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# A prospective, randomised, controlled trial comparing wound dressings used in hip and knee surgery: Aquacel and Tegaderm versus Cutiplast

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ABSTRACT

INTRODUCTION Cutiplast (absorbent perforated dressing with adhesive border; Smith & Nephew) is commonly used following orthopaedic operation, but complications of its use have been reported. A prospective, randomised, controlled study was performed to compare the efficacy of Cutiplast versus an Aquacel (hydrofibre dressing; ConvaTec) covered with Tegaderm (vapour-permeable dressing; 3M).

PATIENTS AND METHODS Two-hundred patients were randomised to receive one of the two dressings following elective and non-elective surgery of the hip and the knee. We were able to study 183 patients. The condition of the wound and any complications such as skin blistering or signs of infection was noted as was the frequency of dressing changes.

RESULTS The Aquacel and Tegaderm dressing was 5.8 times more likely to result in a wound with no complications as compared to a Cutiplast dressing (odds ratio, 5.8; 95% CI 2.8–12.5; $P < 0.00001$).

CONCLUSION Aquacel covered by Tegaderm is a superior dressing to Cutiplast following surgery to the hip and knee.

KEYWORDS

Wound dressings – Blisters – Infection – Randomised trial

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It is well accepted that wound healing is enhanced in a moist environment. Hippocrates first noticed that wounds healed better if kept moist with a poultice and covered with plenty of leaves. This principle, however, was lost through the ages. It was only with Winter's experiments on epithelialisation in pigs that the healing benefits of a moist environment were rediscovered. Winter's publication sparked an era of research that has confirmed that there is faster healing, autolytic debridement, fewer infections and less pain in moist wounds compared with dry wounds.[1,2] Reduction in pain whilst walking and during dressing changes has been attributed to the moist dressing wound interface which protects nerve endings from exposure and drying out.[3]

The main constituents of wound exudates are fluid from leaky blood vessels, secreted materials such as growth factors from surrounding cells, debris from dead cells, and extracellular matrix breakdown. Exudates also contain material derived from contaminating micro-organisms. Exudates from acute wounds are rich in growth factors which are beneficial to acute wound healing in that they promote growth and migration of fibroblasts, endothelial cells and keratinocytes.

Wound exudates, therefore, contribute to the moist healing environment. If a dressing is highly absorbent, the benefits of the moist environment and the growth factors in the exudates are lost as they are absorbed into the dressing. However, in a wound that produces high exudates coupled with a dressing that is incapable of absorbing the exudates rapidly then the surrounding skin suffers from maceration.[4] An ideal dressing would, therefore, be able to absorb excess exudate, but maintain a moist environment for wound healing.

The main problems with surgical wounds following hip and knee surgery are blistering and infection. Skin blistering occurs when the epidermis is separated from the dermis and results from continued friction on the skin. Skin blistering is common on orthopaedic wards with a reported incidence of 13–35%.[5] Dressings are applied for a long period of time,

usually over a joint, where movement causes friction between the skin and dressing causing a shear force. Several other factors may be responsible for the rate of blistering in patients undergoing joint replacement surgery. These include skin changes in older patients, soft tissue oedema following surgery, the type of dressing used and the mode of application of the dressing. Once a blister has occurred, there is a breakdown in the barrier to infection that the skin provides. Wound blistering can lead to complications from superficial infection through to prosthetic implant infection.[6,7]

The majority of wounds provide a favourable environment for microbial colonisation. Many of the micro-organisms found in wounds are potential pathogens such as *Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa* and *Bacteroides* spp. If there is leakage through the dressing with wound exudate or blood, then there is no longer a barrier to prevent microbial contamination. Davis *et al*.[15] measured contamination rates in primary joint prosthesis as high as 63% but an infection rate of only 1%. Some modern wound dressings are considered to possess infection control properties by acting as physical barriers to the dispersal of wound pathogens, and also by reducing airborne dispersal of pathogens on dressing changes. The physical properties of the dressing, such as the arrangement and density of the fibres and gelling characteristics may play a role in the entrapment of wound micro-organisms.[8]

Cutiplast is used as the dressing for orthopaedic procedures in our NHS trust. Complications such as blistering and infection have been observed with Cutiplast. We decided to undertake a prospective, randomised, controlled trial comparing Cutiplast to Aquacel covered by Tegaderm, a dressing that was being used in other surgical directorates at the trust. We were interested in the performance of the two dressings in respect to blistering, infection rates, and the number of dressing changes and hence cost-effectiveness.

The null hypothesis was that there was no difference between the two dressings under investigation.

