacel Surgical® group (29.85 euro).

Total cost was defined as the sum of the cost of the used material (table III), and the cost of a dressing renewal, as determined by the nursing time and the extra cleansing material. The total cost, in function of the cost of a dressing renewal, is illustrated in figure 1. This graph shows that a decrease in dressing renewals has a greater effect on the total cost, when the cost of a dressing renewal (nursing time, sterile material,...) is taken into account. The Opsite Post-op Visible® thus appears to be the cheapest, followed by Mepilex Border®. The value on the x-axis of the crossing point of the Cosmopor

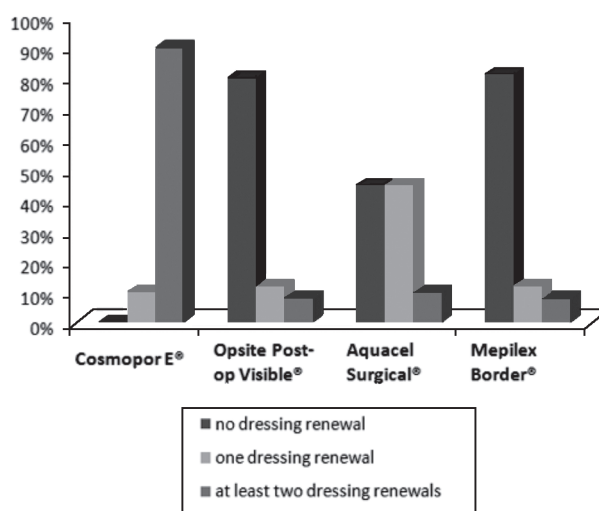


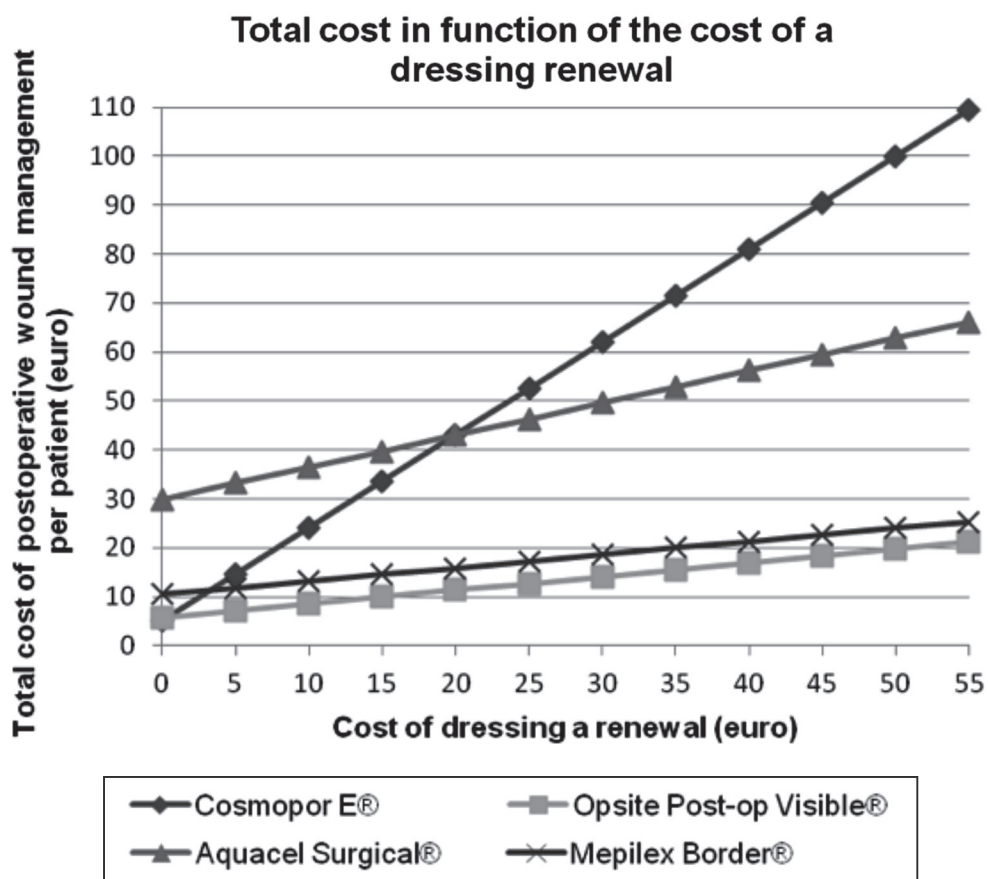
Fig. 1. — The distribution of the number of dressing renewals per wound dressing.

E® line and the Opsite Post-op Visible® line is 0.70. This means that as soon as the cost of a dressing renewal (x-axis) including sterile material and nursing time reaches 0.70 euro, the use of Opsite Post-op Visible® is cheaper than the use of Cosmopor E®. The use of Mepilex Border® is cheaper than Cosmopor E® when the cost of a dressing renewal (x-axis) is more than 4 euro. For Aquacel Surgical® the cost of the nursing time and extra cleansing material should be more than 18 euro to become cheaper than the standard wound care protocol with Cosmopor E®.

