

ALHYDRAN

medical after care
for the skin



Since 2008, there is a new standard
in the after care of burns and scars.

First summary of clinical and case studies

All you ever wanted to know about ALHYDRAN , and more...

The skin is the largest organ of the body and its most important task is to protect the body against external influences. If the skin is damaged, a scar begins to form and this damaged part of the skin no longer functions properly.

This happens, for example, with burns, chronic wounds, dry skin, or other skin damage such as radiotherapy, laser treatments and peelings. This vulnerable skin lacks the qualities to protect the body properly. Therefore, this damaged skin requires extra care and treatment.

What is ALHYDRAN ?

ALHYDRAN is a concentrated, medical, powerful moisture regulating gel-cream which combines the strength of:

- freshly processed, pure Aloë Vera Gel (Aruba Aloe Barbadensis) and
- high quality oils and ingredients such as Jojoba oil, Vitamin E, and Vitamin C.

ALHYDRAN does not contain added scent, is gentle on the skin, and hypoallergenic. The delicate perfume of ALHYDRAN is the one of freshly harvested aloe vera gel, as main ingredient of the medical gel cream. ALHYDRAN has not been tested on animals.

The therapeutic and hydrating properties of Aloë Vera Gel for vulnerable skin have been well known for years. The Aloë Barbadensis from Aruba has been specially selected for ALHYDRAN because Aruba has the ideal climate for the Aloë Vera so that ALHYDRAN offers the highest concentration of effective gel.

Where can you use ALHYDRAN for?

ALHYDRAN has been developed for the after care and treatment of the damaged skin immediately after wound closure.



After care for burns



Treatment of non-matured scars



After care for skin transplants and donor sites



Hydration of dry, sensitive skin around chronic wounds



After care for laser treatments

Other indications:

After care of damaged skin after radiotherapy or peelings
Reduction of itching and treatment of (very) dry skin

What kind of effect can you expect from **ALHYDRAN** ?

After-care for burns:

ALHYDRAN has a therapeutic effect on the newly closed skin during the after-care of burns (both deeper burns and first degree burns) and skin transplants. It reduces itching and redness and ensures that the skin becomes more flexible. It helps to prevent scars.

Prevention of scar formation:

By means of early application of ALHYDRAN, immediately after wound closure, the skin remains flexible and gets an optimal treatment to prevent scar formation. When dealing with abnormal scar formation (hypertrophic, keloid) ALHYDRAN is an excellent completion of existing scar treatments.

ALHYDRAN also helps to reduce itching and softens the color of scars.

Treatment of the skin immediately after wound closure:

ALHYDRAN is designed for the treatment of newly closed skin from acute and chronic wounds. ALHYDRAN softens and hydrates the skin and helps to prevent the formation of (irritating) scars.

Treatment of the (very) dry skin.

ALHYDRAN hydrates and softens the skin. Moreover, it reduces itching and treats the (very) dry, irritated, and vulnerable skin.

Clinically tested

ALHYDRAN has been developed and clinically tested at length for the after-care of burn patients in both the Clinic of Plastic and Reconstructive Surgery and the Burns Centre of the University hospital of Ghent (Belgium).

1. Two years of experience with a new product based on Aloë Vera for Hydration of burn Scars. EBA Congress 2007; S. Monstrey MD, PhD; Burn Centre UZ Gent

2. "Itching, is there a remedy?"; a pilot study with a rehydration gel-crème in burn patients. EBA 2007; H.J. van Kempen RN; Burn Centre Rijnmond Zuid Rotterdam

How do I use **ALHYDRAN** ?

Apply ALHYDRAN at least three times a day or whenever the skin itches, is dry, or feels irritated.

Apply ALHYDRAN thinly and rub it in slowly until it is absorbed completely by the skin.

Do not apply ALHYDRAN to an open wound.

You must not use ALHYDRAN if you have a pronounced allergy to one of the components.

Can I use **ALHYDRAN** in combination with pressure- and silicone therapy?

ALHYDRAN can be used perfectly well together with pressure suits, silicone sheets, and/or silicone pressure suits.

Before putting on:

Treat the skin with ALHYDRAN approximately 15 minutes before putting on the pressure stockings or garments or silicone bandage. (If applicable, remove the surplus gel crème after 15 minutes with a dry cloth.)

After wearing pressure:

Treat the skin with ALHYDRAN after removing the pressure stockings/ garments or silicone bandages.

