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Abstract: BACKGROUND: To evaluate efficacy and cost-effectiveness of a plant-derived wound dressing (ONE), a mixture of hypericum oil (Hypericum perforatum L.) and neem oil (Azadirachta indica A. Juss.), in scalp wounds with exposed bone. PATIENTS AND METHODS: All patients with scalp wounds with exposed bone, following the excision of skin tumors, and treated with ONE in 2011 were included. Time of healing, wound size, area of exposed bone, ease of handling, pain, and complications were evaluated. Costs of dressings and nursing time were compared with those cited in literature for other treatment modalities. RESULTS: Fifteen consecutive patients with a mean age of 76.87 ± 10.3 years (59-90 years) were analyzed. The mean wound size was 10.9 ± 6.84 cm(2) (0.4-22.6 cm(2)) with 4.8 ± 5.9 cm(2) (0.3-20.7 cm(2)) of exposed bone. The time of complete healing by secondary intention was 8.1 (4-20) weeks. Rapid formation of granulation tissue was observed which after 4 weeks covered the entire exposed bone surface in 11 of 15 cases (73%). Dressing change was simple with no pain reported; no infections or other complications occurred. Using ONE for a mean healing time of 56.7 days resulted in mean costs of EUR 423.73, which is substantially lower than those published for fascia lata, negative pressure therapy, or collagen matrix followed by skin grafting (EUR 1,612.82, EUR 4,411.80 and EUR 1,503.72, respectively). CONCLUSION: This retrospective, non-controlled analysis supports ONE as a simple-to-use and safe treatment option for scalp wounds with exposed bone. Treatment costs compare favorably to those published for other treatment modalities.

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A Plant-Derived Wound Therapeutic for Cost-Effective Treatment of Post-Surgical Scalp Wounds with Exposed Bone

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Keywords
Wound dressing · Neem oil · Hypericum oil · Scalp wounds with exposed bone · Secondary intention healing

Summary
Background: To evaluate efficacy and cost-effectiveness of a plant-derived wound dressing (ONE), a mixture of hypericum oil (*Hypericum perforatum* L.) and neem oil (*Azadirachta indica* A. Juss.), in scalp wounds with exposed bone. **Patients and Methods:** All patients with scalp wounds with exposed bone, following the excision of skin tumors, and treated with ONE in 2011 were included. Time of healing, wound size, area of exposed bone, ease of handling, pain, and complications were evaluated. Costs of dressings and nursing time were compared with those cited in literature for other treatment modalities. **Results:** Fifteen consecutive patients with a mean age of 76.87 ± 10.3 years (59–90 years) were analyzed. The mean wound size was 10.9 ± 6.84 cm^2 (0.4–22.6 cm^2) with 4.8 ± 5.9 cm^2 (0.3–20.7 cm^2) of exposed bone. The time of complete healing by secondary intention was 8.1 (4–20) weeks. Rapid formation of granulation tissue was observed which after 4 weeks covered the entire exposed bone surface in 11 of 15 cases (73%). Dressing change was simple with no pain reported; no infections or other complications occurred. Using ONE for a mean healing time of 56.7 days resulted in mean costs of EUR 423.73, which is substantially lower than those published for fascia lata, negative pressure therapy, or collagen matrix followed by skin grafting (EUR 1,612.82, EUR 4,411.80 and EUR 1,503.72, respectively). **Conclusion:** This retrospective, non-controlled analysis supports ONE as a simple-to-use and safe treatment option for scalp wounds with exposed bone. Treatment costs compare favorably to those published for other treatment modalities.

