



## CLINICAL EXPERIENCE INTERIM REPORT 11/2011

In 2011 clinicians and wound experts from different Swiss hospitals generated 105 case reports from patients whom they treated with 1 PRIMARY WOUND DRESSING®. The 105 cases are divided into 37 acute and 68 chronic wounds with an average patient age of 70 years (female: 51, male: 54) and a standard deviation of ±16. The patients had the typical concomitant diseases that go along with their age and primary diagnoses.

WOUND TYPE	CASES
Postsurgical wounds	25
Ulcer cruris	30
Decubitus	19
Trauma	7
Diabetic foot ulcer	4
Other	20 <sup>1</sup>

<sup>1</sup> Parchment skin (3), fibrin removal (3), Wound dehiscence (2), EB simplex (1), other (11)

### IMPORTANT PARAMETERS FOR THE 3 MOST PREVALENT WOUND TYPES OF THIS SURVEY

	Postsurgical wounds	Ulcer cruris	Decubitus
Cases	25	30	19
Age (Years) <sup>1</sup>	69 ± 17	72 ± 14	79 ± 10
Previous treatment duration (Days) <sup>1</sup>	23 ± 34	236 ± 125 <sup>2</sup>	116 ± 111 <sup>2</sup>
Treatment duration with 1 PRIMARY WOUND DRESSING® (Days) <sup>1</sup>	47 ± 33	68 ± 40	80 ± 49 <sup>3</sup>
Cases with wound closure	20 <sup>4</sup>	10 <sup>5</sup>	15 <sup>6</sup>
Cases with accelerated granulation if compared to the clinical experience of the treating specialist	16 (64%) <sup>7</sup>	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 1 week treatment	1/10 <sup>8</sup>	9/18	10/16
Adherence of secondary dressing	2	4	0

<sup>1</sup> Average and standard deviation

<sup>2</sup> Limitation of previous treatment duration to max. 1 year for the cases with a value > 1 year

<sup>3</sup> 1 extreme case with a treatment duration of 300 days was not included into the calculation

<sup>4</sup> By the time of the evaluation the treatment of 4 cases was still ongoing. The treatment was stopped in 1 case due to a possible allergic reaction

<sup>5</sup> By the time of the evaluation the treatment of 4 cases was still ongoing. The treatment did not result in wound closure in 9 cases and it was stopped in 7 cases due to different reasons (pain, surgical intervention, possible allergic reaction)

<sup>6</sup> By the time of the evaluation the treatment of 1 case was still ongoing. The treatment did not result in wound closure in 1 case. 2 patients died during the treatment (no connection to the therapy)

<sup>7</sup> Data is missing for 9 cases

<sup>8</sup> 5 of 10 patients had initial pain of >2 (scale: 1-10)

## CONCLUSIONS

### TREATMENT DURATION AND WOUND CLOSURE

- The average previous treatment duration was 5 months.
- The average treatment duration with 1 PRIMARY WOUND DRESSING® was 2 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 9 cases was still ongoing. The treatment did not result in wound closure in 24 cases over a treatment period of up to 12 weeks. The treatment was stopped in 7 cases due to different reasons (pain, surgical intervention, possible allergic reaction). 2 patients died during the course of treatment (no connection to therapy).

#### Institutions that performed treatments with 1 PRIMARY WOUND DRESSING®:

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

## 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 the fastest in postsurgical wounds (64%) and decubitus (89%).
- Of particular note is a series of 13 scalp wounds with exposed bone following skin tumor excision. The treatment of such wounds is very challenging as they show no or only very slow formation of granulation tissue and are often impossible to heal by secondary intention. Dr. Severin Läubli from the University Hospital Zurich successfully treated the scalp wounds with exposed bone of 13 patients after tumor excision with 1 PRIMARY WOUND DRESSING® (publication under preparation). The results confirm the positive effect 1 PRIMARY WOUND DRESSING® has on the induction of granulation tissue.

### Prof. Dr. Thomas Hunziker, M.D.

Dermatologist

University Hospital Bern, Switzerland

④ creates a moist wound environment. The oil layer prevents the secondary dressing from adhering to the wound. These are minimal requirements a modern wound product has to meet. Furthermore, ④ has an antimicrobial effect and promotes the regeneration of the epidermis. These effects clearly make ④ a modern and convincing wound product of your first choice.

## MACERATION OF THE PERIWOUND SKIN

- At treatment start the periwound skin of 12,3% (13/105) of all wounds were macerated.
- After 50% of treatment the periwound skin of 4% (4/105) of all wounds were macerated. This equals a reduction of 70%.
- 90 wounds did not macerate during the treatment.

## PAIN REDUCTION

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

<sup>1</sup> 5 of 10 patients had initial pain of >2 (scale: 1-10)

## FIBRIN

- The removal of fibrin slough from the wound bed is a serious challenge as it can become a painful experience for the patient or delay wound healing because granulation tissue may be damaged. The application of 1 PRIMARY WOUND DRESSING® may positively support the removal of fibrin slough. This was tested in 3 cases (ulcus cruris) where a reduction of fibrin slough of 80% was observed within the first 3 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 Phytoceuticals. Data was missing for 2 cases.

## ADVERSE REACTIONS

- No serious adverse reactions associated with 1 PRIMARY WOUND DRESSING® were observed in 102 cases (98%). An allergic reaction to 1 PRIMARY WOUND DRESSING® was reported in 3 cases. All the patients reporting an allergic reaction suffered from multiple allergies.

### Dr. Severin Läubli, M.D.

Dermatologist

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Results in various types of acute and chronic wounds suggest that ④ can be used as an effective primary wound dressing that promotes wound healing and protects the periwound skin. The use of ④ led to an impressive induction of granulation tissue, even in very deep wounds. ④ clearly has its finger on the pulse of understanding the cost and time pressure of the wound care industry.