Original Research: The use of Acticoat® and Pin Sealer® to reduce the rate of pin-site sepsis

Introduction

Pin tract infection is a common problem associated with the use of external fixators. Numerous factors may affect the development of pin tract sepsis. One of these is the dressing used at the pin skin interface. A recent systematic review of the literature concluded that there was insufficient evidence to support one particular pin care regimen over another.1

Traditionally, dressings of plain gauze soaked in a glycerol and ichthammol solution or a Betadine® ointment were used, depending on availability. Previously, this was placed at the base of the pins at the time of the surgery, and then changed at random times during the course of the patient’s treatment.

Recently, silver dressings have become available for use on wounds to prevent infection.2 The primary aim of this prospective randomised trial was to establish if the use of a silver dressing at the pin skin interface would decrease pin tract infection, when compared with a traditional dressing.

Skin and tissue movement at the base of the pins is another factor that may influence the rate of pin site sepsis as movement tends to make the wound larger and encourages exudates.3 It has been hypothesised that decreased skin movement around the base of external fixator pins may prevent infection by improving the skin seal around the base of the pins.4 A patented design, Pin Sealer™ (Figure 1), which is made of silicon, was pushed down around the base of the pins to provide pressure on the dressings, in an attempt to prevent skin movement at the pin skin interface. These were prospectively randomised to half of the pins to assess their effect. Therefore, a secondary aim of the study was to assess the efficacy of the Pin Sealer™.

One of the common external fixators used for open, middle-third tibial fractures at our institution is the Hoffmann® fixator. This is applied in a biplane configuration with four pins proximal to the fracture site and four pins distal to the fracture site, as per the model in Figure 2.

Method

Patients presenting at our institution with open middle-third tibial fractures, who were amenable to a Hoffmann® external fixator with the above configuration, were recruited to the study. Therefore, each patient receiving this configuration of the external fixator would have eight pins inserted that could be randomised to receive different types of dressings.

Abstract

A prospective randomised trial was performed to compare Acticoat® dressings with or without Pin Sealer™, to plain gauze soaked with Betadine® ointment with or without Pin Sealer™, as a dressing for the pin sites of external fixators. Twenty-five patients with 224 pin sites on open tibial fractures were followed-up for weekly observation for six weeks. The pin sites were graded from 1-6 in increasing order of severity and the dressings changed weekly. The average pin site grading of Acticoat® with Pin Sealer™ was 1.399, Acticoat® without Pin Sealer™ 1.452, Betadine® without Pin Sealer™ 1.646 and Betadine® with Pin Sealer™ 1.805. Statistical analysis showed that Acticoat® with Pin Sealer™ had a lower pin site grading than Betadine® with Pin Sealer™.

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Figure 1: A patented design, Pin Sealer™
The pins were numbered from 1 to 8, starting with the most proximal medial pin proceeding distally, and then crossing over to the lateral pins, so that the most lateral distal pin would be numbered “5” and then progressing proximally the last pin numbered “8” would be the most proximal lateral pin. Obviously, this would occur in an anticlockwise direction when looking at a left leg, and a clockwise direction when looking at a right one. This ensured that all pins marked 1-4 would be placed in the anteromedial tibial border through relatively thinner tissue.

For the purposes of the study, two different types of dressing were applied to the pins, namely plain gauze with Betadine® and an Acticoat® disc.

The Acticoat® disc (Smith and Nephew) consisted of a 2 mm-thick foam disc 23 mm in diameter, coated with silver on one side, with a single radial cut allowing it to be passed around a pin (Figure 3). These two dressings were then applied to the base of the pins either with or without the addition of Pin Sealer™ (Figure 4).

The Pin Sealer™ is a silicon rubber disc that fits over the pin and can be pushed down onto either dressing, providing a uniform force on the underlying dressing. The skirt of the sealer then covers the dressing. This allows easy application of an Opsite™ (Smith and Nephew) dressing and a good seal if used with negative pressure wound therapy.

Therefore, the purpose of the Pin Sealer™ was twofold:

- To provide a standard downward force on the underlying dressing, thus preventing mobility of the skin at the base of the pin.
- To provide a convenient area for adherence of the dressing material covering any vacuum-assisted wound closure or so-called negative pressure wound therapy dressing that might be applied to open wounds commonly found in tibia fractures requiring external fixation.