Schlüsselwörter
Wundverband · Neemöl · Johanniskrautöl · Skalpwunden mit freiliegendem Knochen · Sekundäre Wundheilung

Zusammenfassung
Hintergrund: Diese retrospektive, nicht-kontrollierte Analyse untersucht die Frage, ob durch Tumorexzision entstandene Skalpwunden mit freiliegenden Knochen mit einem pflanzlichen Wundtherapeutikum (ONE), bestehend aus Johanniskrautöl (*Hypericum perforatum* L.) und Neemöl (*Azadirachta indica* A. Juss.), mittels sekundärer Wundheilung kosteneffektiv behandelt werden können. **Patienten und Methoden:** Eingeschlossen wurden alle Patienten mit einer Skalpwunde mit freiliegendem Knochen als Folge einer Tumorexzision, die in 2011 mit ONE behandelt wurden. Dabei wurden die Abheilungsdauer, die Veränderung der Wundfläche, die Fläche des freiliegenden Knochens, Schmerzen und Einfachheit der Anwendung untersucht. Die verursachten Kosten wurden mit anderen Behandlungsmaßnahmen verglichen, die sich aus der Literaturrecherche ergeben haben. **Resultate:** Die Patienten waren durchschnittlich 76,87 ± 10,3 Jahre (59–90 Jahre) alt. Die Skalpwunden hatten eine durchschnittliche Wundgröße von 10,9 ± 6,84 cm^2 (0,4–22,6 cm^2) mit durchschnittlich 4,8 ± 5,9 cm^2 (0,3–20,7 cm^2) freiliegendem Knochen. Die Zeitdauer bis zum kompletten Wundverschluss durch Sekundärheilung betrug 8,1 Wochen (4–20 Wochen). Es konnte eine rasche Bildung von Granulationsgewebe beobachtet werden, was bei 11 von 15 (73%) Fällen innerhalb von 4 Wochen zu einer kompletten Deckung des freiliegenden Knochens führte. Der Verbandswechsel war einfach und schmerzfrei; es gab keine Anzeichen für eine Infektion oder andere unerwünschte Wirkungen. Die durchschnittlichen Behandlungskosten betrugen 423,73 EUR und lagen damit deutlich niedriger als die aus der Literatur bekannten Kosten für Lappenplastik (1612,82 EUR), Unterdrucktherapie (4411,80 EUR) oder Kollagen-Matrix mit nachfolgender Deckung durch Spalthaut (1503,72 EUR). **Schlussfolgerung:** Diese retrospektive, nicht-kontrollierte Analyse bestätigt, dass ONE eine einfach anzuwendende, kostengünstige und effektive Behandlungsoption von Skalpwunden mit freiliegendem Knochen ist.

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Introduction

Deep scalp wounds with the exposure of calvarian bone present the challenge of closing the periosteal defect as the exposed bone presents a very hostile environment for wound healing due to insufficient vascularization. Surgical options, such as grafting and skin substitutes [1, 2], are limited due to the minimal vascularization of the bone surface and therefore usually require removal or drilling holes in the tabula externa [3]. These procedures offer fast solutions, but usually require the patients to be able to undergo anesthesia. Furthermore, they are expensive which is also true for other advanced methods, such as negative pressure wound therapy (NPWT) or collagen matrix. Their use must be weighed against the level of risk and resources available. Healing of wounds with exposed bone by secondary intention is usually very slow and typically involves a moist wound-healing environment [4]. Although traditionally regarded as painful and risking infection, this has not been confirmed in the published literature [5, 6].

A new plant-derived wound therapeutic in spray form available on the Swiss market (1 Primary Wound Dressing® (ONE), Phytoceuticals AG, Zurich, Switzerland) was evaluated in our clinic on postoperative scalp wounds with exposed bone. The spray consists of a mixture of hypericum oil (*Hypericum perforatum* L.) and neem oil (*Azadirachta indica* A. Juss.), designed to create a moist wound-healing environment, with an oil layer preventing the secondary dressing from adhering to the wound. It is thought to have an antimicrobial effect [7]. Its spray application, providing easy use by patients as well as clinicians, and its action of supporting the appropriate moisture balance of the wound suggest it as a useful alternative to existing treatments.

An initial retrospective study [8] was carried out on 9 outpatients with postoperative scalp wounds with exposed calvarian bone following excision of skin tumors, at the Department of Dermatology of the University Hospital of Zurich, Switzerland, from January to July 2011. The promising results with fast induction of granulation tissue led to interest in a larger series and a more detailed analysis of the costs involved with different treatment modalities.

