Non-healing wounds under community care successfully managed with a simple to use natural oil-based spray dressing.

A review of heterogenous case studies of non-healing wounds.

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Abstract:

Objective: To evaluate the efficacy of a plant-derived wound dressing (1 Primary Wound Dressing "ONE", Phytoceuticals Ltd.) from the clinicians' perspective on complex and /or non-healing wounds.

Method: Retrospective report by clinicians on complex and/or non-healing wounds selected by themselves in the normal course of care. Time to healing, ease of use, pain, peri-wound skin and complications were evaluated.

Results: Fifteen wounds of various aetiologies (on fifteen patients), were managed with ONE and a secondary (non-interactive) dressing appropriate to the wound condition. The patients' mean age was 64.8 (38-90 years) with thirteen wounds having a duration of between 60 days and 10 years, whilst two wounds, one post operative and one a gangrenous diabetic foot ulcer had duration of only 7 days. Six of the wounds healed in a period ranging from 25 to 56 days, the remaining nine did not heal but reduced in wound area from between 22% to 98% of their original size on commencement of treatment. No incident of maceration during the use of ONE was reported. Ten out of fifteen wounds had healthy wound edges at the close of treatment with ONE. Twelve patients under the prior dressing regime reported pain; six recorded decreasing pain scores during the treatment. Dressing change was easy and without pain and there were no complications.

Conclusion: ONE has a place in the healthcare practitioners portfolio as a simple and easy to use topical wound dressing which may offer a cost-effective and safe treatment option for complex and /or, non-healing wounds. Further structured research is warranted to confirm the clinical and economic efficacy of ONE for these wounds.

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The care of hard-to-heal wounds has long been acknowledged to be problematic (EWMA, 2008); with evidence from the literature regarding variations in wound care practice, which compound the problem (Harding, 2000). This may be due to a combination of resource and treatment-related factors as well as the skills and knowledge of the healthcare professional. Ousey and Shorney (2009) remind us that appropriate

selection of treatment based on the underlying cause and condition of the wound, together with accurate documentation are indicators of quality of care.

A vital component of wound management is an understanding of the patient's physical (such as underlying pathology, comorbidities etc.,), psychological and social factors. Patient comfort and acceptability of a treatment regimen are important factors when determining the success or otherwise of the regimen and in optimising their wellbeing (International Consensus, 2012). If none of these factors are considered the result can be wounds, simple in origin remaining open for protracted periods of time to the resultant distress of the patient and cost to the health service.

The fifteen cases outlined are of patients with wounds of different aetiologies but sharing the common factors of having complex co-morbidities and /or old age, of being cared for in a community setting and their wounds being considered to be complex or non-healing, i.e. not showing signs of progressing to healing [EWMA 2008]. The duration of the wounds ranged from seven days to ten years. All of the wounds had been managed in the community using a selection of modern wound dressings including foams, hydrocolloids, hydrofibres. The community healthcare professionals caring for these cases reported retrospectively on their experience using "1 Primary Wound Dressing" ("ONE"), a wound spray consisting of a specially formulated mixture of Hypericum oil (*Hypericum perforatum*) and Neem oil (*Azadirachta indica*). In eight cases the spray was applied daily, in four cases 2- 3 times a week on the wound and the periwound skin and in three the frequency of dressing change was not recorded.

The wound and periwound skin was then covered in thirteen of the cases with a simple non-interactive secondary dressing (i.e., non-woven gauze or absorbent pad). The choice of the secondary dressing was based on the amount of wound exudate present. ONE was supplied free of charge by the manufacturer. A qualified wound care specialist employed by the manufacturer interviewed the healthcare professionals caring for these patients. They reported on its ease of use with no reports of pain at wound dressing change (often the most common trigger for pain in chronic wounds (Meaume et al, 2004)), or problems with periwound skin resulting from the dressing.

A total of nine wounds closed under treatment with ONE; Six healed (fully epithelialised) at 25 to 56 days from the first application of ONE (see Table 1). In three cases a Leg Ulcer, Burn and Donor site (items 3, 4, & 5 in Table 1 below) the healthcare professionals reported that granulation formed faster than they had expected. Three others healed between 71 to 87 days. Figures 1 and 2 show healing of a venous leg ulcer on a 38 year old female (case 14 in Table 1) with a history of recurrent ulceration.

Fig 1: Start of treatment

Fig 2: Healed ulcer

Of the remaining six, two patients died before wound closure occurred, wound area decreased in the other four to between 22% to 98% of their original size at the outset of treatment, but treatment with ONE was

discontinued (reasons given in Table 1 below). A 70-year-old gentleman with a history of diabetes and concomitant gangrene presented with a large ulcer on the plantar aspect of his foot (See Figure 3), this responded to treatment and healed at 71 days from start of treatment (See Figure 4).

Figure 3. Diabetic Ulcer

Figure 4. Healed Ulcer

When considering the use of an oil-based dressing the healthcare professional may have the concern that the dressing will negatively affect the exudate management of the wound increasing the risk of maceration to the peri-wound skin. No incidents of maceration were reported during the use of ONE in these cases and in ten cases the peri-wound skin was observed to be healthy (see Table 2).

Table 1. Patient Data, duration of the wound before the use of "1" and dressings used, time to healing.

