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# A retrospective cohort study of Acticoat™ versus Silvazine™ in a paediatric population

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## ABSTRACT

We wished to determine whether changing our centre's practice of using Acticoat™ instead of Silvazine™ as our first-line burns dressing provided a better standard of care in terms of efficacy, cost and ease of use. A retrospective cohort study was performed examining 328 Silvazine™ treated patients from January 2000 to June 2001 and 241 Acticoat™ treated patients from July 2002 to July 2003. During those periods the respective dressings were used exclusively. There was no significant difference in age, %BSA and mechanism of burn between the groups. In the Silvazine™ group, 25.6% of children required grafting compared to 15.4% in the Acticoat™ group ( $p = 0.001$ ). When patients requiring grafting were excluded, the time taken for re-epithelialisation in the Acticoat™ group (14.9 days) was significantly less than that for the Silvazine™ group (18.3 days),  $p = 0.047$ . There were more wounds requiring long term scar management in the Silvazine™ group (32.6%) compared to the Acticoat™ group (29.5%), however this was not significant. There was only one positive blood culture in each group, indicating that both Silvazine™ and Acticoat™ are potent antimicrobial agents. The use of Acticoat™ as our primary burns dressing has dramatically changed our clinical practice. Inpatients are now only 18% of the total admissions, with the vast majority of patients treated on an outpatient basis. In terms of cost, Acticoat™ was demonstrated to be less expensive over the treatment period than Silvazine™. We have concluded that Acticoat™ is a safe, cost-effective, efficacious dressing that reduces the time for re-epithelialisation and the requirement for grafting and long term scar management, compared to Silvazine™.

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## 1. Introduction

Silver products have been used as antimicrobials for thousands of years [1] and have been used to treat burns for approximately 200 years [2]. Silver ions disrupt the membrane respiratory electron transport chains in numerous microorganisms [3–5]. There are many different silver-containing treatments for burns on the market today, either as creams or silver coated dressings.

Silver sulphadiazine (SSD) (Silvazine™; Smith & Nephew, Flamazine™; Smith & Nephew) was introduced in 1968 by Charles Fox as a topical treatment for all depths of burns [6,7]. It is a topical compound of silver nitrate and sodium sulphadiazine prepared in a 1% water miscible cream. SSD is now the most widely used topical treatment for burns. The biologically active form of silver released from SSD is  $Ag^+$ . Silvazine™ (Smith & Nephew, Clayton, Australia) available since 1971, is an Australasian preparation of 1% silver

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sulphadiazine cream also containing 0.2% chlorhexidine digluconate. Silvazine™ is active against a wide range of Gram-positive and Gram-negative bacteria, yeast and moulds [8–10] and remains active for 12–24 h post-application [11]. The formulation was the result of clinical trials at the Royal Melbourne Hospital (Australia) in response to an outbreak of *Staphylococcus aureus* in the burns unit that was resistant to standard SSD [12]. Silvazine™ needs to be reapplied daily after bathing the wound and removing the old cream.

Acticoat™ (made in Canada for Smith & Nephew Healthcare, Hull, England) invented by Professor Rob Burrell is a nanocrystalline silver dressing which has been available since the late 1990s [13]. The dressing is composed of two layers of silver-coated high density polyethylene (0.2–0.3 mg silver/mg polyethylene) bonded on either side of an absorbent rayon/polyester core. Silver ( $Ag^0$  clusters and  $Ag^+$ ) is released onto the wound bed from the dressing when 100% humidity is achieved by adding water. The silver is continually released over several days, meaning that the dressing does not require daily changing and can be left on for 3 days. Acticoat™ has been shown to be effective against an array of bacteria and fungi [14,15]. While Acticoat™ has been used widely by some burns units, it is not as popular in others due to its perceived high cost.