Methods

A retrospective review was performed on all patients with postoperative scalp wounds with exposed calvarian bone following excision of skin tumors, at the Department of Dermatology of the University Hospital of Zurich, Switzerland, from January to December 2011.

All wounds had initially been treated with a split thickness skin graft which did not take due to insufficient blood supply after removal of the periosteum or desiccation of the tissue in the healing process. Once the exposed bone was apparent in the healing process, the wounds were managed with the wound dressing (ONE), applied daily on the wound and periwound skin. Saline solution was used in 8% of dressing changes; no other antiseptic was applied. The wound and periwound skin was then covered with a nonwoven gauze (Vliwasoft®, Lohmann and Rauscher, Neuwied, Germany) or an absorbent dressing (Primapore, Smith and Nephew, Hamburg, Germany). The choice of the secondary dressing was based on the moisture levels of the wound. Necrotic and fibrinous tissue was removed with a curette or tweezers and scissors.

Treatment with ONE was maintained up to complete closure of the wound which was defined as 100% epithelialization. The treatment period was defined as the time between the first application of the dressing and complete wound closure. All of the patients provided informed consent for their data to be submitted for publication.

Each patient attended the outpatient clinic at least once every 2 weeks to have the wound checked and dressed by the clinic nurse. Daily dressing changes were carried out at the patients' homes, either by a family member or a community nurse. Before starting treatment and at each visit to the outpatient clinic, the wound was photographed, and the wound surface area and surface area of exposed bone were measured from the photographs using special software (synedra View). At each follow-up visit, pain, clinical side effects, and signs of infection were recorded.

Material and labor costs were assessed retrospectively by recording from the clinic's patient notes, in particular the materials used at dressing change, the number of clinic visits made, and the time taken to perform the dressing changes. At every clinic visit, patients were asked about the number of dressing changes and time taken for the dressing changes at home. The actual units of ONE used were recorded, and the costs were allocated to each dressing change based on the number of spray discharges per unit as advised by the manufacturer. Labor costs were allocated for clinic visits using the relevant Swiss TARMED tariff and for the home-based dressing changes assuming the labor cost per hour of the community nurse. An average of clinic visits and home dressing changes for all 15 patients was taken from the records.

After wound healing had occurred, patients were followed up with a clinical visit or by telephone in April 2012 to confirm the persistence of healing and the cosmetic outcome as assessed by them. The cosmetic result was not assessed by use of a validated scar or cosmesis scale.

Results

Clinical Outcomes

In the reviewed period, all 15 patients with postoperative scalp wounds with exposed calvarian bone following the excision of skin tumors were treated with ONE. The patients' mean age was 76.87 ± 10.3 years (59–90 years). In 7 patients, the excised tumors were squamous cell carcinomas (SCC), in 6 basal cell carcinomas (BCC). The diagnoses of the remaining 2 patients were lentigo maligna (n = 1) and atypical fibroxanthoma (AFX; n = 1; table 1). All of the wounds were on the scalp. Secondary diagnoses included arterial hypertension (n = 6), allergies (n = 1), and non-skin malignant tumors (n = 2). The mean surface area of the wound on presentation was 10.9 ± 6.84 cm^2 (0.4–22.6 cm^2). All of the wounds had bone exposed, and the mean surface area of exposed bone was 4.8 ± 5.9 cm^2 (0.3–20.7 cm^2). The wounds of all 15 patients were healed by secondary intention with no other intervention (table 1). The mean treatment period until 100% epithelialization of the wounds was 8.1 ± 4.4 weeks (range 4–20 weeks; table 1). The mean reduction in wound surface area after 4 weeks of treatment was 7.6 cm^2, from a mean of 10.9–3.3 cm^2 (a reduction of 70%), and the mean reduction of the surface area of exposed bone was 4.4 cm^2, from a mean of 4.8–0.4 cm^2 (92% reduction; figs. 1 and 2).

