1 Primary Wound Dressing®: clinical experience

A novel wound dressing, formulated from natural oils, promotes effective healing, protects periwound skin and leads to an impressive induction of granulation tissue, even in deep wounds

Severin Läuchli
University Hospital Zurich, Switzerland
President, Swiss Association for Wound Care (SAfW)

In 2011, a novel natural primary wound dressing (1 Primary Wound Dressing®; Phytoceuticals) based on Neem oil and St John's Wort oil was introduced to the Swiss wound care market. In India, the Neem tree is one of the most important plants used in traditional medicine and is sometimes referred to as 'Sacred Tree' because all parts of the plant are used for the treatment of a variety of diseases. St John's Wort plays a central role in Western traditional medicine and is widely known as a herbal treatment for depression (a different extract of the plant is used in the 1 Primary Wound Dressing®). This novel, innovative product has received a CE Mark in the European Union.

Mode of action

The wound healing effects are brought about by the oil film that is created on the wound and the surrounding skin and the fatty acids present in the oil. The product:

- exerts an antimicrobial effect
- protects the skin and supports a healthy skin barrier function and
- enables a balanced moist environment obtained by the semi-occlusive layer the oil layer creates.

Cell proliferation is activated and despite the moist environment bacterial load remains under control because of the antimicrobial effect. In addition the oil layer prevents the secondary dressing from adhering to the wound, thereby preventing damage to the granulation tissue during dressing changes, which leads to improved epithelisation and reduced pain.

Table 1: Hospitals participating in the case reports

Hospital	Location
University Hospital Zurich	Zurich
Bern University Hospital	Bern
University Hospital Basel	Basel
Aarau Cantonal Hospital	Aarau
Bellevue Veins clinic	Kreuzlingen
Waid City Hospital	Zürich
Laufen Cantonal Hospital	Laufen
Nursing Home Eichhof	Luzern

Clinical experience

Clinicians and wound experts from a number of Swiss hospitals generated 105 case reports from patients who had been treated with the novel wound therapeutic (Tables 1 and 2). The 105 cases are divided into 37 acute and 68 chronic wounds with an average patient age of 70 years (female: 51 years; male: 54 years; standard deviation ±16). The patients had the typical concomitant diseases associated with their age and primary diagnoses. Table 3 summarises the important parameters for the three most prevalent types of wound in the case studies.

Table 2: Summary of the case reports

Wound type	Number of cases
Postsurgical wounds	25
Ulcus cruris	30
Decubitus	19
Trauma	7
Diabetic foot ulcer	4
Other	20[1]

[1]*Parchment skin = 3; fibrin removal = 3; wound dehiscence = 2; EB simplex = 1; other = 11*

"Wound healing is brought about by the oil film and fatty acids"

Results

Treatment duration and wound closure

- The average previous treatment duration was five months
- The average treatment duration with 1 Primary Wound Dressing® was two months
- The treatment with 1 Primary Wound Dressing® led to wound closure in 63 of 105 patients (acute: 31, chronic: 32). By the time of the evaluation the treatment of nine cases was still ongoing. The treatment did not result in wound closure in 24 cases over a treatment period of up to 12 weeks.

Table 3: Important parameters for the three most prevalent wound types of the survey

	Postsurgical wounds	Ulcus cruris	Decubitus
Number of cases	25	30	19
Age (years)[1]	69 ± 17	72 ± 14	79 ± 10
Previous treatment duration (days)[1]	23 ± 34	236 ± 125[2]	116 ± 111[2]
Treatment duration with 1 Primary Wound Dressing® (days)[1]	47 ± 33	68 ± 40	80 ± 49[3]
Cases with wound closure	20[4]	10[5]	15[6]
Cases with accelerated granulation if compared with the clinical experience of the treating specialist	16 (64%)[7]	11 (37%)	17 (89%)
Cases with a reduction of the macerated wound area after 50% of treatment	0/0	4/6	2/3
Cases with pain reduction of > 50% after one week's treatment	1/10[8]	9/18	10/16
Adherence of secondary dressing	2	4	0