In mid 2001 after trialling the use of Acticoat™ on a small number of patients and obtaining very positive outcomes, we changed our treatment policy and started using Acticoat™ on all burn injuries, regardless of the depth. We wished to determine whether our centre's policy of changing our main burns dressing from Silvazine™ to Acticoat™ decreased the requirements for skin grafting and long term scar management. We also wanted to see if it had a positive effect on the amount of labour needed for dressing changes. This study compares Silvazine™ and Acticoat™ with regards to efficacy of healing, microbial properties, cost effectiveness and ease of use.

## 2. Methods

### 2.1. Patient collection

A retrospective chart audit was conducted, investigating two cohorts of Paediatric Burns patients treated at the Royal Children's Hospital Stuart Pegg Paediatric Burns Centre, Brisbane. The study periods were:

1. January 2000–June 2001. All patients treated with Silvazine™.
2. July 2002–July 2003. All patients treated with Acticoat™.

The following information was extracted from the charts:

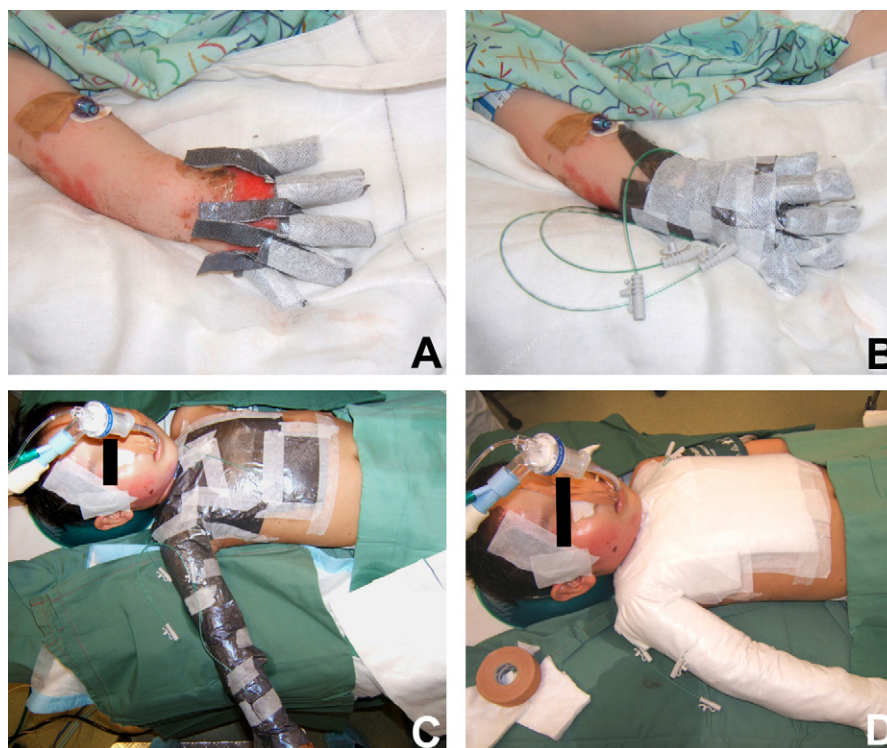
- Percentage of body surface area of burn (BSA).
- Time to full re-epithelialisation.
- Whether skin grafting was required.
- Whether patients required scar management for >1 month after re-epithelialisation.
- Whether patients had fever with positive blood cultures.

### 2.2. Treatment

For all patients treated with Silvazine™, the Silvazine™ cream was applied daily and covered with Melolin™ (Smith & Nephew, Hull, England) and a soft crepe bandage. It was replaced every day after bathing and the removal of the old cream. Bathing was in warm water containing 0.1% chlorhexidine gluconate.