Four different configuration patterns of dressing could occur on each pin. These were:

- Acticoat® with a pin sealer.
- Acticoat® alone.
- Betadine® gauze with a pin sealer.
- Betadine® gauze alone.

These four different dressings were randomly assigned to different pin numbers by a computer randomisation process and then placed in an envelope which was opened in theatre when the patient presented for surgery. As each patient in the study had eight pins, two pins had identical dressings.

The dressings were applied in theatre and then changed weekly for six weeks. The pin site status was recorded at each dressing change by the same dressing nurse. Since there were eight pins per patient, and each pin was observed each week for six weeks, there were a total of 48 observations per patient over the study period.

Pin site infection was graded from 1-6. This is a modification of a grading system ascribed to Moore and Dahl, as published by Schoenecker et al.6

Four of these pins were on the medial side of the leg in the relatively thin subcutaneous tissue on the anteromedial aspect of the tibia, with the other four pins approximately 90 degrees to the anteromedial pins penetrating the thicker tissue on the lateral aspect of the tibia. Therefore, the different skin thicknesses on the different sides of the leg would confer different properties, especially those relating to movement of tissue around the base of the pins, depending on the site of the pin.
Grade 1: Dry, clean, skin well applied to the pin.
Grade 2: No inflammation and dry crusted exudate around the pin.
Grade 3: Inflammation with some exudate.
Grade 4: Inflammation with some skin retraction.
Grade 5: Inflammation with pus.
Grade 6: A loose pin.

Six different surgeons were responsible for the application of external fixators in this study. All of the surgeons were trainees in a single institution where they were taught to make a small skin incision blunt dissect down to bone, to drill the bone, and then insert the pin to try and cause as little thermal necrosis to the bone and skin as possible.

Twenty-eight patients were recruited. There were 24 males and four females. The average age was 32 years (16-60 years). There were 12 left legs and 16 right legs each with an eight-pin biplane Hoffmanns® external fixator, giving a total of 224 pins.

If all 224 pins were observed every week for six weeks, there would have been a total of 1 344 pin observations. However, three patients did not attend the six weeks of follow-up (patient 12 did not attend weeks 2-6, patient 21 did not attend weeks 5 and 6, and patient 27 did not attend weeks 3-6). This left a total of 1 239 pin observations.

The Gustilo and Anderson classification was used to grade the open fracture. This was recorded to see if there was any correlation between increased grade of the open wound and overall pin site sepsis.

The time from admission to theatre was recorded to assess whether or not this influenced rates of pin tract infection. Because of the nature of the trauma, it was very difficult to accurately determine the time of the incident.

Results

Of the 1 239 pin observations, 831 were grade 1 (67%), 334 grade 2 (27%), 52 grade 3 (4%), 14 grade 4 (1.1%), and eight grade 5 (0.6%).

The mean grade of each pin dressing was recorded over the six-week period and is shown in Table I.

The Acticoat® dressing with Pin Sealer® had the lowest pin tract grading, but only reached statistical significance when compared to the Betadine® dressing with or without Pin Sealer® as shown in Table II.

The average pin site grading of all pins numbered 1-4 (these are the ones placed on the anteromedial aspect of the tibia where the subcutaneous tissue is thin) was 1.34. The average pin site grading of all pins numbered five to eight (these are the pins on the lateral aspect of the tibia through the thick muscular tissue) was 1.42.

The average grade of all pins with Pin Sealer™ was 1.602, and those without Pin Sealer™ had an average grade of 1.549.

According to the Gustilo and Anderson classification of open fractures, there was one grade 0, 15 grade 2, nine grade 3a and three grade 3b open tibia fractures.

The average time to theatre was 10 hours from time of admission in the trauma unit. Fourteen patients went to theatre in under six hours, 11 patients between 6 and 12 hours and three patients after 12 hours.

### Table I: The mean grade of each dressing recorded over the six-week period

<table>
<thead>
<tr>
<th>Dressings</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>SE</th>
<th>95% CI for mean</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>P Act</td>
<td>55</td>
<td>1.399</td>
<td>0.514</td>
<td>0.069</td>
<td>1.260-1.538</td>
<td>1.000</td>
<td>2.857</td>
</tr>
<tr>
<td>Act</td>
<td>56</td>
<td>1.452</td>
<td>0.328</td>
<td>0.044</td>
<td>1.364-1.539</td>
<td>1.143</td>
<td>2.571</td>
</tr>
<tr>
<td>Bet</td>
<td>57</td>
<td>1.646</td>
<td>0.483</td>
<td>0.064</td>
<td>1.518-1.774</td>
<td>1.286</td>
<td>3.143</td>
</tr>
<tr>
<td>P Bet</td>
<td>56</td>
<td>1.805</td>
<td>0.390</td>
<td>0.052</td>
<td>1.701-1.910</td>
<td>1.429</td>
<td>3.000</td>
</tr>
<tr>
<td>Total</td>
<td>224</td>
<td>1.576</td>
<td>0.461</td>
<td>0.031</td>
<td>1.516-1.637</td>
<td>1.000</td>
<td>3.143</td>
</tr>
</tbody>
</table>

