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Treatment of chronic wounds using a semipermeable hydroactive wound dressing

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Summary: Chronic wounds are an increasing challenge for medicine and society. Treatment optimization aims to improve therapeutic and cost efficacy, compliance and tolerability. In an open, prospective trial 26 patients (mean age 69 years) with leg ulcers caused by chronic venous insufficiency (13), postthrombotic syndrome (9) or other causes (Diabetes mellitus, ulcerated scar, peripheral arterial occlusion disease – one patient each) were treated with a non-occlusive hydroactive wound dressing (Askina Transorbent®) for 6 weeks or until complete healing. Wound area (cm^2), granulation, necrosis and fibrin coverage (4-point score) were analyzed. Side effects were recorded. We noticed 5 drop outs (3 because of non-compliance, 1 because of pain, 1 because of hypergranulation). In the remaining 21 patients wound area was reduced from 11.2 cm^2 to 2.4 cm^2. Eleven patients showed complete healing, 9 a more than 50% reduction of wound area, 1 patient had a reduction of wound area of less than 50%. Those patients with an incomplete healing on average had a wound area twice as large as complete responders. Granulation markedly increased during the first two weeks of treatment (1.8 vs. 4.0 score points). The fibrin coverage continously decreased during the first 5 weeks (1.0 vs. 0.2 score points). Neither leakages, dermatitis nor maceration of the perilesional skin were observed. No signs of disintegration of the dressing were found. Antibiotics were not used. The ulcer treatment with Askina Transorbent® is effective, safe and easily combinable with compression bandages.

Introduction

Chronic wounds represent one of the biggest problems in the public health services in the industrial states. In Great Britain alone the annual cost for ulcer treatment is reckoned to be 450-500 million British pounds (Anonymous 1994). For those affected, it is above all the impairment of quality of life due to lower leg ulcers which is of primary importance (Creutzig et al. 1997; Wollina 1998a).

The prognosis for venous leg ulcers is determined by the initial size, the duration of the ulceration and by age. Patients with post-thrombotic syndrome exhibit a less favourable prognosis overall for complete healing (Skene et al. 1992).

Local treatment of chronic wounds has undergone a fundamental change over the past two decades. Following Winter's experimental work in animals which was able to show that a moist environment represents a basic prerequisite for optimum wound healing (Winter 1962; Winter and Scales 1963), numerous products in various product classes have been developed (Wollina 1997) since the introduction of the first synthetic wound coverings.

Semi-occlusive transparent dressings and hydrocolloid dressings were the first commercially available representatives of a new generation of synthetic wound dressings.

A synthesis of the positive quality features of film dressings and hydrocolloids (prevention of infection, moist wound environment, promotion of granulation and epithelial layer regeneration, alleviation of pain) with simultaneous avoidance of certain disadvantages (leakage, insufficient liquid handling, loosening of constituents as in hydrocolloids with the danger of granuloma formation) is the declared aim of new dressing material classes such as alginate and foam polymer dressings. It has been shown in practice that for particular product features, such as for example the fluid handling capacity (rate of water absorption and evaporation) using an appropriate combination of various materials in a composite or laminate dressing the efficacy can be considerably improved. In comparative investigations in vitro as well as in animal experiments the superiority of a non-occlusive

hydroactive wound dressing was shown compared with hydrocolloids regarding biocompatibility, stability and wound closure (Gilbert and Schenk 1989, Gilbert et al., 1990).

Below we will report on our own experience with the clinical use of a semipermeable hydroactive wound dressing in the treatment of chronic venous ulcers and other chronic wounds.

Patients and methods

In a clinical application study, 26 patients with 1 or 2 ulcers of the lower extremities predominantly resulting from venous insufficiency were treated with a semipermeable hydroactive wound dressing (Askina Transorbent®, B. Braun Petzold/Melsungen).

Inclusion criteria were :
- Minimum age 18 years.
- Ulcers with a wound size of between 2 and 80 cm^2, as well as a depth of less than 1 cm.
- Absence of wound infection and slough (i.e. <25% of the wound surface covered).
- Sufficient nutrition of the patient is ensured.
- Verbal and written consent to participate in the study.

