Clinical trial

Natural coniferous resin salve used to treat complicated surgical wounds: pilot clinical trial on healing and costs

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Abstract
Resin is a natural product of coniferous trees. Salves manufactured from spruce resin (Picea abies) have been used for centuries to treat wounds and skin infections. We report a pilot clinical trial designed to investigate healing rates, factors that contribute to delayed wound healing, cost-effectiveness and incidence of allergic reactions when resin salve is used to treat complicated surgical wounds. The trial involved 23 patients in whom wound healing after surgery was delayed. These patients were assigned to resin salve treatment. The primary outcome measure was the number of days to complete wound healing. Se-condary objectives included an assessment of factors contributing to delayed wound healing, an estimation of associated costs and an investigation into the occurrence of allergic reactions related to resin salve therapy. The study achieved a healing rate of 100%. The mean ± SD healing time was 43 ± 24 d. The mean ± SD wound size (length × width × depth) was (29 ± 19) × (12 ± 7) × (4 ± 3) mm. Wound size, use of corticosteroids or other immunosuppressants and immobilization were statistically significant (P < 0.05) contributors to delayed wound healing and impaired re-epithelialization. The total mean ± SD costs of the resin salve treatment were €45.0 ± 26.0 per patient during the entire treatment period and €1.2 ± 0.5 per treatment day. The rate of allergic reactions was 0%. The results of this pilot trial indicate that complicated surgical wounds may be treated successfully with resin salve. The treatment method is clinically effective and cost-effective, and the rate of allergic reactions is low.

Introduction
Resin is a natural product of coniferous trees. In the Nordic countries, salve prepared from the resin of the Norway spruce (Picea abies) has been used for centuries to treat skin wounds, ulcers and skin infections.¹⁻⁴ Wound healing may be impeded by any of several obstacles, including advanced age, infections, immobilization, ischemia, malnutrition, smoking, hyperglycemia, anemia, certain chronic diseases (e.g. diabetes, cancer, hepatic or renal failure) and the use of certain drugs (e.g. corticosteroids and other immunosuppressive drugs).⁵⁻⁶ From a surgical perspective, infection of the surgical site contributes markedly to delayed wound healing.⁷⁻⁹ Recent observations have shown that spruce resin exhibits strong antimicrobial activity against certain strains of bacteria and fungi that typically colonize wounds, cause infections and impede wound healing. Both in vitro and in vivo studies have shown that resin salve has significant antibacterial activity against pathogenic Gram-positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococcus species (VRE). The antifungal effect of the resin is exerted against the common dermatophytes of the skin, scalp and nails. Of the dermatophytes, Trichophyton rubrum, Trichophyton tonsurans and Trichophyton mentagrophytes have thus far been shown to be sensitive to the resin.⁵⁻¹⁰⁻¹² In the setting of a randomized, controlled clinical trial, resin salve proved to be more effective than sodium carboxymethylcellulose hydrocolloid polymer with or without ionic silver (Aquacel® or Aquacel Ag®; ConvaTec Ltd, London, UK) in the treatment of severe pressure ulcers.¹³ The objective of this study was to investigate the healing rate and healing time of complicated surgical wounds.

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In addition, factors contributing to delayed wound healing, cost-effectiveness and incidence of allergic reactions to resin salve therapy were studied.

Materials and methods

Study setting and patient population

This was a clinical trial involving 23 patients whose wounds had not healed by primary intent after surgery. Based on our earlier experience, we hypothesized that the resin salve treatment might promote and accelerate the healing of such complicated surgical wounds. The inclusion criterion was the presence of a complicated, open, chronic surgical wound that had not healed by routine outpatient measures by 2 weeks after elective surgery. Exclusion criteria included life expectancy of <3 months, and the presence of wounds caused by trauma surgery or wounds scheduled for skin transplantation.

The primary outcome measure was the number of days to complete wound healing (i.e. full re-epithelialization of the wound). Secondary objectives were to assess factors contributing to the delay in wound healing, to estimate the costs of resin salve therapy and to study the rate of allergic contact dermatitis. Safety and compliance were monitored during the study every 2 weeks as part of regular control procedures in place in the outpatient department. If symptoms of contact dermatitis appeared, resin salve treatment was immediately discontinued.