ALHYDRAN ESSENTIALS

- ALHYDRAN is a medical gel cream for the treatment of vulnerable skin immediately after wound closure
- ALHYDRAN is certified as a medical device, class 1
- ALHYDRAN does not contain fragrances, is skin friendly and hypo-allergenic. The natural perfume of the gel cream is the perfume of freshly processed Aruba Aloe Vera, the major ingredient of the gel cream.
- ALHYDRAN was extensively tested since 2003 in the Department of Plastic and Reconstructive Surgery and the burn center of the University Hospital of Ghent (Belgium) in the after care of burns patients.
- ALHYDRAN already has the first preliminary clinical studies and started publishing case studies since summer 2008.
- ALHYDRAN exists in 3 packaging sizes: 30ml, 100ml and 250ml.

TWO YEARS OF EXPERIENCE WITH A NEW PRODUCT BASED ON ALOE VERA FOR HYDRATION OF BURN SCARS



AUTHORS: **S. Monstrey, MD, PhD, A. Pirayesh, MD, E. Lambrecht, RN, S. Lauwaert, RN, J. Verbelen, RN, MN, H. Hoeksema, RC**

INSTITUTE: Department of Plastic & Reconstructive Surgery - Burn Centre, University Hospital Gent, De Pintelaan 185, 9000 Gent, Belgium



Fig. 1

Introduction: In humans deep dermal burns unfortunately do not heal by regeneration of the damaged skin but by the formation of scar tissue (Fig.1). While the prevention of hypertrophic scars (Fig. 2) with pressure garments and silicone inlays has been widely studied, very little evidence has been published on the optimal skin care after burns. The different structure of scar tissue with the absence of sweat and sebaceous glands results in drier, less elastic and itchy skin. Treatment of these annoying skin problems is of utmost importance for the burn patient. An inquiry in the major European burn centres revealed a plethora of creams and ointments that are used for scar treatment after burns but without any standard therapy. Aruba Aloe Balm (Formula F-BC-096) containing 45% of pure, freshly processed Aruba Aloe Vera gel (Fig. 4) obtained directly from the plant (Fig. 3) was used during the last two years for about 50% of our burn patients. We evaluated the presence of residual defects, elasticity of the skin, subjective feeling of the patient especially itching and ease of use, and the final aesthetic outcome.



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6

Methods: All treated patients children and adults had skin grafts or burns with a conservative healing time of > 18 days. Patients underwent a treatment regimen with pressure and silicone garments. Patients were asked to moisten the scars with a thin layer of the product 3 times a day. In order to avoid biased results the Balm (Formula F-BC-096) was delivered in blanc white tubes (Fig. 8) and patients were not aware of the composition of the product. Follow up visits including clinical assessment and digital photography of the scar were done on a regular basis for at least one year as usual in our centre. For some patients in which a control product for comparison was used measurements for skin elasticity (*Dermalab*) (Fig. 6) and colour (*Deraspectrometer*) (Fig. 5) were performed.

Case 1 : Scar formation after surgery

Start with Alhydran®



3 months with Alhydran®



5 months with Alhydran®



Case 2 : Scald

1 day post burn



Start with Alhydran®



1 year with Alhydran®



Results: No allergic reactions related to the product were noticed. In general the aesthetic outcome of patients treated with the Balm (Formula F-BC-096) was better than in patients treated with other moisturizers as scored in the Vancouver Scar Scale. However these are subjective findings, they were confirmed by objective measurements of the *Dermalab* and *Deraspectrometer* in patients where additionally a control product was used. All patients preferred the test product above other products we always used before in our centre. In more than 90% of the patients itching was reduced as they needed less medication and were more comfortable during the day and especially children had a more quiet sleep. Combination possibilities with pressure garments and silicone sheets are outstanding.

Conclusion: After a survey throughout the burn centres of Europe we noticed that there is definitely no standard for hydration of scars and the use of these moisturizers. After two years of excellent results using this new product we think now there is the possibility to set this standard. Till 2007 this product was not distributed outside the Caribbean. In an attempt to make this product available for all patients in Europe a new brand name **Alhydran®** (Fig.7) was chosen for distribution. A prospective, randomized, double blinded, controlled clinical trial of the **Aruba Aloe Balm (Formula F-BC-096)** in the treatment of split thickness donor sites after wound closure is already registered at www.ClinicalTrials.gov and is recruiting patients.