For all patients treated with Acticoat™, the Acticoat™ dressing was cut to size, soaked in sterile water, blotted on a clean towel and applied to the burn, blue side down. It was fastened to the skin with Micropore™ tape (3M Health Care, St. Paul, USA). Plastic 5 G feeding tubes (Unomedical paediatric nasogastric tubes, Birkerød, Denmark) were secured to the outside of the Acticoat™ with adhesive tape or fabric zinc oxide tape (Leukoplast®, BSN Medical, Pinetown, South Africa), to act as irrigation tubes. The number of irrigation tubes was dependant upon the size of burn area to be covered with usually one tube required per 20 cm × 20 cm area or one tube per dorsal or ventral side of a jointed area. The Acticoat™ was then covered with Melolin™ and a soft crepe bandage wrapped over the top, ensuring the irrigation tubes were still accessible. Tubular netting bandage (Sutherland Medical Pty Ltd., Oakleigh, Australia) was used over the top and secured with tape. Splinting and positioning was possible over the outer bandages, if required. The Acticoat™ was irrigated with 5–10 ml of sterile water per catheter every 6 h. The dressing was changed every 3–4 days. If patient analgesia was able to be managed with oral analgesics, they were discharged and returned to the centre twice weekly for dressing changes and wound inspection. Parents were informed how to administer care of the Acticoat™ dressing at home and were given enough sterile water and syringes until their return (It is our experience that community pharmacies will often try to sell patients saline instead of sterile water for wound care, so we supply it to prevent dressing deactivation). Parents were instructed to return to the emergency department if the dressings were non-adherent, if the irrigation tubes fell or were pulled out or if the patient became generally unwell. For pain management, parents were instructed to give regular pain relief in the form of Painstop® (Paracetamol 24 mg/ml, Codeine phosphate 1 mg/ml, Paedpharm Pty Ltd., Bondi Junction, Australia) at six hourly intervals if required. If the pain couldn't be managed in this way, they were to present to the emergency department. This advice was the same for Acticoat™ and Silvazine™ treatment. In order to determine the ease of use of Acticoat™ at home, a random sample of 20 caregivers of patients were questioned regarding the ease of use and observed pain in their children.

The innovative method of keeping Acticoat™ moist with irrigation tubes was developed by our centre. The product description for Acticoat™ states that the dressing should be moistened and secured in place with an appropriate secondary dressing that will maintain a moist wound environment. We developed the irrigation tube technique in an effort to minimize the stress on our paediatric patients caused by removal of the outer dressing and re-wetting of the Acticoat™. Different catheters and volumes of water were tested through trial and error on the skin of staff and wounds of patients to develop the optimum delivery protocol. We developed



**Fig. 1 – Application of Acticoat™ to various areas of the body, with irrigation tubes. Acticoat™ is applied between the fingers in (A) and irrigation tubes secured over the palm and top of hand in (B). There are no tubes attached to the fingers, which are irrigated at the tip of each finger with a syringe. An outer dressing of Melolin™ is placed over the hand and individual finger bandaging is often used for oedema management. Acticoat™ and irrigation tubes are applied to the chest and arm in (C). For the chest area, usually 1–2 tubes are used. For arms, 2–4 tubes are used, 1 tube for each planar surface of each jointed area. Melolin™ is secured over the top of the Acticoat™ in (D), leaving the ports exposed for injection of sterile water.**

different dressing techniques to apply Acticoat™ to different areas of the body, illustrated in Fig. 1.

### 2.3. Cost analysis

The theoretical cost of using Acticoat™ and Silvazine™ to treat burns of 1, 5, 15 and 25% body surface area in a 10-year-old boy were calculated. Primary and secondary dressings, sedation and analgesia, nursing time and frequency of dressing were taken into account. The total cost was calculated using the following formula:

$$\begin{aligned} \text{total dressing cost} = & (\text{dressing material cost} \\ & + \text{sedation and analgesia} + \text{nursing time}) \\ & \times \text{number of dressings} \end{aligned}$$

### 2.4. Statistical analysis

Data for % BSA, patient age and re-epithelialisation time were compared between the groups using Student's *t*-test. The mechanism of burn was compared using a one-way ANOVA procedure. The percent of children requiring grafting and the percent of children requiring long term scar management were compared between the groups using a test of two proportions.