Act: Acticoat® alone, Bet: Betadine® gauze alone, P Act: Acticoat® with a pin sealer, P Bet: Betadine® gauze with a pin sealer
CI: confidence interval, Max: Maximum, Min: Minimum, SD: standard deviation, SE: standard error

### Table II: Coverage (I) vs. Coverage (J) mean difference (I-J)

<table>
<thead>
<tr>
<th>Cover (I)</th>
<th>Cover (J)</th>
<th>Mean difference (I-J)</th>
<th>SE</th>
<th>Significance</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>P Act</td>
<td>Act</td>
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<td>0.0826</td>
<td>0.5230</td>
<td>-0.2156</td>
</tr>
<tr>
<td>P Act</td>
<td>Bet</td>
<td>-0.2471</td>
<td>0.0822</td>
<td>0.0030</td>
<td>-0.4091</td>
</tr>
<tr>
<td>P Act</td>
<td>P Bet</td>
<td>-0.4066</td>
<td>0.0826</td>
<td>0.0000</td>
<td>-0.5693</td>
</tr>
</tbody>
</table>

Act: Acticoat® alone, Bet: Betadine® gauze alone, P Act: Acticoat® with a pin sealer, P Bet: Betadine® gauze with a pin sealer
CI: confidence interval, Lower-bound: Lower-bound, Upper-bound: Upper-bound, SE: standard error
Discussion

It is difficult to control for associated variables with pin tract sepsis. Randomising the dressings on each host meant that host factors that influenced infection, such as immunity and systemic antibiotic administration, would affect all pins on an individual equally and did not have to be recorded.

Most pins achieved the highest grading between weeks 3 and 5, and then improved towards week six. This suggests that this was a problem period, and perhaps it was not necessary to monitor the pins for six weeks. Six weeks was chosen for convenience and to obtain enough observations for statistical purposes. Some authors have protocols that are up to 15 days post-operation.8 We did not record when antibiotics were given. Perhaps the patients received antibiotics at three weeks when the pins started to look infected, and then they improved. Because of these variables, we were unable to make recommendations as to the necessary length of time to continue with pin site care or dressing changes.

Unfortunately, we did not obtain the number of required observations for powerful statistical significance.

The grading of pin sites and whether or not they cause infection is controversial.3-6,8 Over 90% of the pin site observations in this study were grade one or two, objectively benign. This suggests that the problems associated with external fixator pins may not be so advanced after all. No pins in this study were judged to be loose (grade 6) or returned to theatre for debridement or removal.

Table I shows the pin site grade increasing down the list. Acticoat® and a Pin Sealer™ had the lowest average pin site grade. This is perhaps what would be expected. However, Betadine® without Pin Sealer™ had a lower average grade than that of Betadine® with Pin Sealer™. These were then tested for significance. Only the Acticoat® and Pin Sealer™ had a statistically significantly lower average grade than both Betadine® dressings.

Although not statistically significant, the pins on the anteromedial aspect of the tibia had lower pin site grades than those of the pins on the anterolateral aspect (1.34 vs. 1.42). Perhaps, it would have been proven with larger numbers that pins passing through thinner skin and subcutaneous tissue develop fewer infections than those penetrating thicker tissue.

Overall, the use of the Pin Sealer™ did not seem to make a difference. The pin site grade was higher with pins that had Pin Sealer™, compared to that of pins without it (1.602 vs. 1.549).

This study highlights the need for rigorous methodology when analysing a multifactorial issue, such as external fixator pin site sepsis. It can be concluded that Acticoat® discs that were held in place by Pin Sealer™ were better than plain gauze with Betadine® ointment as a dressing for external fixator pins.

Conflict of interest

No benefit in any form was received or will be received from a commercial party that relates either directly or indirectly to the subject of this article.

References