## Patients and Methods

The study period was between February 2002 and February 2003, when patients were entered into a prospective, randomised, controlled trial. Local ethical committee approval was obtained and the patients gave informed consent for the study. Patients who were due to have a total hip or knee replacement or an operation for a fractured neck of femur (dynamic hip screw or a hip hemiarthroplasty) were randomised into one of two groups, using a random number table. One group had Cutiplast the other group had the Aquacel/Tegaderm dressing applied to their wound postoperatively in theatre. Patients were excluded from the trial if they were unable to give informed consent, had a fracture of the neck of femur that was not amenable to treatment by either a DHS or hemiarthroplasty, had a pathological fracture of the hip, or those whom refused to participate in the trial. Cutiplast was applied to the wound without tension to the skin edges. The Aquacel dressing was supplied as a ribbon 2-cm wide and 45-cm long that was folded to achieve a 4-layer deep dressing that was applied to the wound. The Aquacel was covered fully with Tegaderm to achieve a water-impermeable seal.

Wound dressings were changed by the nursing staff and replaced by the same dressing that was applied in theatre. The dressings were changed based on clinical judgement of the nursing staff. Each time a dressing was changed, the 'dressing pain score' was noted, the wound was inspected for blisters and clinical signs of infection such as erythema, high exudates and odour. Strike-through of wound exudate was allowed to happen once in any patient as some wounds had high exudate content and, therefore, exceeded the capacity of the dressing.

A dressing was deemed a failure if strike-through of wound fluids across the dressing occurred on two successive occasions, skin blisters occurred, or any signs of clinically evident infection occurred.

The primary end-point was dressing failure or a wound that no longer needed to be dressed and was free from complications.

## Results

Two-hundred consecutive patients were entered into the trial after exclusion criteria were applied. From the initial 200 randomised patients, 183 were available for study. Seventeen patients were lost in the follow-up period, or had incomplete data. Due to the nature of the dressings, blinding was impossible.

Among the 183 patients, 137 were female and 46 were male, 88 had a fractured neck of femur, 57 osteoarthritis (OA) of the knee, 36 had OA of the hip and 2 had avascular necrosis (AVN) of the hip. Patients with a neck-of-femur fracture were distributed evenly between the four American Score of Anaesthesia (ASA) grades. Elective patients undergoing total knee and hip replacements were mostly distributed in the two lower grades of the ASA score reflecting the nature of elective orthopaedic surgery.

Ninety-eight patients were randomised to Cutiplast and 85 to Aquacel/Tegaderm dressing. There is a strong relationship between the wound dressing and the outcome (Table 1). The odds ratio suggests that the Aquacel/Tegaderm dressing is 5.8 times more likely to result in a wound with no complications than Cutiplast

**Table 1 Wound dressing and outcome**

| | Cutiplast | Aquacel/Tegaderm | Totals |
|---|---|---|---|
| Dressing failed | 53 | 15 | 68 |
| Wound healed | 45 | 70 | 115 |
| Totals | 98 | 85 | 183 |

Odds ratio = 5.8 (95% CI 2.8–12.5; $P < 0.00001$). Dressing failure if strike through of wound fluids across the dressing occurred on two successive occasions, skin blisters occurred, or any signs infection.

(95% CI 2.8–12.5; $P < 0.00001$). Taking blisters alone as a complication, in the Cutiplast group 22.5% of patients had wounds with blisters compared to only 2.4% of the group dressed with Aquacel/Tegaderm.

We found no statistical relationship between a patient's age and the probability of a dressing failure. There was no statistical relationship between ASA score and the failure of the dressing either.

The average number of dressing changes for each of the procedures is shown in Table 2. Mann-Whitney rank sum values show that taken individually, none of the operations performed differed statistically in respect to the number of dressing changes. Although taken the group as a whole, the patients receiving Aquacel covered by Tegaderm had statistically less wound dressing changes. Table 3 shows the average dressing pain scores at the time of the dressing change. Taking the group as a whole, the dressing pain score is statistically lower for the patients receiving the Aquacel/Tegaderm dressing ($P < 0.001$).

Factors with a possible effect on the wound outcome were analysed using a logistic regression analysis using Stata (v. 8. STATA Corp., TX, USA).

## Discussion

One of the main short-comings of this study is that the decision to change a wound dressing was based on the clinical judgement of the nursing staff on the orthopaedic

**Table 2 Number of wound dressing changes**

| | Cutiplast | | | Aquacel/Tegaderm | | | |
|---|---|---|---|---|---|---|---|
| | Number of patients | Mean | SD | Number of patients | Mean | SD | *P*-value |
| DHS | 26 | 5 | 2.0 | 20 | 4.1 | 2.1 | 0.07 |
| Hemi | 22 | 4.2 | 1.6 | 16 | 3.9 | 1.5 | 0.51 |
| THR | 20 | 3.3 | 1.2 | 17 | 3.8 | 1.4 | 0.34 |
| TKR | 27 | 3.7 | 1.7 | 31 | 2.9 | 1.2 | 0.05 |
| Total | 95 | 4.1 | 1.8 | 84 | 3.6 | 1.6 | 0.03 |

*P*-values determined by the Mann-Whitney rank sum test.