The study was approved by the administration of the Helsinki University Hospital and Rheumatism Foundation Hospital. Written informed consent was obtained from all patients.

The study population was aggregated from routine postoperative outpatient department controls at the Rheumatism Foundation Hospital (nine patients, 39%) and Jorvi Hospital (14 patients, 61%) between January 2007 and December 2010. Experts in wound care (AS, RT, HK and OK) diagnosed the presence of a chronic surgical wound that indicated a need for resin salve treatment. These authors also followed up the patients, recorded and documented the clinical data and laboratory findings, and assessed the final outcome. The resin salve treatment was carried out as part of home care without exception. Demographic and pretreatment data for the study patients are shown in Table 1.

### Table 1 Demographic and pretreatment data for study patients (n = 23)

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female, n (%)</td>
<td>8 (35%)/15 (65%)</td>
</tr>
<tr>
<td>Age, years, mean ± SD (range)</td>
<td>49 ± 17 (16–82)</td>
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<tr>
<td>Wound size, mean ± SD (range)</td>
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<tr>
<td>Length, mm</td>
<td>29 ± 19 (5–60)</td>
</tr>
<tr>
<td>Width, mm</td>
<td>12 ± 7 (4–30)</td>
</tr>
<tr>
<td>Depth, mm</td>
<td>4 ± 3 (1–10)</td>
</tr>
<tr>
<td>Area, mm²</td>
<td>424 ± 425 (25–1500)</td>
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<tr>
<td>Wound localization, n (%)</td>
<td></td>
</tr>
<tr>
<td>Lower limb</td>
<td>8 (35%)</td>
</tr>
<tr>
<td>Upper limb</td>
<td>3 (13%)</td>
</tr>
<tr>
<td>Trunk or head</td>
<td>12 (52%)</td>
</tr>
<tr>
<td>Previous local treatment, n (%)</td>
<td>11 (48%)</td>
</tr>
<tr>
<td>Use of corticosteroids, n (%)</td>
<td>3 (13%)</td>
</tr>
<tr>
<td>Other immunosuppressants, n (%)</td>
<td>4 (17%)</td>
</tr>
<tr>
<td>Current smoking, n (%)</td>
<td>2 (9%)</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>2 (9%)</td>
</tr>
<tr>
<td>Immobilization*, n (%)</td>
<td>4 (17%)</td>
</tr>
</tbody>
</table>

*aNeed for assistance in moving, SD, standard deviation.

Figure 1 Norway spruce (Picea abies)

European CE (Conformité Européenne) mark, and is available commercially from Finnish pharmacies (Abilar® 10% resin salve; Repolar Ltd, Espoo, Finland).

Resin salve treatment

Regular daily wound care practice, including daily showers and dressing changes, was maintained. Within this, resin salve was applied to the wound in a layer approximately 1 mm thick and covered with sterile cotton gauze (Tyke HealthCare Ltd, Ulvila, Finland). General instructions for proper wound care and detailed instructions regarding the implementation of resin salve therapy were given by AS, RT, HK or OK as part of outpatient department practice. Despite the positive microbial culture of some wounds, profuse secretion of purulent discharge was not observed and no surgical revision was required for wound necrosis or slough.
Clinical variables
In addition to demographic variables, factors potentially contributing to wound healing were recorded at the beginning of the study. These included: wound size before resin salve treatment (length × width × depth, mm); the presence of rheumatoid disease or diabetes; smoking; use of corticosteroids or other immunosuppressants; immobilization; the presence of wound infection confirmed by a positive microbial culture, and previous attempts to treat the wound with wound care products other than the resin salve. The area of the wound was measured and infection status and any signs of allergic reactions were assessed during outpatient department visits every 2 weeks.

