

Clinical Studies

Evaluation of Polyurethane Dressing with Ibuprofen in the Management of Split-thickness Skin Graft Donor Sites

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Abstract. *Background:* The authors investigated the possible effect of ibuprofen when included in polyurethane dressing foam in the management of pain and healing related to split-thickness skin graft (STSG) donor sites. The study focused on the use of a foam dressing, Biatain-Ibu, the combination of an absorbent hydrophilic polyurethane foam, Biatain, and the active ingredient ibuprofen as an integral part of the matrix. *Patients and Methods:* A prospective study was conducted from October 2006 to April 2007 and included 40 patients undergoing surgery for any reconstructive purposes with the use of STSG. The patients were divided into two groups in a randomized fashion. In the first group of 20 patients, the donor sites were covered using Biatain-Ibu foam dressing. In the second group of 20 patients, the donor sites were closed intra-operatively with a standard dressing which did not contain any known healing promoting agent. To evaluate the extent and quality of the pain experienced by the patients and to score pain over time, the patients in the study were asked to complete a form containing a visual analogue scale and answer questions on the quality of pain and the way normal daily activities were affected. *Results:* The combined use of ibuprofen with bio-occlusive dressings accelerated wound healing compared to fine-mesh gauze dressings and almost eliminated pain and discomfort in all patients treated. In patients receiving topical ibuprofen, itch did not present a major problem. *Discussion:* This study demonstrates that the Biatain-Ibu dressing is a useful tool in the management of STSG donor sites by providing an optimal environment for wound healing due to its bio-occlusive properties and by minimizing pain and discomfort.

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In the field of plastic and reconstructive surgery, the split-thickness skin graft (STSG) is frequently used because of the advantages that this procedure can offer. In the case of burns, trauma, and emergencies, it is sometimes the only surgical possibility. On the other hand, one of the disadvantages of this type of procedure is the subsequent pain at the donor site area during the healing process.

The STSG donor sites are treated with a variety of dressing techniques and materials but their optimal management is still unknown and there is no consensus on the ideal treatment (1-4). The optimal STSG donor site dressing should likely have antibacterial and hemostatic properties, keep the wound moist and be non-adherent to simplify wound care, promote epidermal healing, and minimize patient discomfort. In addition, the dressing should have a limited cost (4-7). Ideally, the properties of the dressing should enable it to remain in place with no need for changing. Furthermore, a major advantage of an ideal dressing would be significant pain relief at the donor site (7).

Polyurethane foam dressing containing ibuprofen relieves pain in patients treated for chronic venous leg ulcers (8). The treatment of STSG donor sites with fine mesh gauze and Jelonet is the traditional treatment presently in use in our Department at the Umberto I Policlinico Hospital of the La Sapienza University of Rome. We designed and performed a prospective study to evaluate the effects of polyurethane foam dressing containing ibuprofen on STSG donor site healing and compared it to fine mesh gauze and Jelonet.

Patients and Methods

This prospective study was conducted from October 2006 to April 2007 and included 40 patients undergoing surgery for any reconstructive purposes with the use of STSG.

Patient selection. Patients requiring a partial thickness skin graft to cover defects of the upper and lower limbs were eligible for inclusion. The cause of tissue loss was lower limb ulcer in eighteen patients, lower limb trauma in ten patients, wide excision for lower limb melanoma in six patients, upper limb trauma in four patients and lower limb osteomyelitis in two patient (Table I).

Exclusion criteria included the presence of local or clinical signs of infection, diseases influencing healing of the grafted area (e.g. vasculitis, diabetes, neuropathies and immunological disorders such as systemic lupus erythematosus), treatment with systemic corticosteroids or immunosuppressants, and known hypersensitivity to ibuprofen or other materials present in the foam dressing, or known allergies to non-steroidal anti-inflammatory drugs (NSAIDs).

The study was open to all patients without exclusion criteria who provided informed consent. Only one grafted area was included per patient. The study area was selected at the discretion of the first author. The patients were unaware of the dressing that was applied to them.

The patients were randomly divided into two groups. The study group included twenty-four males and sixteen females, with a mean age of 54.3 years (range 19-74 years). Age, systemic diseases and other factors were considered so that the patients in both groups had approximately the same characteristics. All STSG were harvested using a Zimmer Electric Dermatome with the same thickness of 0.2 mm from the anterior (22 patients) and anterolateral (18 patients) thigh region.