Table 1. Summary of patients treated with 1 Primary Wound Dressing (ONE)

No.	Sex/age	Diagnosis	0 weeks		2 weeks		4 weeks		6 weeks		Total treatment period, weeks	Point of follow-up post healing, months
			total wound, cm^2	exposed bone, cm^2	total wound, cm^2	exposed bone, cm^2	total wound, cm^2	exposed bone, cm^2	total wound, cm^2	exposed bone, cm^2		
1	male/63	SCC	17.1	6.9	7.7	0	0	0	0	0	4	3
2	male/90	BCC	13.8	7.9	6.3	0.38	4.5	0	0	0	7	4
3	male/89	AFX	10.2	0.5	8.4	0	0.75	0	0.4	0	10	6
4	male/70	lentigo maligna	16.5	3.4	7.4	1.5	1.5	0	0	0	10	9
5	female/84	BCC	11	3	6.2	0.9	1	0	0.2	0	7	12
6	male/74	SCC	0.4	0.3	0.3	0	0	0	0	0	4	12
7	male/75	SCC	5.9	3.4	4.1	1.9	3.2	0.7	1.5	0	8	2
8	male/86	SCC	16.2	4.9	7.1	1.1	5	0.5	2.8	0	10	1
9	male/59	SCC	5.4	2.1	2.8	0.51	2	0	0.3	0	7	2
10	male/61	BCC	2.5	0.4	1.4	0	0	0	0	0	4	not available
11	male/71	BCC	9.1	1.8	3.5	0	2.5	0	0.9	0	7	7
12	male/85	SCC	8.5	1.2	5.9	0	2	0	0.15	0	6.5	3
13	male/78	BCC	3.5	0.5	0.1	0	0	0	0	0	2.5	not available
14	female/87	BCC	22.6	15.2	21.9	13.2	19.6	0.5	13.8	0	14	6
15	male/81	SCC	21.5	20.7	12.4	9	6.9	4.1	5.6	2.9	20	6

SCC = squamous cell carcinoma; BCC = basal cell carcinoma; AFX = atypical fibroxanthoma.

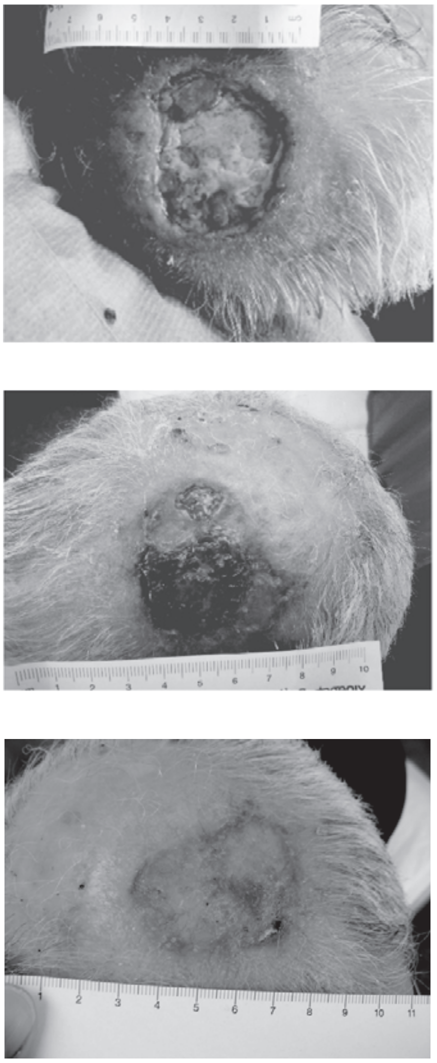

Fig. 1. 63-year-old man with scalp wound after tumor excision with exposed bone following graft failure. Healing process after 3 weeks with granulation tissue covering the bone and after 7 weeks with fully epithelialized wound.

In 7 patients (47% of the sample), the area of exposed bone was completely covered (100%) by granulation tissue after 2 weeks; 6 of these patients had surface areas of exposed bone at the start of treatment < 2 cm^2, but one had a surface area of 6.9 cm^2; this wound bed showed rapid granulation. At 4 weeks, the exposed bone had been completely covered by granulation tissue in 11 patients (73%); the remaining 4 patients had areas of exposed bone of > 3 cm^2 at the start of treatment.