Exclusion criteria were :
- Ulcer size smaller than 2 cm^2 or larger than 80 cm^2, deeper than 1 cm or with exposed tendons or bones.
- Necrotic tissue or scabbing of over 25% of the wound surface.
- Diagnosis of or suspicion of osteomyelitis, carcinoma or infection in the wound area.
- Wound cavity or wound pockets undermining the wound edges by more than 0.5 cm.
- Patients with underlying malignant primary disease or on immune suppressive therapy.
- Insufficient food intake.
- Phlebo-surgical measures during the application observation.
- No patient consent.

The ages were between 41 and 93 years (average age 69). There were 22 women and 4 men amongst the patients. All patients had phlebological investigation including Doppler sonography. In 13 (50%) of the patients there was primary chronic venous insufficiency (CVI), in 10 (38%) a postthrombotic syndrome. One patient was suffering from peripheral arterial occlusion disease. One patient had a lower leg ulcer associated with diabetes mellitus. Another patient presented with a chronic ulcer of the distal lower leg in a burn scar. The average duration of the ulcers was 19 months (range: 2 weeks to 10 years). The average ulcer size at the start of treatment was 11.2 cm^2 (range: 2-35 cm^2) (table 1).

In five patients polyvalent contact sensitization with clinical relevance was found (table 1).

The patients were subject to a standardised investigation programme. Before treatment a detailed history was taken. Then there was thorough clinical investigation including phlebological investigation involving Doppler sonography.

During treatment, topical application of corticosteroids, antibiotics or antiseptics was dispensed with. At the beginning changing of dressings was undertaken mainly once daily and later mostly once a week depending on the amount of exudate. All patients were given a short stretch compression bandaging. There was no change in existing systemic medication.

The wounds were assessed weekly by the study doctor. The wound surface and the wound depth were determined. The state of the wound (granulation, fibrinous coats, necroses, state of infection, exudation), wound environment, tenderness of wound during dressing change, as well as compliance using a point score were evaluated and documented.

The point score was assigned as follows: 0, symptom not present; 1, 25% of the wound surface; 2, 50% of the wound surface or symptom slightly marked; 3, 75% of the wound surface or symptom fairly marked; 4, 100% of the wound surface or symptom strongly marked.

When dressings were removed by a doctor, mechanical removal (curettage) of fibrin and slough was carried out if required. Otherwise wounds were cleaned with Ringer's lactate solution. The observation period lasted 6 weeks or until the wound healed.

Table 1: Patient data

No.	Age	Sex	Ulcus for	Origin	Ulcus size in cm^2	Contact sensitisation
1	77	W	3 weeks	CVI*	25	polyvalent
2	76	M	8 weeks	CVI	2	–
3	76	M	36 months	PTS**	2	–
4	41	W	12 weeks	CVI	4	–
5	50	W	2 months	CVI	3	–
6	71	W	3 months	CVI	3.3	–
7	93	W	18 months	CVI	6	–
8	72	M	12 months	PTS	24	–
9	78	W	6 months	pAVK***	11	–
10	56	M	10 years	CVI	12	–
11	45	W	10 years	CVI	35	–
12	62	W	3 weeks	CVI	9	polyvalent
13	86	W	48 months	D.m.§	13	–
14	73	W	36 months	PTS	9	–
15	76	W	3 months	PTS	2	–
16	71	W	4 months	PTS	5	polyvalent
17	77	W	10 months	CVI	12	–
18	77	W	8 months	PTS	13	–
19	69	W	2 weeks	CVI	2	–
20	77	W	12 months	scar ulcer	14	–
21	74	W	9 weeks	PTS	4	–
22	67	W	16 months	PTS	25	polyvalent
23	68	W	18 months	PTS	24	polyvalent
24	70	W	6 weeks	CVI	10	polyvalent
25	49	W	2 months	PTS	15	–
26	61	W	3 months	CVI	7	–

*CVI: chronic venous insufficiency; ** PTS: postthrombotic syndrome;
***pAVK: peripheral arterial occlusion disease; §D.m.: diabetes melitus.