## 3. Results

There were 328 patients treated with Silvazine™ and 241 patients treated with Acticoat™. All patients had partial thickness or full thickness burn wounds. The average age of patient treated was 48.8 months for the Silvazine™ group and 52.9 months for the Acticoat™ group, with no significant difference between the groups ( $p = 0.313$ ). The average % BSA was 4.4% for the Silvazine™ group and 5.2% for the Acticoat™ group, with no significant difference between the groups ( $p = 0.102$ ). The mechanism of burn was also similar between the groups, with no statistically significant difference ( $p = 0.977$ ) (Fig. 2).

When the patients requiring grafts were excluded, the time taken for complete re-epithelialisation was significantly less in the Acticoat™ treated group ( $p = 0.047$ ) (Fig. 3). The average time for re-epithelialisation was  $14.9 \pm 9.7$  days for the Acticoat™ treated group, compared to  $18.3 \pm 22.3$  days for the Silvazine™ treated group.

The percentage of children requiring grafting was significantly less ( $p = 0.001$ ), by 40% in the Acticoat™ treated group (15.4%) compared to the Silvazine™ treated group (25.6%) (Fig. 4).

The percentage of children requiring long term (>1 month) scar management treatment was reduced in the Acticoat™ treated group (29.5%) compared to the Silvazine™ treated



Fig. 2 – The mechanism of burn injury in each treatment group was similar.

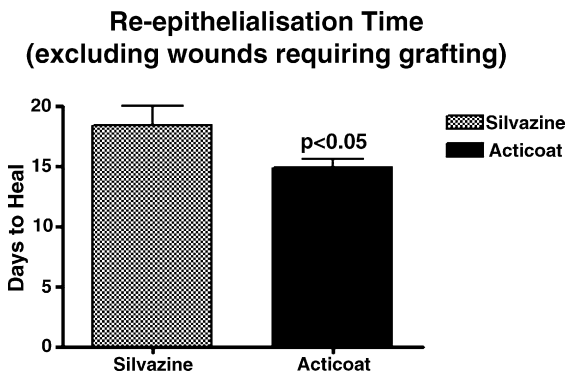


Fig. 3 – The time taken for complete re-epithelialisation of wounds in patients who did not require grafting. Bars are the average ± Standard Error of the Mean.

group (32.6%) (Fig. 5), however this was not significant ( $p = 0.210$ ). Pressure garments are a necessary and costly component of the scar management process and the requirement for garments was found to decrease over the course of

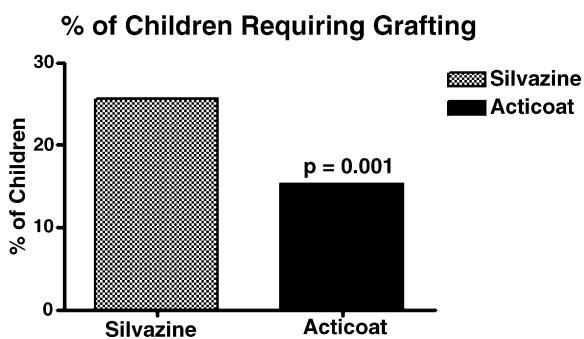


Fig. 4 – The percentage of children requiring grafting in the Silvazine™ treated (25.6%) and Acticoat™ treated (15.4%) groups.

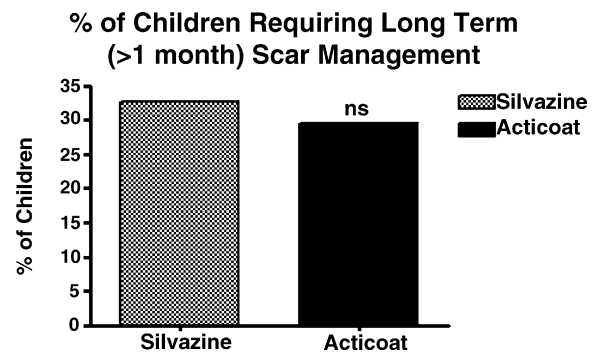


Fig. 5 – The percentage of children requiring long term scar management of their burn wounds in the Silvazine™ (32.6%) treated and Acticoat™ treated (29.5%) groups.

the study, from an expenditure of \$210,000 in 2000–2001, to \$164,000 in 2002–2003 (reduction of 22% during a time when patient numbers increased).