Item	Wound aetiology	Gender/ Age	Underlying pathology	Duration of wound	Dressings used previously	Days of Treatment with ONE to wound closure	Frequency of application. Secondary dressing used
1	**Biopsy (Prurigo Modularis)**	F/ 62	Diabetes mellitus II	60 Days	Betadine Elocom Fucicort	28	Daily Gauze pad
2	**Trauma -Leg**	M/40	CVI	180 Days	Adaptic	50	Daily Adaptic
3	**Undetermined Aetiology Leg Ulcer**	F/ n.a.	Arterial hypertension CVI	210 Days	Aquacel Varihesive Excipial (wound edge) Compression Stocking	50	2-3 x week Gauze pad
4	**Burn on leg**	F/65	Hypertension Dementia Immobile	240 Days	Adaptic Excipial (wound edge)	30	Daily Gauze pad Pressure relief
5	**Non-healing graft donor site**	F/89	Diabetes Mell II Arterial Hypertension	180 Days	Not available	25	Daily Gauze pad
6	**Suture dehiscence after amputation**	M/80	None	105 Days	Medical Honey	56	Daily Gauze pad
7	**Mixed aetiology leg ulcer (2 wounds)**	F/56	CVI, microangiopathy	165 Days	Foam Hydrocolloid	40 days Objective of – to healthy wound bed achieved. 34% area reduction	3 x week Silver x 1 dressing Thereafter Gauze pad
8	**Post –operative wound elbow**	F/90	None	7 Days	Mepitel One + zinc crème & compress	36 days – 92% reduction patient died before wound healed	n/a Ringer's solution Gauze pad
9	**Mixed aetiology leg ulcers (3) after femur fracture**	F/64	Cachexia PAD Undernourished	>2years	Allevyn Foam Aquacel Multiple surgical debridement	20 days -84% reduction in wound area – dressing changed by Family Doctor to hydrofibre	Daily Gauze pad Aquacel for last 7 days
10	**Venous leg ulcer – Post thrombotic syndrome**	M/72	Gout Gonarthritis urica	5 years	Polymem Short stretch compression	200 days – wound not closed but epithelialising 64% reduction in area at close of observation	n/a Gauze pad
11	**Gangrenous Foot ulcer**	M/70	Diabetes	7 Days	Not available	71 days – healed	Daily Gauze pad
12	**Venous leg ulcers (2)**	F/49	None stated Recurrent ulceration	10 Years	Hydrocolloid Calcium alginate Compression	203 days to 27% granulation. Treatment with "1" stopped due to non-responsiveness of	Daily Gauze pad

						wound	
13	**Mixed aetiology leg ulcers (3)**	M/67	None stated Recurrent ulceration	262 Days	Hydrocolloid Calcium alginate	71 days- to healthy wound bed 37% area reduction – died before wound healed	2 x week Gauze pad
14	**Venous leg ulcer**	F/38	None stated Recurrent ulceration	535 Days	Foam Hydrocolloid Silver Compression	87 days – healed	2 x week Gauze pad
15	**Dehiscence post amputation**	M/66	Diabetes Gangrene	35 Days	Inadine	85 days – healed	N/a

Table 2. Condition of the Wound edge and peri-wound skin.

	At start of Treatment with ONE			**At close of treatment with ONE**		
Wound aetiology	**Condition of wound edge**	**Condition of peri-wound skin**	**Pain score (1-10)**	**Wound Edge**	**Peri-wound skin**	**Pain score (1-10)**
Biopsy due to Prurigo Modularis	Data not available	Data not available	Yes (no score given)	Healthy	Healthy	No pain
Trauma –Leg ulcer	Data not available	Data not available	Yes (no score given)	Healthy	Healthy	Yes (no score given)
Undetermined Aetiology Leg Ulcer	Data not available	Data not available	Data not available	Healthy	Healthy	No pain
Burn on leg	Data not available	Data not available	Data not available	Healthy	Healthy	No pain
Non-healing graft donor site	Data not available	Data not available	Yes (no score given)	Healthy	Healthy	No pain
Suture dehiscence after amputation	Macerated	Macerated	Yes (no score given)	Healthy	Healthy	No pain
Mixed aetiology leg ulcer (2 wounds)	Erythema, necrosis	Erythema, dry	9	Healthy	Healthy	3
Post –operative wound elbow	Macerated	Macerated	1	Healthy	Healthy	1
Mixed aetiology leg ulcers (3) after femur fracture	Dry	Hyperkeratosis	2-3	No data	Dry	1
Venous leg ulcer – Post thrombotic syndrome	Macerated	Macerated	Yes (no score given)	Healthy	Healthy	No pain
Gangrenous foot ulcer	Data not available	Macerated	1	Dry	Healthy	No pain
Venous leg ulcers (2)	Dry	Inflamed	2	Weeping	Inflamed	2
Mixed aetiology leg ulcers (3)	Dry	Inflamed	4	Dry	Weeping	3
Venous leg ulcer	Weeping	Hyperkeratosis	Data not available	Healthy	Dry	2
Dehiscence post amputation	Data not available	Necrotic	3	Data not available	Data not available	1

Conclusion: This brief overview of cases reported from the normal practice of community wound care suggests that ONE has a place in the healthcare professional portfolio of dressings as a topical wound therapy simple and quick to use which may offer a cost-effective means of supporting faster wound healing. All of the wounds observed were non-healing and in patients with complex morbidities or extreme age. All had been managed previously with modern wound dressings.

Phytoceuticals Ltd, the manufacturer of ONE is carrying out structured case studies and audits in community and hospital care settings to collect validated data on the clinical and economic benefits of using ONE.

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