Overall Opsite Post-op Visible® was the cheapest dressing.

Table III. — Cost of the dressing materials, based on Belgian retail prices in 2013

| | Retail price in Belgium March 2013 | Mean number of used wound dressings | Cost of absorbing pad (Zetuvit®) | Total |
|-------------------------|---------------------------------------|--|-------------------------------------|--------|
| Cosmopor E® | €0.99 | 2.9 | €2.12 | €5.00 |
| Opsite Post-op Visible® | €2.81 | 1.28 | €2.12 | €5.71 |
| Mepilex Border® | €8.26 | 1.27 | / | €10.49 |
| Aquacel Surgical® | €17.98 | 1.66 | / | €29.85 |



The x-axis : representing the cost of a dressing renewal as a continuous variable. The y-axis represents the total cost .of a dressing including the price of the dressing material, the number of dressing renewals, and the cost of a dressing renewal. The latter is hard to determine and is therefore represented as a variable x on the horizontal axis

Fig. 2. — Total cost of postoperative wound management per patient, in function of the cost of a dressing renewal.

Table IV. — Comparison of patients' assessment of pain, irritation , freedom of movement and comfort

| | Cosmopor E® | Opsite Post-op Visible® | Aquacel Surgical® | Mepilex Border® | Kruskal-Wallis test |
|---|-------------|-------------------------|-------------------|-----------------|---------------------|
| Pain (VAS : 0-10) (mean) | 1.87 | 0.80 | 0.62 | 0.35 | p = 0.015 |
| Disagreeable sensation : itchiness, irritation, discomfort (1-5) (mean) | 4.42 | 4.20 | 4.52 | 4.73 | p = 0.575 |
| Freedom of movement (1-5) (mean) | 4.00 | 4.64 | 4.38 | 4.85 | p < 0.0001 |
| General comfort (1-5) (mean) | 4.29 | 4.56 | 4.21 | 4.85 | p = 0.002 |

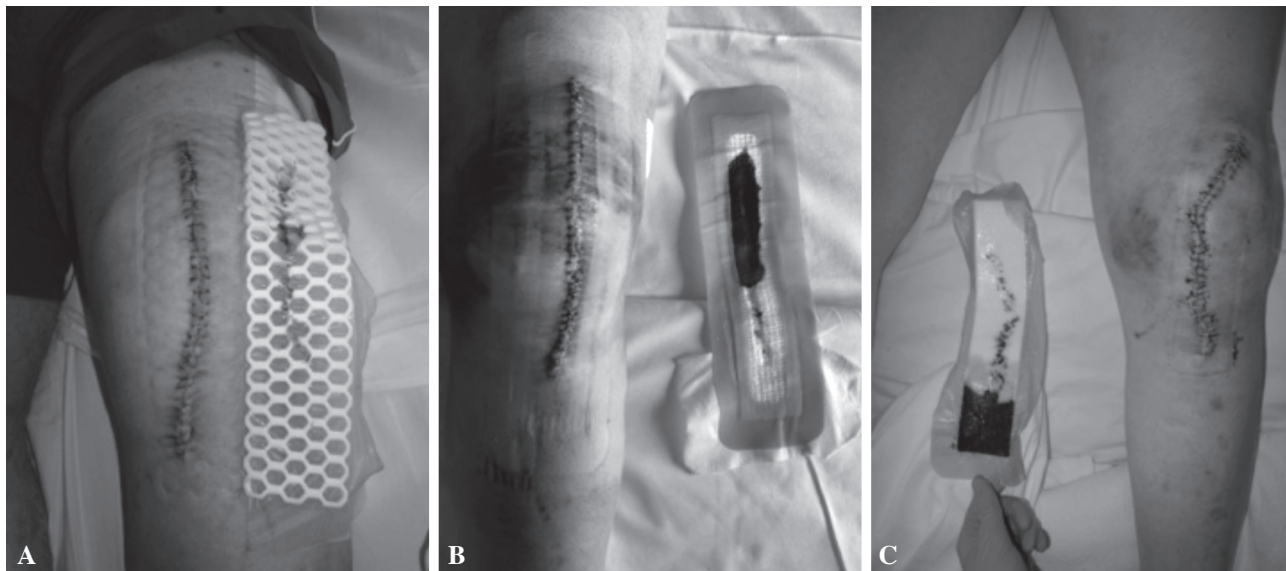


Fig. 3. — Wound at postoperative day 5. (A) Opsite Post-op Visible®, (B) Aquacel Surgical®, (C) Mepilex Border®

Assessment by the patient (Table IV)

The pain perceived while removing the Mepilex Border® dressing is negligible (mean VAS of 0.35). Cosmopor E® renewal gives most pain but still only a mild pain sensation (mean VAS 1.87) (p = 0.015). Mepilex Border® scores best with regard to freedom of movement (p < 0.0001) and general comfort (p = 0.002), followed by Opsite Post-op Visible®. Disagreeable sensation of the dressing in terms of itchiness, irritation and discomfort was very mild in all four groups.