Over the time period of the study, there were only 2 patients who had positive blood cultures. One Silvazine™ treated patient who cultured *Salmonella enteritidis* and one Acticoat™ treated patient cultured a Non-fermenting Gram Negative *Bacillus*. Since switching to Acticoat™ as our primary dressing, we have not seen any more positive blood cultures than during the period we were using Silvazine™ exclusively.

Over the time period of the study (2000–2003), the number of inpatient bed days decreased, even though the total number of new patients increased. By the end of 2003, when Acticoat™ was being used exclusively, there were far less occasions of service per patient than there were in 2001 (Fig. 6).

To determine the ease of use of Acticoat™ at home, a random selection of 20 caregivers were questioned. All caregivers (100%) reported that the process of flushing the Acticoat™ tubes at home was easy to do, with only one caregiver (5%) reporting a problem with use (the tube fell out at home, and the patient had to return to the centre to get the wound re-dressed). In terms of the discomfort shown by the children, 40% of the caregivers perceived that their child was experiencing discomfort when the tubes were flushed. However, 100% reported they were able to manage this pain. Initially, there were some problems with patients pulling out the tubes, however as our dressing technique has evolved this

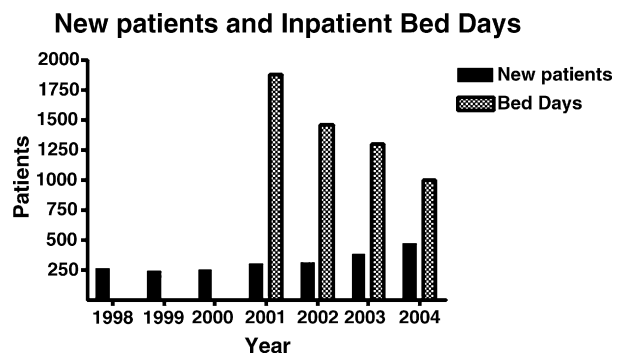
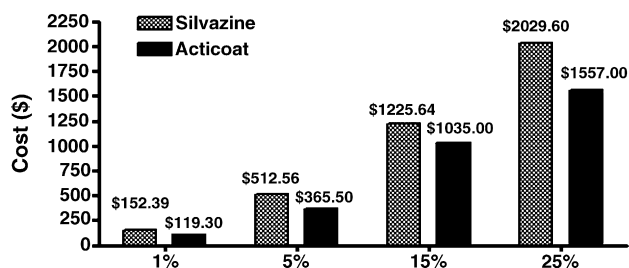


Fig. 6 – The number of new patients and inpatient services during the time of the study period. Inpatient bed day data prior to 2001 was not available.



### Total Cost Until Full Re-epithelialisation



**Fig. 7 – The theoretical cost of each dressing on different %TBSA burns in a 10-year-old boy. Calculations took into account the dressing cost, nursing cost and cost of sedation and analgesia.**

has been less frequently noted. Specifically, with toddlers, we now always secure an extra irrigation tube to the burned area, in case one is pulled out. We also ensure that the tubes are secured away from hands and are not clearly visible to younger patients.

A theoretical cost analysis was calculated for a 1, 5, 15 and 25% burn in a 10-year-old boy by taking into account the cost of the dressings, nursing costs and sedation and analgesia and multiplying that by the estimated time until full re-epithelialisation. (Fig. 7). The cost of dressing with Silvazine™ was more than the cost of dressing with Acticoat™.

## 4. Discussion

The ideal burns dressing is one which will allow a burn wound to heal rapidly, restoring skin structure and appearance as much as possible to normal, with little scarring. For children, it should also need to be changed infrequently with minimum discomfort. In order for it to be accessible to everyone, the dressing must also be cost effective.