**Table 3 Wound dressing pain scores**

| | Cutiplast | | | Aquacel/Tegaderm | | | |
|---|---|---|---|---|---|---|---|
| | Number of patients | Mean | SD | Number of patients | Mean | SD | *P*-value |
| DHS | 26 | 1.3 | 1.1 | 19 | 1.0 | 0.8 | 0.39 |
| Hemi | 21 | 1.7 | 1.2 | 16 | 0.8 | 0.8 | 0.02 |
| THR | 19 | 2.5 | 1.6 | 17 | 1.2 | 1.3 | 0.01 |
| TKR | 27 | 2.2 | 2.0 | 31 | 1.6 | 2.0 | 0.23 |
| Total | 93 | 1.9 | 1.6 | 83 | 1.2 | 1.5 | 0.001 |

*P*-values determined by the Mann-Whitney rank sum test.

wards, and so some dressings may have been changes prematurely or left too long. It was felt that there was no way of overcoming this problem; it would have been impossible for one nurse to have changed every dressing of the 183 patients. The study was not blinded to the nurses as the dressings used look very different. It was felt that knowledge of the current dressing type used would be unlikely to change the outcome of wound healing or wound complications.

Dressings currently used in orthopaedic practice include adhesive, occlusive or vapour permeable, gauze and tape, and hydrofibre.

### Adhesive dressings

Adhesive dressings have a high incidence of skin blistering. It is thought that the way the dressing is applied may affect the incidence of blistering; companies manufacturing the dressings advise a tension-free application. Gupta *et al.*[6] investigated this effect with a two-phase trial: the first phase involved pre-stretching the dressing and the second phase used the dressing without pre-stretching. Their findings suggest there is no difference in the rate of skin blistering whether the dressing is pre-stretched or not. Koval *et al.*[9] recently published a prospective, randomised trial of dressings held with either a non-stretchable silk tape or a perforated cloth tape. In their study, the dressing tapes were applied avoiding skin tension. They found that the risk of developing a skin blister was 41% with the non-stretchable silk tape and 10% with the perforated cloth tape, suggesting that the dressing material is an important factor in the production of skin blisters

### Occlusive dressings

Occlusive dressings, such as Tegaderm, produce a moist and relatively hypoxic environment under the dressing. The hypoxia accelerates angiogenesis and promotes the wound repair process.[5] Occlusive dressings can contain small amounts of exudate without leaking from the sides of the dressing. Several studies[5,11] have shown that despite there being no material to absorb the exudates, no problems were found with skin maceration. In fact, less wound inflammation occurred with no increase in infection rates. Patients also reported less pain following dressing changes, the dressings were more comfortable to wear, and, as they are water-impermeable, they allowed the patient to shower.

### Hydrofibre dressings

Hydrofibre dressings absorb fluid directly into the body of the dressing, significantly increasing the volume of fluid that can be absorbed – a process called vertical wicking. This process removes excess exudate from the wound, prevents lateral wicking that can cause maceration of the wound edges, but still maintains a moist environment for wound healing.[10] Most neutrophilic granulocytes migrate with the flow of wound fluid and are absorbed by the dressing. They seem to concentrate around the fibres in a similar way to those in the normal tissue matrix. Fibronectin plays a key role in binding cells to the wound tissue matrix and acts as a chemo-attractant for granulocytes. Biopsies have shown a large amount of fibronectin and active granulocytes around Aquacel fibres.[12] The Aquacel dressing allows adherence of the dressing to the wound by a build up of a fibrin layer, unlike other dressings where the tissues adhere by in-growth into the dressing and thus removal of such dressings causes damage to the wound bed. The fibrin layer that separates the wound and dressing appears to act as a physical barrier between activated granulocytes in the dressing which have antimicrobial action, and macrophages in the wound bed. The fibrin barrier means that the macrophages receive little stimulation from the granulocytes and, therefore, concentrate primarily on wound healing activities, and also prevents hydrolytic enzymes produced by the granulocytes causing damage to the wound bed.[12]

Other factors need to borne in mind when deciding on the ideal wound dressing for surgical wounds following orthopaedic surgery. Wear time of dressings, and hence cost-effectiveness must come into the equation. Hermans and Skillman[13] and Moore and Foster[14] looked at wear times and cost-effectiveness of hydrofibre dressings. They concluded that wear time was better for hydrofibre dressings, so the number of wound dressing changes was reduced. The hydrofibre dressings are more expensive than traditional adhesive dressings but this is counterbalanced by the frequency of dressing changes. In our study, the total number of wound dressing changes was statistically less for Aquacel/Tegaderm than for Cutiplast, although for each individual operation there was no difference. A larger sample size would be needed to show a true difference.

## Conclusions

Our null hypothesis that there was no difference between the two dressings under test has been disproved. An elective operation is predictive of a healed wound but this effect is modified when other factors are added to the equation. The wound dressing remains the single best indicator of a healed wound. Age, sex and ASA score show no statistical relationship to outcome.

Aquacel covered by Tegaderm is a more expensive dressing than Cutiplast. However, Aquacel/Tegaderm results in less wound complications, is changed less, and is less painful to change than Cutiplast. Aquacel covered by Tegaderm is a superior dressing to Cutiplast following elective and non-elective orthopaedic operations on the hip and knee.

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