Result

A total of 21 patients completed the study. Complete ulcer healing was achieved in 11 cases (fig. 1). 10 patients showed a reduction of wound size. Amongst these in 9 out of 10 an obvious improvement occurred (wound surface reduced by a minimum of 50%). In one case the reduction of the wound surface was <50%). The maximum reduction in a wound surface within 6 weeks was 16.5 cm^2 in our patient population. Patients without complete healing in 6 weeks had a starting wound surface double the size of those healing completely on average. Amongst these patients were 3/10 with chronic venous insufficiency and 5/10 with postthrombotic syndrome. Other factors for different healing progress could not be identified in these two groups (table 2).

Stimulation of granulation with subsequent reduction of wound depth was achieved in all wounds (fig. 2). In 4 (of 21) patients hypergranulation required cauterisation using argentum nitricum which was undertaken without interrupting the wound treatment with Askina Transorbent®. Fibrinous slough (score reduction by 0.8 points) and necrosis (score reduction by 0.25 points) were reduced in all patients. Notable pain did not occur at dressing changes. Maceration of the surrounding skin was not observed. Undesirable reactions were not documented in any case. Eczematous or other inflammatory changes in the perilesional skin were not apparent in any patient, not even in those with existing polyvalent sensitization.

Compliance was assessed overall as good to fair by the study doctor.

Handling the wound dressing was easy. Disintegration of the wound dressing did not occur in any instance, even at weekly dressing change intervals. Leakage was not observed with proper application (maintainenance of a minimum of 2 cm contact surface for the wound dressing on perilesional skin) (fig. 3).

In 5 patients the treatment could not be assessed. The reasons for this were compliance problems in 3 instances. Two drop outs resulted from hypergranulation (#4) or painfulness of the wound (#5) respectively.

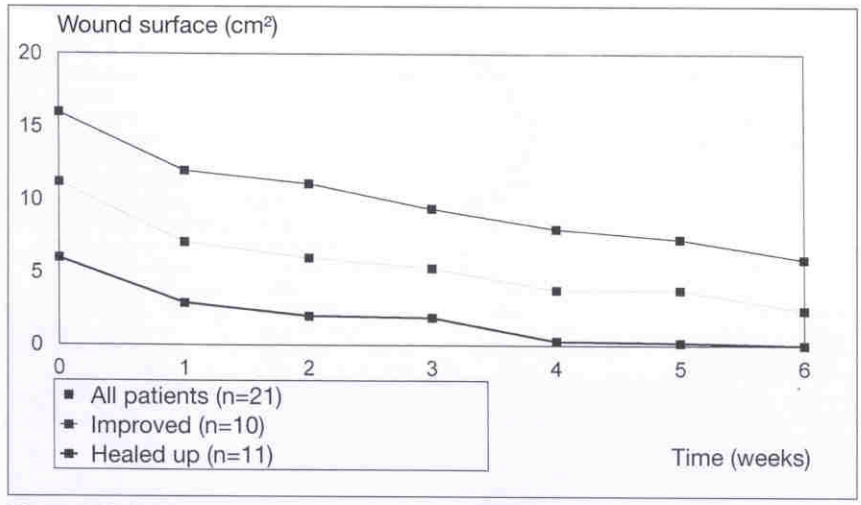

Figure 1: Reduction in wound surface under Askina Transorbent®

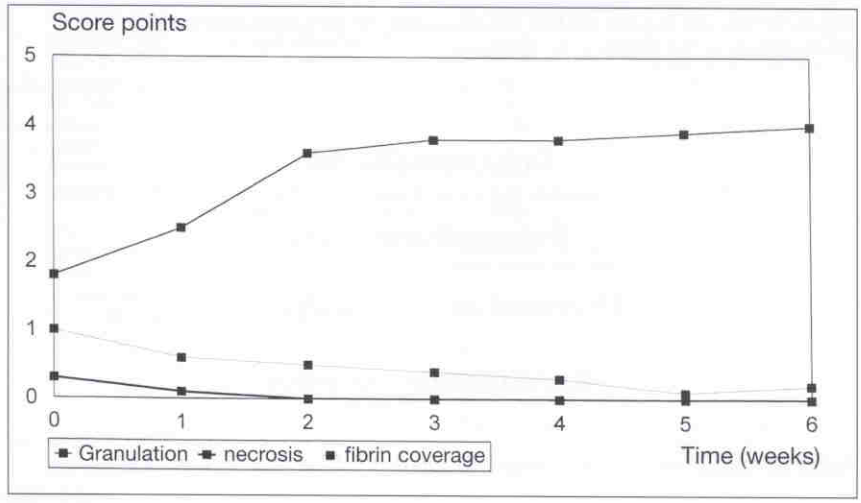

Figure 2: Influence of granulation, necrosis and fibrin coverage under Askina Transorbent®