No patient reported severe pain during the entire treatment period nor were dressing changes reported to be painful. No wound was assessed as showing clinical symptoms of superficial or deep infection. None of the patients showed signs of allergic reactions, and no other side effects were observed. Patients came for a follow-up visit in April/May 2012 or could be contacted by telephone. All of them confirmed persistence of healing and none reported problems or wound dehiscence. One patient reported slight itching at the wound site and one an occasional slight feeling of tension in the scar. All patients reported a satisfactory cosmetic outcome of treatment with ONE.

Table 2. Average cost of care with dressing changes at home performed by community nurse

At outpatient clinic – dressing change performed by clinic nurse	
Average time for dressing change in the outpatient Clinic, min	10
Cost per min, CHF	2.4
Labor costs for each dressing change, CHF	24
Cost of ONE per dressing change, CHF	3.0
Total costs per dressing change in the outpatients clinic, CHF	27
At home – dressing change performed by community nurse	
Average time for dressing change, min	5
Cost per min, CHF	2.2
Labor costs for each dressing change, CHF	11
Cost of ONE per dressing change, CHF	3.0
Primapore Dressing (7.5 × 5)	0.5
Total costs per dressing change at home, CHF	14.5
Average number of dressing changes at the hospital	8
Average number of dressing changes at home	51.4
Total cost of average wound management, CHF	961.9

Table 3. Average cost of care with dressing changes at home performed by family member

Average number of dressing changes in the hospital (USZ)	8
Average number of dressing changes at home	51.4
Calculation of total costs (hospital costs 8 changes × CHF 27)	216.0
Home costs (materials only – no labor)	
ONE, CHF	3
Primapore Plaster, CHF	0.5
Total materials, CHF (3.5 × 51.4 changes)	179.90
Total costs of average wound management, CHF	395.90

USZ = University Hospital Zurich

Costs of Treatment

On the average, there were 8 visits to the outpatient clinic and thus just as much dressing changes. The average number of dressing changes taking place at home was 51.4. 12 patients (80%) had home dressing changes carried out by a family member and 3 patients by a community nurse. Costs were allocated to the time of the community nurse but not to that of the family member. The tariff for labor costs at the outpatient clinic included items with a unit price < CHF 3 (EUR ca. 2.50), such as gloves, sterilization of instruments, cotton swabs, and simple secondary dressing.

The total mean per capita cost for treatment with ONE at the outpatient clinic and for dressing changes carried out by the community nurse at home was CHF 961.90 (EUR ca. 800) and for treatment by the outpatient clinic with home dressing changes done by a family member CHF 395.90 (EUR ca. 330). This gave a range of average weekly costs of EUR 40.70–98.80 per capita (see table 2 and 3 for explanation of the calculation of costs).

The total cost for all 15 patients was calculated by adding the total cost for the 3 patients who had dressings changed by nurses both at the outpatient clinic and at home, and the total costs for the 12 patients who had dressings changed by nurses at the outpatient clinic, but by family members at home. This total was then divided by the total number of patients to arrive at the mean per capita cost shown in table 4.