[1] *Average and standard deviation*

[2] *Limitation of previous treatment duration to maximum of one year for the cases with a value > one year*

[3] *One extreme case with a treatment duration of 300 days was not included in the calculation*

[4] *By the time of the evaluation the treatment of four cases was still ongoing. The treatment was terminated in one case owing to a possible allergic reaction*

[5] *By the time of the evaluation the treatment of four cases was ongoing. The treatment did not result in wound closure in nine cases and was stopped in seven cases for different reasons (pain, surgical intervention, possible allergic reaction)*

[6] *By the time of the evaluation the treatment of one case was still ongoing. The treatment did not result in wound closure in one case. Two patients died during the treatment (unconnected to the therapy)*

[7] *Data are missing for nine cases*

[8] *Five of 10 patients had initial pain of >2 (scale: 1–10)*

The treatment was stopped in seven cases because of different reasons (pain, surgical intervention, possible allergic reaction). Two patients died during the course of treatment (no connection to therapy).

Granulation

- The wound care specialists carrying out the evaluations noted that in 57 of 105 cases (54%) the granulation phase was induced faster than what they would have expected from their clinical experience. Granulation was induced fastest in postsurgical wounds (64%) and decubitus (89%).
- Of particular note is a series of nine scalp wounds with exposed bone following skin tumour excision. Treating this type of wound is very challenging because they have no, or only very slow formation of, granulation tissue and are often impossible to heal by secondary intention. The Department of Dermatology of the University Hospital Zurich successfully treated scalp wounds with exposed bone in nine patients after tumour excision with 1 Primary Wound Dressing® (see Box 1). The results confirm the positive effect 1 Primary Wound Dressing® has on the induction of granulation tissue.

Maceration of the periwound skin

- At treatment start the periwound skin of 12.3% (13/105) of wounds were macerated
- After 50% of treatment the periwound skin of 4% (4/105) of all wounds were macerated; this equates to a reduction of 70%
- A total of 90 wounds did not macerate during the treatment.

Fibrin

- The removal of fibrin slough from the wound bed is a serious challenge because it can be a painful experience for the patient or it can delay wound healing because granulation tissue might be damaged. The application of 1 Primary Wound Dressing® may positively support the removal of fibrin slough. This was tested in three cases (ulcus cruris) where a reduction of fibrin slough of 80% was observed within the first three days of treatment. 1 Primary Wound Dressing® was applied daily and no additional debridement methods were performed.

Adherence of the secondary dressing

- In 96 cases dressing changes were carried out without complications. In 7 of 105 cases the secondary dressing did adhere to the wound. The reasons for adhering were a smaller amount of 1 Primary Wound Dressing® applied and longer intervals between dressing changes than recommended by the manufacturer. Data were absent for two cases.

Adverse reactions

No serious adverse reactions associated with 1 Primary Wound Dressing® were observed in 102 cases (98%). An allergic reaction to

Table 4: Summary of the observed pain reductions experienced with 1 Primary Wound Dressing®

	Number of patients with pain at treatment start	Number of patients with a pain reduction of > 50% after one week of treatment	Number of patients with pain at end of treatment
All 105 cases	65	38 (-42%)	30 (-54%)
Postsurgical wounds	10[1]	9 (-10%)	8 (-20%)
Ulcus cruris	18	9 (-50%)	9 (-50%)
Decubitus	16	6 (-63%)	3 (-83%)

[1] *Five of 10 patients had initial pain of >2 (scale: 1–10)*

Box 1: Focused series

Postsurgical scalp wounds with exposed bone

Background

The treatment of scalp wounds with exposed bone is very challenging. Current conservative treatment options involve moist wound care and additional advanced wound care interventions. Bioengineered skin substitutes or surgical interventions often become necessary when conservative treatment options do not lead to satisfying results. The purpose of this retrospective non-controlled analysis was to evaluate the effectiveness of 1 Primary Wound Dressing® in scalp wounds with exposed bone following skin tumour excision.

Methods

Nine patients whose soft tissue defects following the excision of skin tumors were treated with 1 Primary Wound Dressing® were analysed retrospectively. No additional treatments were used. Time to healing, percentage of wounds with covered bone after four weeks, ease of handling, pain and incidence of complications were evaluated.