Discussion

Classical hydrocolloids consist of several components. The hydrogels are based on hydrophilic polymers which absorb water. In doing so there is swelling of the dressing. Hydrocolloids combine gels with elastomers and adhesives. Both groups are characterised by promotion of granulation and biocompatibility for keratinocytes variable from product to product, so that they can be used for superficial wounds without restricting new growth of the epithelium (Wollina et al. 1996). However, these dressings are partly degraded in the wound, so that the need to clean the wound arises. It is not uncommon for these dressings to leak (Gilbert et al. 1989)

Foam dressings are made from polyurethane foam. The main applications are deep or sloughy wounds, which can be packed and freshened up very well with these dressings (decubitus, conditioning of transplant areas, ulcus cruris venosum). Particularly wound cleaning and granulation are promoted. Further developments using additional components have overcome the disadvantages referred to above and render the use of hydropolymers promising also in the epithelisation phase.

The semipermeable wound dressing used by us consists of an amorphous hydrogel acrylate polymer as well as a polyurethane foam layer combined with a polyurethane film (so-called laminate dressing), which ensure stability of

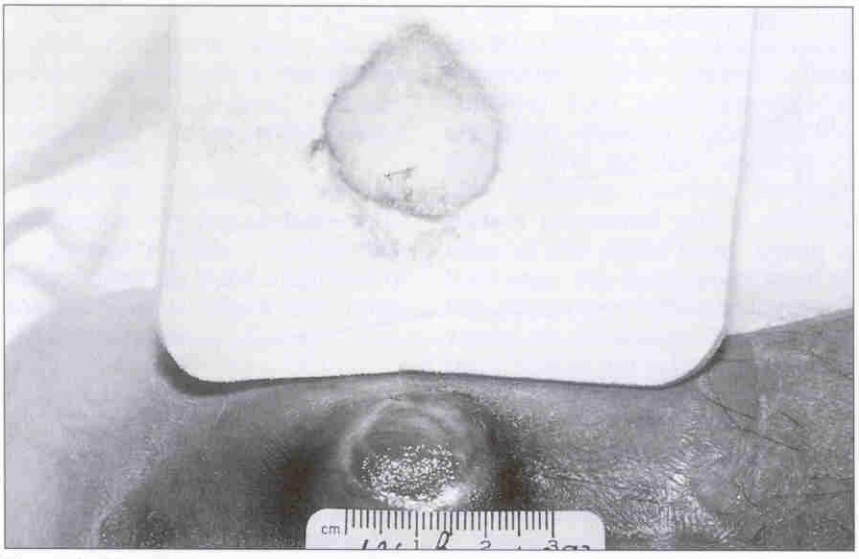

Figure 3: Clinical progress control: No maceration of the perilesional skin, no disintegration of the dressing, no leakages.

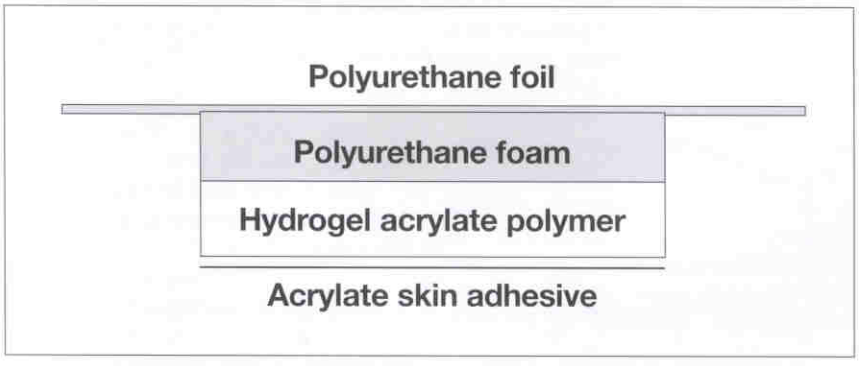

Figure 4: Askina Transorbent® - diagramatic structure (after Gilbert et al.1989)

