ORIGINAL ARTICLE

Cutaneous Burns Treated With Hydrogel (Burnshield) and a Semipermeable Adhesive Film

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Hypothesis: A transparent adhesive film possessing selective permeability combined with a hydrogel (Burnshield) may be effective in burn patients to reduce skin maceration, improve medication, control pain more effectively, and reduce the incidence of late complications (hypertrophic scars).

Design: This is a prospective study; the mean follow-up in all patients was 28.4 months (range, 14-35 months). The external part of the film is impermeable to fluid and microorganisms, but allows transpiration of water vapor from the cutis. The permeability to water vapor of a semipermeable film in contact with liquids is measured in grams per meters squared every 24 hours at 37°C, and is defined as the moisture vapor transmission rate. In this study, a film with a moisture vapor transmission rate of 1600 g/m^2 every 24 hours at 37°C was used.

Patients: For about 2 years, this type of therapy was used in the first aid treatment of 48 burn patients, 4 of whom were lost during therapy and 4 of whom were unavailable for follow-up.

Interventions: The patients were treated with hydrogel and a semipermeable film at first medication, and some were treated in this way during subsequent medications.

Main Outcome Measures: The mean reepithelialization time of all patients was 17 days (range, 4-60 days); 8 (20%) of 40 patients with complications were treated with a gel (Same Plast Gel). Late complications were observed: hypertrophic scars in 2 patients (5%) and dyschromic lesions in 6 (15%).

Results: The most frequent complication, which occurred at various stages during medication, was skin maceration (15 [34%] of 44 patients). Other complications recorded during therapy were infections in 2 patients (5%), vertigo in 1 patient (2%), and abundant fibrin production in 1 patient (2%). In some of the patients, associated diseases and/or conditions were found: hepatic cirrhosis, diabetes mellitus, epilepsy, and pregnancy (33rd week) (each found in 1 patient each). Four patients were sent to the burn unit, 3 with second-degree burns of the hand and 1 with first-/second-degree burns of the abdomen and thigh, with 12% of the total body surface area burned.

Conclusions: In the reepithelialization phase, complications were recorded in 8 of the 40 patients: 7 (18%) had residual inflammation and 1 (2%) had a hypertrophic scar. During the follow-up, late complications were recorded in 2 (5%) of the 40 patients. A gel was used in 8 patients: in 6 of the 7 patients with residual inflammation, the complication resolved, while in 1, despite therapy, the residual inflammation evolved into hypertrophic scarring. Treatment with the gel in the 2 patients with late lesions reduced the thickness and extent of the lesions, with minimal aesthetic and functional damage.

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THE RESULTS OF PREVIOUS studies[1-3] suggest that the cooling effect in the treatment of burns, which is well-known as an emergency therapeutic measure, should also be regarded as providing topical hydration of the lesion, apart from its cooling and systemic effect. Excess hydration produces maceration of the skin, which can lead to greater exposure to infection in the burn zone.

Previous studies have focused on the problem of pain and the complications represented by hypertrophic scars, and have obtained encouraging results for both. This study seeks to confirm these findings, using a combination of hydrogel (Burnshield) and a semipermeable adhesive film (SAF).[4,5] Recently, attention has been given to the practical use of this medication and the complication of skin maceration in the lesion zone.[5] Both problems have been attempted to be resolved by using an SAF. Patients with residual inflammation or hypertrophic scarring during follow-up received therapy with a gel (Same Plast Gel) for a variable period.

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METHODS

STUDY DESIGN

This study was performed from February 1, 2001, to December 31, 2002, in the Emergency Department at San Donà di Piave.

Forty-four patients received the therapy in question for skin burns of varied nature and variable degree (first to third) in several re-

Table 1. Data for Percentage of Skin Burned in the Patients

% TBSA	No. of Patients
1	16
2	8
3	2
4	3
5	3
6	4
8	1
9	2
10	2
12	1
15	1
18	1
Total	**44**

Abbreviation: TBSA, total body surface area.