Cost analysis
To assess the total costs and daily costs of resin salve treatment, an average treatment cost (mean ± SD) per patient was calculated and total costs were extrapolated for the whole study group. Costs are expressed in euros (€). Cost analysis was based on the consumer price of the Abilar® resin salve and the Tyke HealthCare cotton gauze as recorded by the University Pharmacy in Finland on April 1, 2011. The following variables were recorded: (i) wound size (mm²); (ii) daily consumption of resin salve (g) extrapolated in relation to wound size (mm³); (iii) wound healing time (d); (iv) number (n) of 20-g tubes of salve purchased during the treatment period per patient; (v) cost of the 20-g tube of salve (€), and (vi) cost of any accessory products required (gauze).

Statistical analyses
Data analyses and reporting were based on STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.12 Qualitative data are expressed as frequencies and percentages and quantitative data as the mean ± SD. Continuous variables and proportions were compared using the Mann–Whitney non-parametric U-test or Student’s t-test, as appropriate. In univariate and multivariate logistic regression analyses, healing time was regarded as the dependent variable and other covariates, either dichotomous or continuous, were used as regressors. The use of corticosteroids and use of other immunosuppressive drugs, and diabetes and smoking, were combined into composite regressors because their incidences were low (fewer than five cases each). There were no missing data or loss to follow-up. Differences with a P-value of <0.05 were considered statistically significant. Analyses were conducted using SPSS Version 17.0 (SPSS, Inc., Chicago, IL, USA).

Results
Healing rate and time
The healing rate of the chronic, complicated surgical wounds was 100% (23/23 patients). The mean ± SD healing time was 43 ± 24 d (range: 10–87 d; median: 41 d) (Fig. 2). Healing times did not differ statistically significantly between males and females. Detailed results of healing times are shown in Table 2. Figures 3 and 4 show wounds in two patients before and after resin salve treatment.

Table 2 Healing time of chronic complicated surgical wounds treated with resin salve (n = 23)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Healing time, d, mean ± SD</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole study population (n = 23)</td>
<td>43 ± 24 (10–87)</td>
<td>0.238</td>
</tr>
<tr>
<td>Male (n = 8)</td>
<td>49 ± 23 (21–82)</td>
<td>0.238</td>
</tr>
<tr>
<td>Female (n = 15)</td>
<td>39 ± 25 (10–87)</td>
<td>0.238</td>
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<tr>
<td>Wound localization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower extremity (n = 8)</td>
<td>56 ± 22 (19–87)</td>
<td>0.171</td>
</tr>
<tr>
<td>Upper extremity (n = 3)</td>
<td>41 ± 18 (30–61)</td>
<td>0.310</td>
</tr>
<tr>
<td>Trunk or head (n = 12)</td>
<td>34 ± 25 (10–77)</td>
<td>0.171</td>
</tr>
<tr>
<td>Previous local treatment</td>
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</tr>
<tr>
<td>Yes (n = 11)</td>
<td>50 ± 24 (19–82)</td>
<td>0.186</td>
</tr>
<tr>
<td>No (n = 12)</td>
<td>36 ± 24 (10–87)</td>
<td>0.186</td>
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<tr>
<td>Wound infection</td>
<td></td>
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<tr>
<td>Yes (n = 10)</td>
<td>47 ± 25 (19–82)</td>
<td>0.310</td>
</tr>
<tr>
<td>No (n = 13)</td>
<td>39 ± 24 (10–87)</td>
<td>0.310</td>
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<tr>
<td>Diabetes or current smoking</td>
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<tr>
<td>Yes (n = 3)</td>
<td>50 ± 16 (32–61)</td>
<td>0.438</td>
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<tr>
<td>No (n = 20)</td>
<td>42 ± 25 (10–87)</td>
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<tr>
<td>Immobilization*</td>
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<tr>
<td>Yes (n = 4)</td>
<td>76 ± 14 (56–87)</td>
<td>0.007</td>
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<tr>
<td>No (n = 19)</td>
<td>36 ± 20 (10–71)</td>
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<tr>
<td>Use of corticosteroids or other immunosuppressants</td>
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<tr>
<td>Yes (n = 5)</td>
<td>68 ± 15 (56–87)</td>
<td>0.01</td>
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<tr>
<td>No (n = 18)</td>
<td>36 ± 21 (10–77)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*Need for assistance in moving.
SD, standard deviation.
Contributors to delayed wound healing

In univariate linear regression analysis, immobilization ($P = 0.001$), the use of corticosteroids or other immunosuppressants ($P = 0.004$), and wound size in terms of maximal length ($P = 0.016$) and depth ($P = 0.002$) were statistically significantly associated with prolonged wound healing (Table 3).