Fig. 7



Fig. 8

”Itching, is there a remedy ? ” a pilotstudy with a rehydration gel-creme in burnpatients



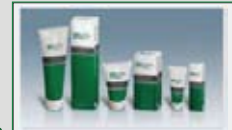
H.J. van Kempen ¹RN, BHSc, J.Doktér MD, I.M.M.H. Oen MD

Burn Centre:nurse and skin therapist(1), medical coordinator(2), research coordinator(3)

Medical Centre Rijnmond-Zuid Rotterdam, the Netherlands; kempenh@mcrz.nl

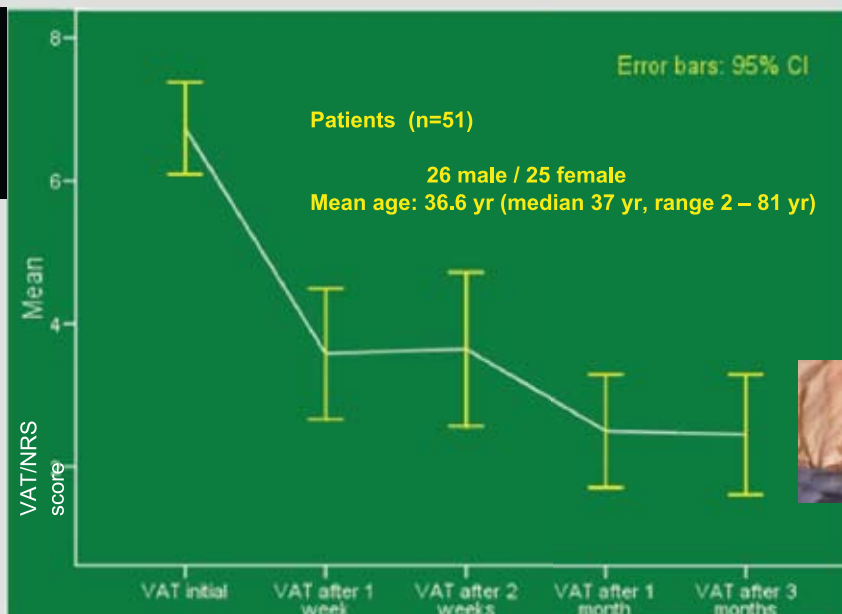
Introduction

Itching after burns is a matter of body and mind, but little is known regarding its exact mechanism. Results of studies show a gradual decrease in itch intensity in time, but still moderate to serious itch several years after burns (van Loey e.a.). In 2006 a gel-creme that supposed to decrease itch was introduced in our Burn Centre. The main ingredients of Alhydran® are Aloë Vera (Aruba Aloe Barbadenis), vitamins C and E and Jojoba oil. To determine its efficacy we performed a pilotstudy.



Methods

Since November 2006 in the outpatient clinic of the Burn Centre Medical Centre Rijnmond-Zuid itching is scored in patients using the Visual Analogue Thermometer (VAT) or the Numeric Rating Scale (NRS 0-10). Measurements were done before application of Alhydran® and after 1 week, 2 weeks, 1 month and 3 months after the start of treatment. Follow up data were collected on outpatient visit or by phone.



Results

Data analyses with ANOVA and T-test show before starting Alhydran® that the mean VAT/NRS for itch intensity is 6.7(see graphic). There is a decrease in time: the mean score after one week is 3.5, after two weeks 3.6, after one month 2.5 and after three months 2.4. There is no relation between VAT/NRS and gender, age, TBSA%, location, cause of burn or combination therapy with other scar treatment. Besides a decreased VAT score parents of young children mentioned their child was more at ease and had a better night's rest. One patient had discontinued Alhydran® because there was no itch anymore after 1 week and 1 patient reduced antihistaminic medication. Two patients said they stopped the creme because of irritation of the skin.

Conclusions

”Itching can make you crazy”. Our first experience indicates that this gel-creme could decrease itch intensity after burns, which contributes to improvement of quality of life. Ongoing research will include additional assessment by a Burns Itch Questionnaire, scar evaluation like the Vancouver Scar Scale, Patients and Observer Scar Assessment Scale, cuto – and dermaspectrometrie and a Quality of Life questionnaire.