If a burn wound re-epithelialises within three weeks it will heal with less chance of scarring [16,17]. Any treatment which increases the rate of re-epithelialisation has the potential to prevent scarring. The ability of Acticoat™ to increase the speed of wound healing compared to Silvazine™ was reflected in the decreased requirement for grafting and scar management. Others have also found that the use of Acticoat™ lead to a decrease in the number of grafts required in their unit [18,19]. Silver treatments (including Acticoat™) are reported to have a toxic effect *in vitro* on newly growing keratinocytes, limiting their growth and *in vitro* wound healing [20–22]. Acticoat™ also appears to not be beneficial for donor sites, causing delayed healing [23]. In this study, Acticoat™ was better for burn wound healing compared to Silvazine™. However, the possible growth inhibitory effects of any silver containing dressing should always be weighed up against the other advantages the dressing may have.

Silver containing compounds on wounds are primarily used for their antimicrobial/antifungal properties. Acticoat™ is reported to be as efficacious or a better antimicrobial agent than Silvazine™ [11,14,24]. In the population of children who present to our centre with small percentage area burns, toxic

shock syndrome is a condition that clinicians should always be alert to [25]. In UK units, 2.5% of children admitted with burn injuries show symptoms of TSS [26]. In previous studies, others have found that using Acticoat™ lead to a decrease in the incidence of infection [19,27,28]. In our centre, Acticoat™ has limited the number of total blood infections even though the number of patients treated increases every year. We have not seen a case of toxic shock in our centre for the past 40 years.

One of the biggest advantages in the change of practice to using Acticoat™ has been the cessation of daily bathing required for Silvazine™. This lead to two important outcomes for the centre: a reduction of cost of labour and a reduction of trauma (to both the wound with no scrubbing, and to the patient). Decreasing the number of dressings to every 3–4 days instead of daily substantially reduces the cost of treatment, in terms of nursing time and decreased pain medication [29]. The cost-reducing effect of less frequently changed, efficacious dressings can be so impressive that even the most expensive dressings can be shown to be cost effective if they lead to decreased surgical procedures and a reduction in nursing time [30]. Here, we found that although Acticoat™ is perceived to be an expensive dressing per sheet, it proves to be far more economical over the treatment of the patient in terms of nursing time and repeated dressings.

In the time covered by this study (2000–2003), the number of inpatient bed days decreased dramatically even as the total number of new patients increased. Today in our centre we have considerably decreased the number of inpatients from what they were in 2000. Almost all of our patients are now treated on an out-patient basis which has lead to a substantial reduction in expenditure for our centre as well as other units utilising this practice [19]. Our unique technique of keeping the Acticoat™ moist via water injections through feeding tubes has allowed us to use this dressing on an outpatient basis. Water injections are well tolerated at home and it means the children are more able to resume their normal lives during treatment. It is also more convenient for the parents to not have to attend a daily dressing clinic for 14 days in a row, as they did when Silvazine™ was being used. Methods used by others to keep the Acticoat™ moist include wetting the outer dressings which in turn moisten the underlying Acticoat™ or placing an occlusive dressing such as Duoderm® (ConvaTec) over the Acticoat™ to keep the moisture in after application. We do not use occlusive dressings over the top of Acticoat™ as in our tropical, often humid environment the dressings become too moist and the healing burn becomes macerated. Irrigation tubes are the best way to keep the dressing moist, but not soaked. Irrigation tubes are also ideal for the paediatric population, for whom even the perception of treatment or a dressing change can cause great distress. By using this technique, the Acticoat™ can be irrigated without removal of the outer dressings, leading to much less stress for the child.

Decreasing the number of dressing changes also leads to a decrease in the emotional and psychological trauma suffered by the children and their caregivers. Although this was not measured in this study it has been well documented by others [29,31]. In this study, as reported by others [28], there was a stinging sensation felt on application of Acticoat™ and for up to 30 min after application. However this pain is well managed

with analgesia such as paracetamol or ibuprofen. This pain is generally only felt when the wound is recent and/or partial thickness and was also observed in 40% of patients during the tube flushing procedure for home care.