In the first group of twenty patients, the donor sites were covered using Biatain-Ibu foam dressing (Biatain-Ibu; Coloplast SpA, Bologna, Italy). The donor sites were then covered with gauzes intraoperatively as a secondary dressing so that the donor sites were totally covered. In the second group of twenty patients, the donor sites were closed intraoperatively with a standard dressing (Jelonet gauze) that does not possess properties reported to affect wound healing. The secondary dressing used was the same in both groups. The limb involved was then immobilized and the dressings in both groups were kept *in situ* throughout the healing process without being changed. Dressings were removed 9 days from surgery (range 7-10 days). Interestingly, twelve patients out of twenty in the first group had been previously operated on using the standard STSG donor site dressing. In all cases, postoperative antibiotic therapy was prescribed and in 18 cases (lower limbs), antithrombotic prophylaxis was also administered during the time of immobilization. Patients were discharged from hospital on the 7th postoperative day (range 6-12 days).

Materials. Biatain-Ibu is a foam dressing that is the combination of an absorbent hydrophilic polyurethane foam and the active ingredient ibuprofen (ibuprofen concentration: 0.5 mg/cm²) as an integral part of the matrix. Ibuprofen is a widely used and safe NSAID that in this manner is released continuously for up to 7 days directly into the wound bed upon contact with wound fluid. The release of ibuprofen affects pain and edema locally at the surface covered by the dressing, thus avoiding possible toxicity (9). The structure of the foam, which is similar to that of lung alveoli, allows the dressing to absorb large amounts of exudates and keep the exudates away from the wound bed, reducing the risk of leakage and maceration. The dressing is also adhesive having a soft, low friction top film that makes positioning easy. The semi-permeable top film is selectively permeable allowing the passage of gases and water vapor, while providing a bacteria-proof and water-resistant outer layer. Due to its retention properties, the dressing can be used safely under compression bandaging.

Pain assessment. To evaluate the extent and quality of pain experienced by patients and to score pain over time in a comparative and reproducible fashion, the patients in the study were asked to complete a form containing a visual analogic scale (VAS) and questions related to the quality of pain and the interference that

Table I. Cause of graft harvest in both groups of patients.

No. of patients	Patient characteristics
18	Lower limb ulcer
10	Lower limb trauma
6	Lower limb melanoma
4	Upper limb trauma
2	Osteomyelitis of the lower limb
Total	40

this may have with normal daily activities such as sleeping, mobility and food intake. The form was meant to be as intelligible and clear as possible for the patient. With the VAS, the patients indicated the level of pain experienced using a scale pre-drawn ranging from 0 cm indicating no pain to progressive levels of pain to a scale of 10 cm for unbearable pain. The patients were asked to describe the sensation experienced choosing different possibilities and the interference that this had with their quality of life (normal daily activities including sleeping, mobility, and food intake). The patients were requested to record daily for ten days. This methodology allowed us to compare not only the two groups but also the differences associated with previous surgery in five patients.

Results

Dressings in the two groups of patients were kept in place for a minimum of 9 days to a maximum of 12 days (range 9-12 days). The mean STSG donor site area was approximately 10×10 cm, ranging from 4×8 to 10×24 cm. None of the patients in group 1, treated with the Biatain-Ibu dressing, experienced any pain (VAS score 0) while the dressing was in place, apart from two patients who experienced itch on day 3 that disappeared by day 4. All donor site wounds healed and required no further dressing by postoperative day 10 (Table II). Twelve patients in this group previously operated on using standard STSG dressing, noticed dramatic pain reduction compared to wounds from the previous surgery. In the second group of patients treated with the standard dressing, eighteen patients experienced itch from day 3, four patients until day 5, and eight patients until day 7. The remaining patients experienced itch only for the day of onset. Fourteen patients marked the VAS scale with a score of 2 on postoperative days 1 to 3; two patients marked 5 on the scale on days 1 and 2, which decreased to 3 on day 3, to 1 on day 4 and eventually to 0 from day 5 onwards. None of the patients required dressing change (Table II, Figures 1 and 2).

No infection nor bleeding of the wound, that required further treatment, was detected in the two groups. At one year of follow-up, there was no difference detected by the doctors in the resulting scar and healing time among the patients under evaluation.

Table II. Results by groups of patients.