Case Study 1: Scald (treatment of old scars after scald) Ankara, Turkey*

AL20-001

Case ALHYDRAN: Hot water burn (scald)

ALHYDRAN

1. Case study description

patient age	4,5 years
sex	female
cause	hot water burn
therapy to wound closure	modern wound care dressings
start after care	1,5 years after wound closure
therapy after wound closure	ALHYDRAN, after one month completed with pressure therapy

2. Evolution of the wound



3. Experiences of the medical team

- The good hydration by ALHYDRAN improves the flexibility of the vulnerable skin and has a positive effect on the itching and the redness. Scars become more flexible.
- The use of pressure garments (after one month ALHYDRAN therapy) has a good effect on the aspect (flattening) of the scar.
- The use of ALHYDRAN contributes significantly to the reduction of itching and redness. The scar becomes more flexible.

4. Experiences of the patient (and the parents)

- Improved flexibility of the skin, less itching and redness
- Clear improvement of the mobility and a visual improvement of the look of the scars.

Case: Lotus MDC, Ankara, Turkey, Can Sukan

Case ALHYDRAN: Flame burn (lower) leg

1. Case study description

patient age	15 years
sex	female
cause	Flame burn
therapy to wound closure	1 week Flammazine, thereafter hydrocolloid gel + Jelonet as wound dressing and light therapy to enhance wound healing
start after care	ALHYDRAN, immediately after wound closure
therapy after wound closure	Pressure garments and Silicone sleeve + hydration with ALHYDRAN (2 to 3 times a day). After one year follow up with ALHYDRAN alone.

2. Evolution of the wound



3. Experiences of the medical team

- Wound healing after 19 days.
- Evolution to complete maturation within 1 year, with excellent results regarding to color (slight hypo pigmentation) and elasticity of the scar.
- Absolutely no hypertrophic scarring and impairment of mobility.

4. Experiences of the patient (and the parents)

The patient was originally not very excited by the typical Aloe Vera smell of the Alhydran. However this patient was very satisfied by the other properties of the gel cream such as easiness of application and the hydration after application, resulting in much better suppleness of the skin. Also less itching was noticed by this young girl.

Case: University Hospital Gent – department of Plastic and Reconstructive Surgery and the Burns Center, Belgium, Prof. S. Monstrey and H. Hoeksema.

Case study 3: Vulnerable skin around chronic wounds ZNA Hospital Group, Antwerp, Belgium*

AL20-004

Case ALHYDRAN: Chronic wound

ALHYDRAN

1. Case study description

patient age	79 years
sex	female
cause	open fracture luxation (04-2006), right ankle with osteosynthesis material post operation, a chronic wound developed
therapy to wound closure	curettage and Hydrogel on wound, wound borders with ALHYDRAN
start after care	immediately after wound closure
therapy after wound closure	ALHYDRAN

2. Evolution of the wound



3. Experiences of the medical team

- After luxation fracture and the operation with osteosynthesis material, the wound had never been closed.
- Due to the presence of the characteristics of a chronic wound with underlying OS material, there is a big chance of deeper infections and the wound will be very difficult to close.
- OS material was removed laterally.
- The wound borders have improved significantly due to treatment with ALHYDRAN.
- In the after care only ALHYDRAN was used.

Casus: Ziekenhuisnetwerk Antwerpen, Belgium, Verpleegkundig ziekenhuishygiënist, Wondzorgcoördinator, E. Roovers

Case study 4: Second degree burn after fireworks incident General Hospital, Oranjestad, Aruba*

AL20-005

Case ALHYDRAN: Second degree burn

ALHYDRAN

1. Case study description

patient age	45 years
sex	male
cause	fireworks burn, 31th of December 2006
therapy to wound closure	Flammazine
start after care	5 weeks post accident
therapy after wound closure	ALHYDRAN, 3 daily doses, brought on thick during the first few weeks

2. Evolution of the wound



3. Experiences of the medical team

- Deep second degree burn with serious ankle damage
- Therapy starts with Flammazine, patient evolves well, only a lot of complaints on itching of closed skin
- After 5 weeks: start with ALHYDRAN on the freshly closed skin, 3 times per day.
- ALHYDRAN had good result on the skin, which improved rapidly.
- Itching complaints disappeared immediately when ALHYDRAN was used.

4. Experiences of the patient

- Flammazine gave a lot of itching problems
- Upon start of the treatment with ALHYDRAN, immediate reduction of itching
- Therapy: 3 daily doses, or each time the skin was itching
- After 6 months, the skin was soft and calm, patient started sporting again
- Skin looks good and calm now.
- After 18 months, maintenance of 1 daily dose of ALHYDRAN.