Table 2: Treatment results using Askina Transorbent®

No.	Ulcer size in cm^2 before treatment	Ulcer size in cm^2 after treatment	Progress
1	25	25	Drop out 2 weeks
2	2	0	Complete healing 5th week
3	2	0	Complete healing 3rd week
4	4	1	Drop out 4th week
5	3	2.5	Drop out 3rd week
6	3.3	0	Complete healing 4th week
7	6	0	Complete healing 6th week
8	24	7.5	Obvious improvement
9	11	7.2	Drop out due to transfer
10	12	6	Obvious improvement
11	35	15.7	Obvious improvement
12	9	6.5	Improvement
13	13	1	Obvious improvement
14	9	1	Obvious improvement
15	2	0	Complete healing 5th week
16	5	1.5	Obvious improvement
17	12	6	Obvious improvement
18	13	1	Obvious improvement
19	2	0	Complete healing 6th week
20	14	14	Drop out 3rd week
21	4	0	Complete healing 6th week
22	25	0	Complete healing 5th week
23	24	7.9	Obvious improvement
24	10	0	Complete healing 6th week
25	15	0	Complete healing 6th week
26	7	0	Complete healing 4th week

the dressing, product integrity and also a stable linear water absorption rate over >3 days (Gilbert and Schenk 1989; fig. 4). In a comparative experimental study full thickness wounds in pigs healed more rapidly when using this hydroactive wound cover compared with a hydrocolloid dressing. After 14 days 91% compared to 74% of the original surface showed epithelialisation (Gilbert et al. 1990).

Regarding handling, an advantage was observed in polyurethane foam dressings (Bales et al. 1997, Banks et al. 1997) composite dressings with polyurethane foams (Wollina 1997) and hydroactive wound coverings compared with classic hydrocolloids. This advantage affects both the complete healing rate and the complete healing time, as well as the avoidance of leakage and undesirable side-effects in perilesional skin or wounds, such as maceration, irritation or sensitization (Brown-Etris et al. 1995; Darkovitch et al. 1990). Allergic reactions, especially contact eczemas of the surrounding skin are the most feared undesirable side-effects of the still commonly practiced treatment of wounds with ointments, with ulcus cruris patients being more easily sensitized. Not only topical antibiotics (neomycin amongs others) but particularly emulsifiers (polyoxyethyl compounds and cetostearyl alcohol) (Paschke-Koo et al. 1994) are potent sensitisers. Colophony derivatives are present in individual hydrocolloid dressings which can trigger contact dermatitis (Sasseville et al. 1997). In our study were 5 patients with a high-grade polyvalent type IV sensitization who all tolerated the amorphous hydrogel used by us excellently. A total of 21 patients were able to complete the follow-up observation period of 6 weeks. Of these, 11 showed complete healing and 10 an improvement (in 9 out of 10 instances a very clear improvement finding). Delayed healing was observed more commonly in larger wound areas and in postthrombotic syndrome (see Skene et al. 1992). Our observations lead to the conclusion that after an initial phase of

treatment of 1 to a maximum of 2 weeks, dressing changes are only required once weekly, as has been mentioned in other investigations (Brown-Etris et al. 1995; Darkovich et al. 1990). Granulation of the wound ensures reduction in the amount of exudate. The resulting reduction in dressing change frequency required is in addition to the ease of handling a very fundamental factor in the improvement in efficacy of care (Wollina 1998b).

In summary, excellent clinical efficacy combined with good tolerance even in patients with allergic disease problems has been proved in the present investigation for the semipermeable hydroactive wound covering Askina Transorbent®. Disadvantages of hydrocolloid dressings, such as frequent leakage around the edges were not observed in our patient population. The hydroactive dressing used here is suitable according to experience to date for treatment of non-infected chronic wounds.

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