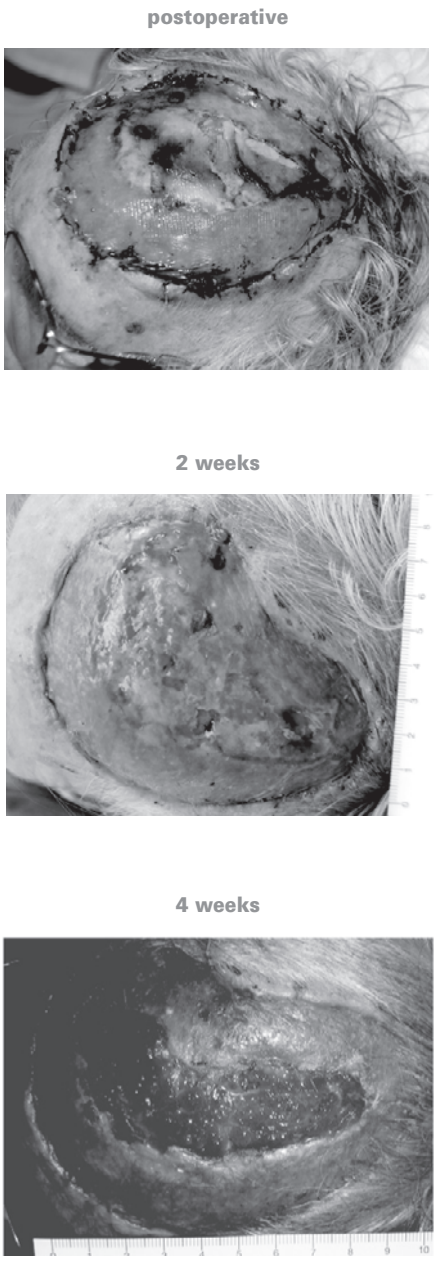

Fig. 2. 90-year-old man with scalp wound after tumor excision with exposed bone following graft failure. Healing process after 2 weeks with some granulation visible on the bone, and after 4 weeks with the entire bone surface covered by granulation tissue.

Table 4. Comparison of reported costs of wound bed preparation and closure with grafting as reported by Inhoff et al [9] with costs associated with wound bed preparation and closure under treatment with ONE

	Fascia lata	Vacuum-assisted closure	Collagen matrix	ONE
Patients, N	5	14	33	15
Mean length of outpatient care after tumor excision, days	48.1	34.7	21.4	56.7
Mean outpatient dressing changes, n	15.3	10.7	6.1	8 at clinic 51.4 at home by family member or community nurse
Mean cost of outpatient dressing changes, EUR	230.73	2,989.42	72.95	423.73*
Mean length of second hospitalization for grafting, days	5.2	5.3	5.3	0 (no graft carried out)
Mean cost of hospitalization, EUR	1,222.68	1,246.19	1,246.19	0
Mean surgical cost, EUR	159.41	176.19	184.58	0
Mean duration of treatment after tumor excision, days	53.3	40	26.7	56.7
Mean total cost, EUR	1,612.82	4,411.80	1,503.72	423.73
Mean total cost per day, EUR	30.26	110.30	56.32	7.47

*12 patients had home dressing changes carried out by family members and 3 by community nurses.

Comparison with a Historical Review of Costs Associated with the Use of Alternative Therapies for Closing Complex Scalp Wounds

The costs derived from the retrospective study were compared with costs reported by Inhoff et al. [9], which were associated with the coverage of exposed bone achieved by infilling with fascia lata, NPWT, or a collagen matrix dressing prior to final grafting. Inhoff et al. reviewed 52 cases treated at the Dermatology Department of the University Hospital of Mannheim, Germany, with a 2-stage process of tumor excision, conditioning of the wound bed to promote granulation in preparation for grafting, and then grafting. After tumor excision, 5 wounds were treated with processed allogenic fascia lata, 14 with NPWT, and 33 with a collagen matrix. The mean costs per wound reported for these procedures for the preparation of the wound bed were compared with the mean costs of our current study. Inhoff et al. did neither report the individual wound surface areas nor the individual areas of exposed bone, so no comparison could be made with the cost to achieve granulation. Inhoff et al. also did not report the incidence of infection or other complications (table 4).

Discussion

In the treatment of scalp wounds, exposure of the calvarian bone presents particular challenges [6]. Speedy closure with a flap and/or skin graft is commonly considered the preferred treatment [10], although this may involve problems arising from donor site mobility, duration of the surgical procedure, and later on absence of hair regrowth, especially in free flap reconstruction. Skin grafts require a vascularized wound bed which, in case of exposed bone, usually requires drilling holes or removing the tabula externa of the calvarian bone. The latter usually requires general anesthesia.

NPWT may be used to support secondary intention healing or graft take [11–13]. Tissue-engineered skin substitutes offer fast cover of scalp wounds, but also require a vascularized wound bed [14]. Both interventions are expensive and may have limited availability in such patients.