Casus: Dr. K. Veel MD, AAB Aruba

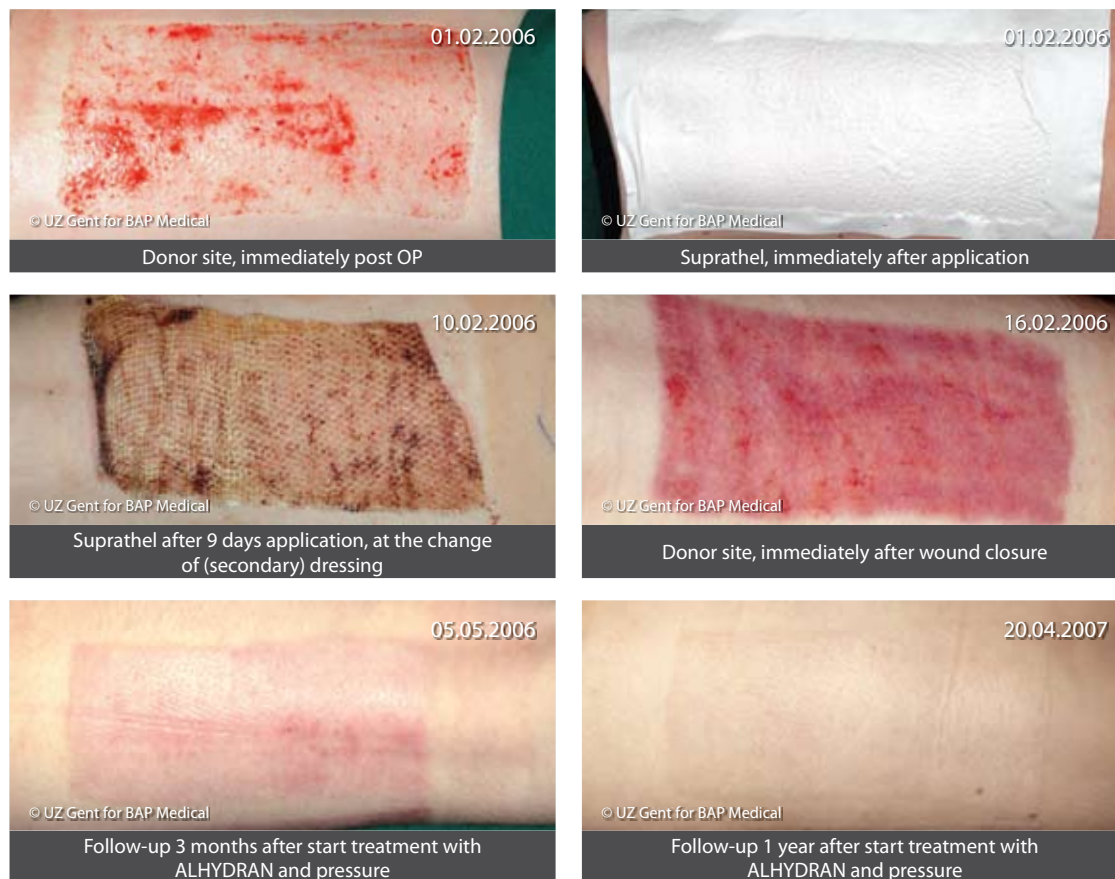
*Pictures and Case Study data are copyright of BAP Medical BV, 2008

Case Suprathel and ALHYDRAN: Treatment of donor site

1. Case study description

patient age	13 years
sex	female
ethiology	donor site
therapy to wound closure	Suprathel 14 days
start after care	ALHYDRAN, immediately after wound closure
therapy after wound closure	pressure garments and hydration with ALHYDRAN (2 to 3 times a day)

2. Evolution of the wound



3. Experiences of the medical team

- Full wound closure within 14 days.
- Evolution to complete maturation within 1 year, with excellent results regarding to color (slight hypo pigmentation) and elasticity of the donor site.
- Significantly less redness and itching during maturation.

4. Experiences of the patient (and the parents)

- No significant pain during wound healing
- No significant itching during the treatment, before nor after wound closure
- Good flexibility and feel of the skin on the donor site

Case: University Hospital Gent – department of Plastic and Reconstructive Surgery and the Burns Center, Belgium, Prof. S. Monstrey and H.Hoeksema.Prof. S. Monstrey & H. Hoeksema

ALHYDRAN

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ALHYDRAN: Assortiment



30 ml



100 ml



250 ml