Table 2. Location of the Burn on the Patients

Location of Burn	No. of Patients
Hand	15
Upper limb	5
Foot	2
Lower limb	9
Thorax	2
Thorax and abdomen	1
Thorax and upper limb	2
Thorax and upper and lower limbs	1
Abdomen	1
Abdomen and lower limb	1
Abdomen and upper limb	1
Hand and lower limb	1
Neck	1
Face and lower limb	2
Total	**44**

gions of the body. The mean amount of burned skin in the 44 patients was 4% (range, 1%-18%). For children younger than 15 years, the Lund and Browder[6] table was used to calculate the percentage of total body surface area (TBSA) burned; the "rule of 9" was used for adults.[7] Of the 44 patients, 26 were male and 18 were female (mean age, 33 years; age range, 1-76 years). Forty-three patients were white, and 1 was black. Of the 44 patients, 12 (27%) were burned at work; the other 32 cases (73%) were domestic injuries.

The burns were caused by chemical agents (acids [n=2] and alkali [n=4]) and physical agents (boiling water [n=14], oily substances [n=8], fire [n=8], heat [n=7], and electricity [n=1]). Of the 44 patients, 17 experienced first- to second-degree burns, 17 experienced second-degree burns, 9 experienced second- to third-degree burns, and 1 experienced a third-degree burn. **Table 1** reports the percentage of skin burned in the 44 patients, and **Table 2** gives the locations of the burns.

Associated conditions (diabetes mellitus, hepatic cirrhosis, and epilepsy) affected the burn and its prognosis in various ways, but the condition of pregnancy in the 33rd week did not. The follow-up consisted of checks every 3 months; 4 patients left the study at various times during treatment in the burn center for specialized surgery (skin grafting).

INTERVENTIONS

All the burn patients were treated with hydrogel and SAF at their first medication. In some patients, this therapy continued for several medications on various grounds. Subsequent medications and medications complicated by skin maceration continued with conventional medication (cotton gauze and hyaluronate sodium). The patients were medicated until reepithelialization every 24 to 48 hours, depending on the degree and extent of the burn. Hydrogel contains 96% water, 1.03% *Melaleuca alternifolia* (essential tea tree oil), and an emulsifying agent with a pH of 5.5 to 7.0; the dressing consisted of an inert polyurethane foam. Of the 44 patients, 19 received 1 application of hydrogel, 8 received 2 applications, 5 received 3 applications, 6 received 4 applications, and 1 each received 5, 6, 7, 8, 13, and 15 applications.

The SAF is made up of 30-µm-thick biocompatible polyurethane, which allows good gaseous exchange and the evaporation of water vapor (moisture vapor transmission rate, 1600 g/m^2 every 24 hours at 37°C), thus limiting maceration. The film is impermeable to bacteria and suitable for all parts of the body, because of its elevated elasticity and impermeability. It, thus, contributes to good daily hygienic practice without the risk of moistening the wound.

DATA COLLECTION AND PROCESSING

The total number of medications was 321 (total mean, 7.3 medications for each patient; range, 1-15 medications). All patients received their first medication with hydrogel and SAF, and this type of medication was applied altogether 128 times, with a mean of 3 times per patient (range, 1-15 times). Conventional medications (cotton gauze, hyaluronate sodium, and petroleum jelly–covered gauze) were applied 193 times, with a mean of 4.3 times per patient (range, 1-15 times). In 15 (34%) of the 44 patients, who at different times during medication presented skin maceration, the application of SAF and hydrogel was suspended in the macerated zone, and the patients received conventional medications until reepithelialization. One patient with a hypertrophic scar on the hand was sent to the referring burn center for treatment during the first days of therapy and was unavailable for follow-up. Eight patients who presented zones of residual inflammation or hypertrophic scars during follow-up received therapy with a gel 3 times per day for a mean of 94.4 days (range, 31-365 days).

THEORETICAL MODEL OF THE PROBLEM

The reasons for using hydrogel in the first and in subsequent medications will be briefly stated. In the first medication, the aim was to achieve the cooling effect that prevents deepening of the lesion, immediately stops pain, and produces local hydration.[2] The second medication was performed to achieve long-lasting pain control.[4] In successive medications, the purpose was to reduce the temperature in the lesion zone (ie, to lower metabolism), to reduce the growth stimulus of granulation tissue (deep lesions), and, consequently, to reduce the possibility of scar sequelae. The underlying hypothesis is reported in clinical experiences and studies.[2-4] Skin temperature in the zones covered by hydrogel is 3°C lower than in untreated areas.[2-4]