Overall Mepilex Border® received the best subjective score from the patients

DISCUSSION

Postoperative wound care is an important element in the outcome of lower limb orthopaedic surgery. Complications such as surgical site infections lead to increased morbidity and costs. The introduction of IWDs may contribute to a lower complication rate in postoperative wound care. Clinical research comparing IWDs is scarce. This is the first consecutively study comparing 3 IWDs (Opsite Post-Op Visible®, Aquacel Surgical® and Mepilex Border®) to each other and to a conventional dressing (Zetuvit® and Cosmopor E®). The aims of the study were to establish which dressing led to least wound

complications, which dressing was the cheapest and which dressing was perceived as most comfortable by the patient.

This study has several limitations. Firstly, the observation of the wound was done by three different examiners. In the beginning of the study, the three examiners did some evaluations together in order to equalize their observation. A photo was taken when an examiner was in doubt about his evaluation. Despite these measures, an inter-observer variability cannot be excluded since a formal study in this regard was not conducted. Secondly, classic randomization was not feasible. The four study dressings were tested consecutively over a period of time until the amount of 25 patients was reached. This alternative way of randomization embodies a major weakness of the study design. Thirdly, to calculate the costs of the material we used the retail price in Belgium. These prices can vary considerably, depending on the area and the time.

(1) In the study group treated with Mepilex Border® least wound complications were observed. In all other study groups complications such as blistering, maceration or erythema occurred. Mepilex Border® required fewest dressing renewals which has important advantages: lower chance of bacterial invasion, lower workload for nursing staff and less discomfort for the patient. Several studies confirm the skin-friendliness of the Safetac soft silicone adhesive technology used in Mepilex Border® dressings, ensuring atraumatic removal (8,12,13,14). Overall, Mepilex Border® performs best in terms of skin protection leading to less pain at the time of dressing removal (8,13). Two studies compared Mepilex Border® to Allevyn Adhesive used in Opsite Post-Op Visible® (12,14). As in our study, adhesive foam dressings were associated with a significantly higher incidence of wound complications at follow-up visits compared with silicone foam. In another study, the use of Opsite Post-Op Visible® resulted in a significant reduction in superficial surgical site infections and other wound complications compared to traditional gauze dressings (1). According to Cai *et al* (5) the use of Aquacel Surgical® significantly reduces the incidence of periprosthetic joint infection compared to conventional wound pad dressings (2,6). Overall, prevention of infectious

complications is considered as the main advantage of these new types of dressings (1,2,5,6). In our study no infectious complications were noted.

(2) Taking into account the additional costs for the nursing time, Opsite Post-Op Visible® was the cheapest dressing. The dressing material of this foam IWD is slightly more expensive than the standard dressing. However, the additional cost is compensated by the cost reduction associated with nursing time for dressing renewal and treatment of wound complications. These findings are consistent with the literature (1). Opsite Post-Op Visible® is associated with a decreased incidence of superficial surgical site infections and other complications compared to a standard gauze dressing. The decreased need for treatment of postoperative complications results in a significant cost reduction (1). The cost of Mepilex Border® has not been studied before. In our study, Aquacel Surgical® appeared to be the most expensive surgical dressing. The reduced number of dressing renewals compared to the standard dressing could not compensate for the high material cost. Literature concerning the economic consequences of the use of Aquacel Surgical® is not straightforward. One trial comparing Aquacel Surgical® to a conventional wound pad dressing, calculated average costs of respectively 14.70 euro and 8.70 euro per patient by the third postoperative day. Other researchers predicted an annual cost reduction of 140000 euro for a hospital because of earlier discharge and reduced nursing staff (11).

(3) Regarding the assessment of the dressings by the patients, pain perception was lowest in the Mepilex Border® group. This is consistent with the literature (8,12,14). Additionally, Mepilex Border® dressings scored best regarding freedom of movement and comfort. Woo investigated patient satisfaction for Mepilex Border® and Opsite Post-Op Visible® (14). Patients' evaluations including their overall experience and dressing comfort were significantly better for the silicone dressing (14). In a study assessing the performance of Opsite Post-Op Visible®, patient comfort was better for the IWD than with a traditional dressing (9).

In conclusion, IWD performed superiorly compared to standard wound dressings. This is consistent with previous reports (1,2,5,6,8,10,12). In our

study of wound care after TKA Mepilex Border® appeared to cause least wound complications. Patients' satisfaction was highest for this silicone adhesive dressing. Overall, only one dressing, Opsite Post-Op Visible® was cheaper than Mepilex Border®, but was associated with more mild discomfort and complications.

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