The multivariate linear regression model that showed the strongest correlation with wound healing time (adjusted $R^2 = 0.679$) included covariates of age, sex, wound size in terms of length, width, depth and wound area, use of corticosteroids or other immunosuppressants, smoking, presence of diabetes, immobilization and wound infection confirmed by positive bacterial culture. The covariates were entered into the multivariate regression model using a stepwise method. Statistically significant covariates for impaired wound healing were wound length ($P = 0.001$), use of corticosteroids or other immunosuppressants ($P = 0.014$) and immobilization ($P = 0.041$) (Table 3).

Costs

At the start of the study, the average wound area was 424 mm$^2$ and the amount of resin salve required for treatment was approximately 0.4 g/d. Thus, a 20-g tube of salve would last up to 50 d for a patient with a wound of this size at the start of treatment. Based on these extrapolations, the mean ± SD total cost of resin salve treatment for a mean treatment period of 43 d was €45.0 ± 26.0 (range: €22.0–102.0) per patient. The mean ± SD daily cost was €1.2 ± 0.5 (range: €0.5–2.2) per patient.

Allergic reactions and compliance

No adverse events or allergic reactions (i.e. contact dermatitis) related to resin salve therapy were reported during the study period. Compliance with the resin salve treatment was exceptionally good because there were no interruptions in the sample of patients recruited during the study.

Bacterial culture

Ten patients (43%) had a positive microbial culture. The bacterial strains were: *Staphylococcus aureus* ($n = 5$, 50%); *Staphylococcus epidermidis* ($n = 1$, 10%); *Pasteurella multocida* ($n = 1$, 10%); a combination of *Streptococcus agalactiae* and *S. aureus* ($n = 1$, 10%); a combination of *Acinetobacter* and *Streptococcus* ($n = 1$, 10%), and a combination...
Infection contributes to impaired wound recovery and re-epithelialization. Interestingly, the presence of a wound infection verified by positive bacterial culture...
Treatment of surgical wounds with coniferous resin salve

Clinical trial

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(43%, 10/23) had no marked influence on overall wound healing time in the present study. Although a positive bacterial culture, together with clinical signs of infection, is indisputable evidence for postoperative wound infection, a positive bacterial culture did not imply any significant deterioration in wound healing in this series. This may be explained by the antimicrobial properties of the resin salve, which have been clearly documented: resin is strongly antimicrobial against a wide range of Gram-positive and -negative bacteria, as well as against dermatophytes. Therefore, observations of accelerated wound healing regardless of positive bacterial culture may be based on the resin’s capability to disinfect a wound by dispersing microbial biofilm from the wound cavity.\(^{10-12}\)

By contrast, in some cases, a positive bacterial culture probably indicated contamination from the patient’s normal microbial flora rather than a true surgical wound infection. It is clear that, in such cases, the positive bacterial culture did not have any clinical significance or impact on wound healing (i.e. the microbes were just wound commensal flora). However, it is noteworthy that oral antibiotics were administered in our series only if the wound was clearly infected, and only when both clinical and laboratory-confirmed evidence of wound infection, including a body temperature >38 °C, redness or significant suppuration of the wound, and a C-reactive protein concentration of >40 mg/l, were available.