RESULTS

CHARACTERISTICS OF SUBJECTS

Overall, the mean period for the passing of pain after the application of hydrogel was 2.3 minutes (range, 1-5 minutes). Antibiotic therapy was used in 2 patients (5%) for infection in the burn zone. One case of vertigo (2%) was

recorded 4 to 5 hours after the application of hydrogel, an adverse reaction to hydrogel that resolved spontaneously and has already been mentioned in the literature.[8] Skin maceration was recorded in 15 patients (34%). One patient (2%) with second-/third-degree burns of the thorax (10% TBSA) caused by acid underwent fibrinectomy 7 days after the start of therapy, because of abundant fibrin production. One patient with second-/third-degree flame burns of the thorax and upper and lower limbs (15% TBSA) received 2 applications of silver nitrate 2 days following the appearance of excessive granulation tissue in the thorax, which occurred 49 days after the start of therapy. Another patient with second-degree hand burns caused by a firecracker explosion (1% TBSA) was sent to the burn center after the appearance of hypertrophic and retractile scars 6 days after beginning therapy. Four patients were transferred to the burn center for continuation of the treatment, 3 with hand lesions and 1 with lesions in the abdomen and thigh. Three of these patients presented second- and third-degree burns, with burned skin ranging from 1% to 2% TBSA, while the fourth had second-degree burns on 12% TBSA. Of the 44 patients, 3 were admitted to the pediatric unit after initial first aid therapy. These 3 patients were a 1-year-old child with first-/second-degree burns of the face and upper and lower limbs (6% TBSA), a 2-year-old child with second-/third-degree burns of the thorax and lower limb (15% TBSA), and a 2-year-old child with first-/second-degree burns of the abdomen and thigh (12% TBSA). All the patients admitted, including those discharged from the pediatric unit, were observed in the first aid outpatient department until reepithelialization and throughout follow-up. Burn-associated diseases variously affected the patients' subsequent evolution. The patient with cirrhosis and second-/third-degree burns (6% TBSA) of the lower limbs showed an insufficient capacity for repair of the damage, with a reepithelialization period of 60 days. The diabetic patient with second-/third-degree burns of the lower limbs (5% TBSA) showed repair of the damage after 33 days. In the epileptic patient, the basic disease was the cause of the gravity of the lesions; during a seizure, the patient's hand had remained in contact with a heater for an unspecified period, causing second-/third-degree burns (2% TBSA). Six days after beginning therapy, this patient was sent to the burn center for continuation of treatment. The pregnant patient (33rd week) with first-/second-degree hand burns (1% TBSA) did not have any problems repairing the damage.

MAIN FINDINGS

The mean reepithelialization time of all patients in the study was 17 days (range, 4-60 days). At reepithelialization, a hypertrophic scar was recorded in 1 patient (2%) and zones of residual inflammation were recorded in 7 (18%). Forty patients joined the follow-up study, and 8 (20%) of these patients with complications were treated with a gel. In one patient with residual inflammation, the lesion evolved into hypertrophic scarring despite therapy with a gel. The mean duration of administration of the gel was 94.4 days (range, 31-365 days). The mean follow-up in all patients was 28.4 months (range, 14-35 months). Late complications were observed: in 8 (18%) patients.

COMMENT

In an adult, 3 seconds' contact with water at 60°C is sufficient to cause a third-degree burn, and an increase of 8°C induces the same lesion in 1 second. Burns are to be considered evolutionary lesions. Bearing this in mind, it was found experimentally that there is a rapid and considerable increase in intradermal temperature in the wound zone and that there is a rapid reduction in intradermal temperature to below 40°C within 3 minutes of the removal of the cause of the burn. However, postburn structural and functional alterations last for some hours, and are caused by the inflammatory reactions due to the liberation of chemical mediators, hematic perfusion, and electrolytic exchanges.[2] An experimental study[1] has indicated that within the first hour postburn there is maximum tissue swelling and that in the wound zone the coefficient of capillary filtration increases by approximately 100%; microvascular permeability increases and peripheral resistance to the hematic flow is considerably reduced, indicating marked vasodilatation. Based on the results achieved, the same study attributes the formation of edema after thermal lesions to various factors, the most important of which seem to be focal vasodilatation, with an increase in filtration pressure, an increase in extravascular osmotic activity in the damaged tissue, an increase in microvascular permeability, and alterations in the cellular membrane. This physiopathological phase, with its specific clinical manifestations, lasts approximately 8 hours; it can be defined as the "critical phase" to differentiate it from the subsequent clinical course (postcritical phase) and the phase of clinical sequelae (long-term phase).[1] One possible way to diminish the incidence of postburn hypertrophic scars could be to reduce the period of reepithelialization or to lower the temperature in the lesion zone, to reduce stimulation of granulation tissue.[2] Studies should be conducted to investigate these hypotheses, particularly regarding the period of reepithelialization and the use of new materials. The lowering of the temperature in the lesion zone has already been described in the literature,[2] but remains to be confirmed by broader clinical studies. The literature[9] reports an incidence of postburn hypertrophic scars in 45% to 70% of patients. In the present study, the percentage of patients with hypertrophic lesions was decidedly low (5%), probably because of the effectiveness of the repeated applications of hydrogel according to the second hypothesis underlying the rationale of this study (ie, reduction of the temperature in the lesion zone by the use of hydrogel). It is the essential task of emergency services in severely burned patients to provide primary care (hydration, analgesia, and medication of the burn) and tests (chest radiography and bronchoscopy) and, once the patient is stabilized, to organize transfer to a burn center for the continuation of treatment.[10]