Results

The mean age of the patients studied retrospectively was 81.2 years (range 63–90 years), and the mean size of the lesion was 13.2cm^2 (range 0.4–22.6cm^2) for the overall wound and 6.8cm^2 (range 0.3–20.7cm^2) for the exposed bone area.
The postoperative scalp wounds of all patients treated with 1 Primary Wound Dressing® healed by secondary intention. The time to complete healing ranged from 4 to 20 weeks. Within the first four weeks of treatment impressive effects were observed, notably the rapid induction of granulation tissue which covered the entire exposed bone surface in six out of nine cases after this period of 28 days, and a reduction in the mean area of exposed bone of 95% at day 28. The mean wound area was reduced by 74% within four weeks. Dressing changes were easy, and without pain or complications.

Conclusion

This retrospective non-controlled analysis suggests that 1 Primary Wound Dressing® is a very simple to use, safe and potentially effective therapy for the treatment of scalp wounds with exposed bone. Furthermore, the treatment with 1 Primary Wound Dressing® generates significantly less costs compared to most alternative treatment options for these difficult to treat wounds.

Fig. 1: Wound at treatment start. The wound size is 22.6cm^2 with an exposed bone area of 15.2cm^2.

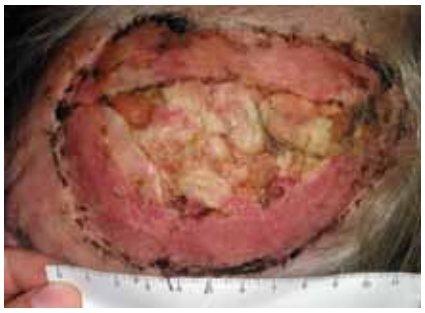

Fig. 2: Wound after two weeks of treatment. The wound size is 21.9cm^2 with an exposed bone area of 13.2cm^2.

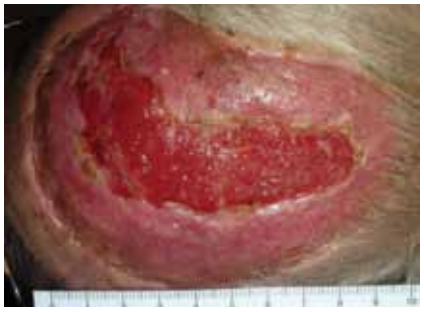

Fig. 3: Wound after three weeks of treatment. The wound size is 19.6cm^2 with an exposed bone area of 0.5cm^2.

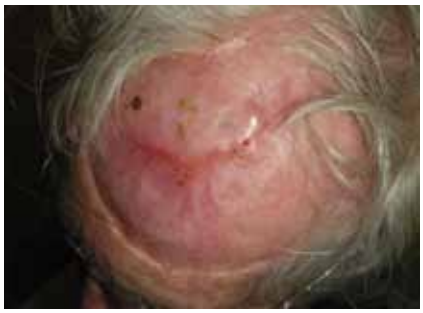

Fig. 4: The wound is completely healed after 14 weeks of treatment.

Figures 1–4 show the treatment of a 22.6cm^2 wound with exposed bone at the vertex after excision of a basal cell carcinoma. Figure 3 shows the same wound after three weeks' treatment with 1 Primary Wound Dressing®. The wound ground is nearly complete, covered with granulation tissue partially reepithelialised. After 14 weeks, 100% of the wound is covered by epithelium.

1 Primary Wound Dressing® was reported in three. All the patients reporting an allergic reaction suffered from multiple allergies.

Pain reduction

Table 4 summarises the observed pain reductions experienced with 1 Primary Wound Dressing®.

Conclusions

Results from extensive case studies in different types of acute and chronic wounds suggest that 1 Primary Wound Dressing® can be used as an effective primary wound dressing that promotes wound healing and protects the periwound skin. 1 Primary Wound Dressing® leads to an impressive induction of granulation tissue, even in very deep wounds. It proved to be simple to use and increases patient comfort greatly. ✦