This study confirmed the classical and well-known risk factors for impaired wound healing: the use of corticosteroids or other immunosuppressive regimens, immobilization and wound size made statistically significant contributions to the impairment of wound healing. The best multivariate model to describe the duration of wound healing at an adjusted coefficient of determination (\(R^2\)) of 0.679 and a standardized regression coefficient (beta) of 0.532 indicated that an increase in wound length of approximately 2 mm prolongs average healing time by 1 d and that a chronic, complicated wound 3 cm in length should heal, on average, in 15 d. Although logistic regression models are frequently used in observational studies, the impact of an observed risk factor must be interpreted extremely carefully [i.e. as the regressor on the outcome (dependent variable)]. Patients differ not only in terms of the presence or absence of the risk factor being tested, but also in terms of numerous other patient-related factors, which can potentially contribute to outcome and are thus able to bias the results. By contrast, some of the most important reasons for using multivariate models are to control potential confounding factors, minimize the impact of these confounders on the outcome and, thus, enable the emergence of actual risk factors.\(^{17}\)

Estimating the costs incurred by wound care and conducting a reliable comparison of the costs of wound care products is a difficult enterprise.\(^{16,18,19}\) There are approximately 300 topical wound care products on the market and consumer prices, packet sizes and daily usage vary markedly. In addition, recommendations and guidelines related to wound care are heterogeneous among hospitals and specialist wound care units.\(^{10}\) Nevertheless, we attempted to estimate the costs of resin salve treatment of chronic, complicated surgical wounds and concluded that resin salve treatment is inexpensive and cost-effective in comparison with, for example, medical honey or sodium carboxymethylcellulose hydrocolloid polymer treatment, both of which are commonly used for wound care. Furthermore, the average wound healing time in our study was somewhat shorter than in earlier studies\(^{15–16}\) and the current price of resin salve in Finland is only 10–20% of the consumer price of medical honey (Actilite\(^\circ\text{C}\); Episil\(^\circ\text{C}\) Border\(^\circ\text{C}\)) or sodium carboxymethylcellulose hydrocolloid polymer without or with ionic silver (Aquacel\(^\circ\text{C}\); Aqualine\(^\circ\text{C}\); Duoderm Extra Thin\(^\circ\text{C}\)). A recent randomized clinical trial by Ubink et al.\(^{16}\) compared the effectiveness and cost of occlusive dressings against those of gauze dressing for local wound care in surgical patients. The authors reported that the overall daily cost per patient was €7.48 in the occlusive dressings group and €3.98 in the gauze dressings group.\(^{16}\) The overall daily cost of resin salve treatment was approximately €1.2 ± 0.5 per patient in the present study.

Resin allergy has been reported to occur at a prevalence of 1–3% in the general population.\(^{21–23}\) This study included 23 patients treated with resin salve, among whom no allergic reactions occurred. An earlier study involving 21 patients in whom severe pressure ulcers were treated with resin salve for 56 months reported that only one patient dropped out because of severe allergic contact dermatitis.\(^{11}\) It appears that the risk for allergic contact dermatitis is low, but the risk for resin sensitivity must be taken into account in nursing practice.

Although our follow-up was complete and no patients were lost to follow-up, the study has some limitations. It represents a non-randomized, uncontrolled pilot clinical trial, in which surgical patients were recruited from only two centers by four researchers. Thus, the study carries a risk for selection bias because patients were recruited into the study by the authors only, and not all patients from the two recruiting centers who would have fulfilled the entry criteria were recruited. Our results will require consolidation in a randomized controlled study setting in the future. In addition, we were unable to report patients’ blood glucose and hemoglobin levels during the treatment period and this ignorance of these potential contributors to wound healing in this clinical trial is an obvious limitation. However, there are some obvious obstacles to patient recruitment, including the general lack of interest.
in this type of non-conventional wound treatment. We hope that the good results documented in trials thus far will kindle an interest in the use of resin salve to cure difficult-to-treat, chronic, inflamed surgical wounds.

In conclusion, this study suggests that resin salve treatment is a clinically effective and cost-effective means of promoting the healing of chronic, complicated surgical wounds.

Acknowledgments

The authors thank Professor Seppo Sarna, for reviewing the statistical analyses in this paper and Dr Robert Paul, for editing the language.

References

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