Secondary intention healing has been considered to be painful, risking a high infection rate and requiring extensive care, but this is not substantiated in literature. Comorbidities or side effects of oncologic treatments may further delay tissue regeneration. Inhoff et al [9] comment that healing by secondary intention implies a longer treatment duration and thus greater discomfort for the patient. Furthermore, the authors state that at a cost of about EUR 70 per week, any advantage due to savings on expensive materials (fascia lata, Integra, vacuum-assisted closure) is lost.

Contrary to the comments above, the extension of our case series by 6 patients to a total of 15 supports that secondary intention healing does not inevitably entail infection, pain, or unsatisfactory cosmetic results. None of the 15 patients had clinical signs of infection and none of them reported severe pain. The weekly checks at the outpatient clinic gave the opportunity for visual checking of tumor recurrence. By week 2, areas of exposed bone in 7 of 15 (47%) patients had already been covered by granulation tissue, thus significantly and quickly reducing the risk of complications in the bone, with areas of exposed bone fully covered in 11 of 15 (73%) cases by week 4. The use of ONE therefore contributed to a significant reduction of risk for the studied cohort, and avoided further scarring of donor sites requiring flap or skin-graft techniques. Paucity of infectious complications is also reflected in the literature. For instance, Becker et al. [5] reported no infection in

38 cases, and Snow et al. [6] assessed a very low rate of soft tissue infection (2.7%) in 115 cases. The patients' responses to the telephone survey indicated satisfaction with the cosmetic results. This is also supported by the literature [15]. Gohari et al. [16] compared secondary intention healing with the use of tissue-engineered skin substitutes and showed patient satisfaction with cosmetic outcome, equally positive in both groups.

The present review of 15 patients continues to support that the plant-derived wound dressing ONE is a powerful aid to the healing process of post-surgical scalp wounds with exposed bone. In 11 of 15 patients (73%), the bone was completely covered by granulation tissue after 4 weeks of treatment, and 6 of these wounds were epithelialized after 6 weeks. With the exception of one patient whose complete wound coverage took 20 weeks, there seems to be a clear trend to shorter healing times as compared to the published literature, with the formation of granulation tissue over exposed bone in 14 of 15 cases within 6 weeks, and a mean healing time of 8.1 weeks. Direct comparison of healing times with other studies is difficult, as methodology and patient populations vary, but there seems to be a trend towards longer healing times with other modalities, such as 13 weeks for scalp wounds with exposed bone with a simple wound care regimen of hydrogen peroxide and antibiotic ointment [5].

The use of ONE enables family members to perform dressing changes simply and safely, indicating the potential for significant savings (at a cost of EUR 52 per week using ONE versus EUR 70 per week for secondary intention healing, or EUR 394.24 per week for healing with a collagen matrix followed by grafting [9]). Comparison of costs among different health care systems is difficult. However, it seems appropriate to use the figures of the German study by Inhoff et al. [9], as the health care systems and costs of living in Switzerland and Germany seem sufficiently similar, with costs in Switzerland being typically higher than in Germany. The trend shown in our figures with average total costs to healing using ONE of EUR 423.73, as compared to EUR 1,503.72–4,411.80 using advanced methods such as NPWT or skin substitutes, indicates a substantial potential for cost saving in this patient population.

Limitations

The study includes only a small number of patients recruited from a single center with data analyzed retrospectively. Cosmetic outcomes were not assessed visually using a recognized validated tool, and follow-up took place with a random distribution of time since wound closure. Full data on wound surface area and speed of granulation over bone was not available from the study by Inhoff et al. [9], so that only an illustration of comparative cost could be made. Even if indirect comparison with published data on the management and costs of wound treatments can only give a general indication of comparative benefit, the characteristics of the wounds included in this study are similar to those reported in other published trials. Thus it can be concluded that the results compare favorably, both clinically and economically, with those from the literature.

Conclusion

The results of this extended retrospective review continue to indicate that the plant-derived wound spray ONE is clinically effective for scalp wounds which show exposed bone, and that it may represent a cost-effective alternative to other treatment options. Controlled studies, with a larger population, are still required to further assess the effectiveness and economy of this wound spray.

Disclosure Statement

The authors declare that there is no conflict of interests concerning this paper.

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