Results	Group 1	Group 2
Pain at donor site	No pain	14 pts marked the VAS scale at point 2 from postoperative day 1 to day 3; 2 pts marked 5 on day 1 and 2, decreasing to 3 on day 3, returning to 1 on day 4 and 0 from day 5.
Other complications	2 pts experienced itch on day 3 that disappeared by day 4.	18 pts experienced itch from day 3, 2 until day 5 and 4 pts until day 7; the remaining pts experienced itch only for the day of onset.
Additional medication	No	No

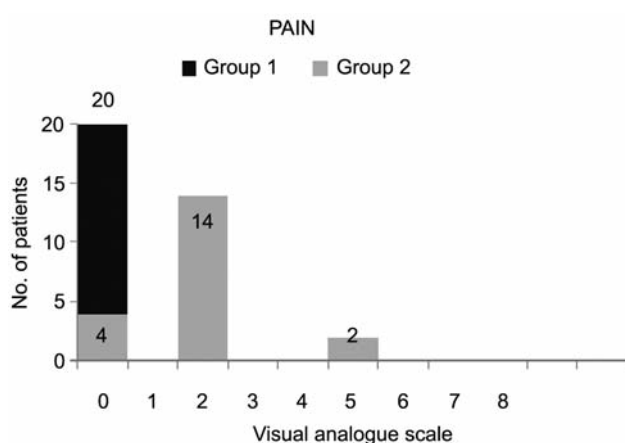


Figure 1. Graph showing VAS results by group 1 and 2 of patients.

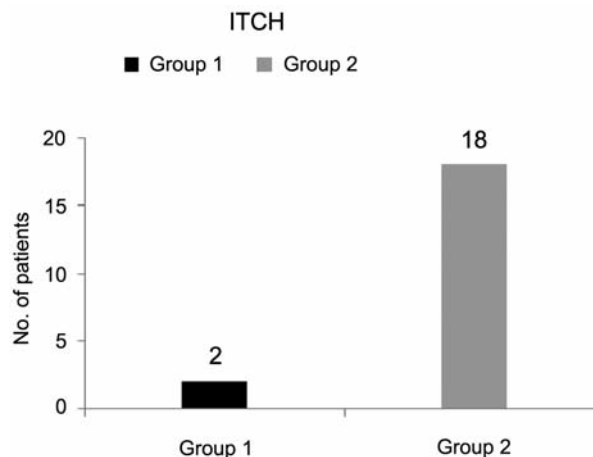


Figure 2. Graph showing other complications experienced by group 1 and 2 of patients.

Discussion

There has never been an “ideal” dressing because all current dressings possess unique properties (7-13). Dressings should provide an optimal environment for moist wound healing and effective exudate management, while relieving pain and discomfort (11, 12). Studies are lacking on the management of pain in STSG donor sites whereas, in our opinion, patient comfort is a major issue for ideal treatment. Moreover, this may represent a priority in patients such as children or in those with acute burns in which donor site morbidity should be minimized. The present study, a prospective clinical trial involving forty patients, investigated the possible effect of ibuprofen when included in polyurethane dressing foam in the management of pain and healing related to STSG donor sites.

Biatain-Ibu has been tested by different authors for the management of chronic wounds, showing that the analgesic activity remains locally within the surface covered by the dressing. Jorgensen *et al.* tested the Biatain-Ibu non-adhesive dressing on ten patients with painful venous leg ulcers and observed a persistent and temporary reduction in wound pain, with improved quality of life and excellent moist wound healing properties (9).

Flanagan examined ten patients with painful chronic leg ulcers treated with foam dressing releasing ibuprofen and appropriate compression bandaging. Eighteen out of the twenty patients reported overall pain reduction, improved mobility, sleep, and mood during treatment. Pain intensity scores decreased during treatment but increased one week after discontinuing treatment (13). Sibbald *et al.* conducted an open comparative, prospective block-randomized study on twenty-four patients with chronic ulcers. Patients were randomized to a 1-week treatment period with either ibuprofen combination dressing (Biatain-Ibu, Coloplast SpA) or the best available and routinely used dressing (14-16). In this study, the combination of foam with continuous release of ibuprofen offered a valuable therapeutic combination dressing for the reduction of pain and potential improvement of final outcome (8).

The results of the current study suggest that the combined use of ibuprofen with bio-occlusive dressings allows for similar wound healing time compared to fine-mesh gauze dressings and almost eliminates pain and discomfort in all treated patients. Itch was not a major problem and was well tolerated. The group of twelve patients that had previously undergone surgery with the standard dressing found the new

dressing more effective in pain management and overall comfort. The absence of pain had a very positive effect on normal daily activities including sleep, mobility, and mood.

Since the dressing was left in place for at least 7 days without need for change, the overall cost was minimized and outpatient management was facilitated. Four patients experienced discomfort at the time of dressing removal due to adherence of the dressing to skin surface which was overcome after moistening it with saline solution. The morbidity of STSG donor site, which is visible scar formation, usually depended on the thickness of the skin graft harvested and was not influenced by the dressing. There was no significant difference in the final esthetic result using the two dressings at 12 month follow-up.

In conclusion, the Biatain-Ibu dressing represents a valuable alternative in the management of STSG donor site by providing an optimal environment for wound healing due to its bio-occlusive properties and reduction of pain and discomfort thus optimizing the quality of life of patients (17-20).

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