There are other advantages we have observed with Acticoat™ in our centre. Acticoat™ allows for better ease of splinting and ranging is possible with the dressings left intact. We have used Acticoat™ not just on burns, but also on open wounds in both children and neonates, necrotising fasciitis, pressure areas on immunosuppressed oncology patients, and limbs affected by meningococemia-induced purpura fulminans. We have used it on meshed grafts, over Integra™ (Ethicon Inc., Johnson & Johnson Medical, Cornelia, USA) and under Vacuum assisted closure™ (VAC) dressings (KCI Inc., Copenhagen, Denmark). We use it on all areas of the body, including the face and perineum. It is safe to use on neonates [32] and we have now successfully treated more than 30 neonates who were less than 27 weeks gestational age with Acticoat™. The only situations for which Acticoat™ is not used are on donor sites, when patients have a known silver allergy or if patients will be having an MRI scan.

Acticoat™ does not appear to cause the pseudo-eschar effects that have been observed with Silvazine™ [15]. One treatment of Silvazine™ can form pseudo-eschar on the top of a wound for up to 1 week. This pseudo-eschar can make a wound appear full thickness (with a white leathery appearance), when it may contain areas which are partial thickness or more superficial. If Silvazine™ has been applied to a burn wound by a referring centre it may be very difficult for the receiving centre to estimate burn depth. When patients are referred from other centres, we always ask if wound has ever been treated with Silvazine™ as this may alter the wound appearance and the treatment. However, Laser Doppler scanning of the treated wound in our centre also allows us to determine accurate burn depth despite the presence of pseudo-eschar.

We apply Acticoat™ to all our burn wounds on admission and in the period before debriding and grafting (contrary to others [31]) and have found that Acticoat™ even helps the wound demarcate more clearly so that superficial areas not requiring grafting are more easily distinguishable from deeper areas. This effect may be related to the reported anti-inflammatory effect of Acticoat™, believed to be due to the continual release of Ag<sup>0</sup> clusters from the dressing. Acticoat™ has been shown to reduce the levels of Matrix Metalloproteinases and proteases and increase the frequency of cellular apoptosis within the wound [33].

As we have been using Acticoat™ in our centre for a number of years since this study, we have further refined our dressing technique. Instead of using Micropore™ or Elastoplast® tape, the Acticoat™ and tubes are now all fastened using Fixomull® retention tape (BSN Medical, Hamburg, Germany). This allows for much easier removal of all the securing tape using Zoff™ adhesive remover (Smith & Nephew, Clayton, Australia), with less trauma to the patient. Instead of irrigation with 5–10 ml of sterile water, we now only use 2–3 ml of water per tube, to prevent the Acticoat™ becoming too moist. When patients are discharged home, caregivers are instructed to only irrigate the Acticoat™ three times a day, rather than the four times per day they received as inpatients under hospital care. This is so the patients do not

need to be woken in the middle of the night. When patients are immobilised on a warm Clinotron II bed (Hill-Rom Industries, Montpellier, France), the dressings dry out more quickly, so we increase the frequency of fluid delivery, rather than the amount of fluid delivered. If too much fluid is administered via the tubes it soaks through into the bed, wetting the beads so they need to be replaced. To ensure the Acticoat™ is irrigated appropriately when patients are admitted, we have an Acticoat™ maintenance sheet in the patient chart. The sheet lists the body position where the tubes sit, the volume to administer and the frequency of irrigation and is checked off by the nurses. When the patients are discharged, they are given a pamphlet with this information on it so the parents are aware of the irrigation schedule.

This trial is a retrospective cohort study comparing two different time periods and as such, there may be unknown factors which are different between the treatment groups. However the introduction of Acticoat™ to our centre has dramatically altered our practice, shifting our care from an inpatient service to an outpatient one. When choosing a dressing the health care provider has to weigh up the efficacy of healing compared to antimicrobial effectiveness, ease of use, cost, safety and pain experienced by the patient. In our centre, Acticoat™ has proven to be better than Silvazine™ for most of these criteria.

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