In retrospect, in this study, the staff who used an SAF and hydrogel for medication pronounced a positive judgment regarding ease of application. The patients' judgment, as reported in the literature, was also positive, because they were able to attend more efficiently to their personal hygiene because of this medication.[11]

In summary, a considerable reduction in cases of skin maceration during therapy and good pain control were recorded. With regard to the late complications (hypertrophic scars), the positive data of previous research[5] has been confirmed, and such late complications were considerably less than those reported in the literature.[9,12-15]

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Announcement

As a member of the International Committee of Medical Journal Editors (ICMJE), *Archives of Surgery* will require, as a condition of consideration for publication, registration of all trials in a public trials registry (such as http://ClinicalTrials.gov). Trials must be registered at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after July 1, 2005. For trials that began enrollment before this date, registration will be required by September 13, 2005, before considering the trial for publication. The trial registration number should be supplied at the time of submission.

For details about this new policy, and for information on how the ICMJE defines a clinical trial, see the editorials by DeAngelis et al in the September 8, 2004 (2004;292:1363-1364) and June 15, 2005 (2005;293: 2927-2929) issues of *JAMA*. Also see the Instructions to Authors on our Web site: www.archsurg.com.

ness greater than 4 mm, but also 5 other factors were identified by univariate analysis. Multivariate analysis, however, left only Breslow thickness, previous tempering, and extracapsular invasion as significant predictors of recurrence. Furthermore, the same analysis was performed specifically for surgical field recurrence.

The 52% failure rate is in no way "very high." It is within the 50% to 60% range typical of stage III melanoma. The high percentage of systemic events does not necessarily reflect a surgical failure (most of the time it does not), and has nothing to do with "experienced hands," as put by Dr Badruddoja.

In-transit failure reflects the biology of the tumor, and is not a surgical failure. Dr Badruddoja's statement in this regard is not in line with the current concepts on this phenomenon.

Dr Badruddoja argues that lumping together prophylactic lymph node dissection, RLND for micrometastases and RLND for macrometastases is a methodological mistake. This may be correct, but one should remember, that intermediate-thickness melanoma is associated with 20% to 25% lymph node involvement. For the issue of tempering, including the prophylactic lymph node dissection cases in the analysis might have only reduced the impact of tempering on the entire series by "diluting" the number of surgical field recurrences.

The purpose of this article was to explore the pattern of recurrence after RLND, with a particular search for predictors of overall and surgical field failures. Previous tempering was identified as the only significant predictor of surgical field recurrences. Such interventions are avoidable, and avoiding tempering may reduce the rate of surgical failures. Dr Badruddoja's letter opted not to refer to this at all.

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Correction

Notice of Duplicate Publication. The article by Osti,[1] in the January issue of the ARCHIVES (2006;141:39-42), is virtually identical to an article by the same author, published in another journal in 2004.[2] Well before publication, Dr Osti signed a statement that the article had not been published and was not under consideration elsewhere, and also received a letter of acceptance from the ARCHIVES with a reminder of the policy on duplicate publication. The ARCHIVES has not received any explanation or apology from Dr Osti.

1. Osti E. Cutaneous burns treated with hydrogel (Burnshield) and a semipermeable adhesive film. *Arch Surg*. 2006;141:39-42.
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