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A Prospective, Within-Patient Controlled Study to Compare the Ability of the Non Adherent Drawtex® Hydroconductive Dressing to a Transparent Polyurethane Film Dressing (Standard of Care) on the Healing of Split-Thickness Skin Graft Donor Sites*

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Abstract

Background: Dressing of split-thickness skin graft donor sites can be traumatic for the patient. The most advanced and expensive dressings have been compared to the most basic of dressings, with little or no consensus and an unpersuasive level of evidence. We aimed to determine the efficacy of the locally manufactured non-adherent, hydroconductive Drawtex® dressing and compare it to our current standard-of-care dressing, a thin transparent polyurethane film, in the healing of split-thickness donor sites. **Methods**: This prospective, within-patient controlled study included 27 adult participants, each with two split-thickness skin donor sites. The 54 donor site wounds were compared with regard to time to re-epithelialisation, perceived pain and healed wound quality. **Results**: By day 5, complete healing of donor site wounds, defined as >90% of epithelialized surface, was significantly higher in the hydroconductive dressing group compared to the polyurethane film group (22.2% and 3.7%, respectively; $p < 0.0001$). The hydroconductive dressing-treated donor site wounds were significantly less painful at 24-hours,

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48-hours and 7-days post-operatively, and had fewer complications and superior wound healing quality. **Conclusion**: We have demonstrated that the relatively cheap and readily available dressing made locally in South Africa, Drawtex®, is at least as safe, and potentially superior in wound healing, when compared to our current standard-of-care dressing.

Keywords

Re-Epithelialization, Prospective Studies, Wound Healing, Split-Thickness Skin Graft Donor Site, Hydroconductive Dressing, Pain

1. Introduction

Split-thickness skin graft donor sites are partial-thickness wounds that healed by the process of epithelialisation. These wounds are painful and run the risk of infection, conversion to full-thickness wounds, and scar hypertrophy. Many therapies have been introduced for the treatment of a split-thickness skin graft donor site wound. The ideal dressing should be one that maintains a moist pH-balanced wound, manages exudates, limits infections, protects the healing tissue beneath the dressing from further trauma, reduces pain to the patient, and requires only infrequent dressing changes.

There is extensive literature available on the dressings and management of split-thickness skin graft donor site wounds. A wide variety of dressings, ranging from simple dressings, such as transparent polyurethane film, to more complex dressings like silver (Acticoat®) or growth-factor impregnated dressings (rh-aFGF) have been studied in the management of split-thickness skin graft donor site wounds, with lack of consensus from these studies [1] [2].

Most studies compare dressings to one another based on, but not limited to, the following criteria: days to re-epithelialisation, Visual Analog Scale (VAS) pain scores and wound quality, factoring in the incidence of complications and cost effectiveness. In a review article of 33 studies in 1998, the available empirical evidence regarding split-thickness skin graft donor site dressings was integrated and the authors concluded that transparent polyurethane film was the best dressing of care with the fastest healing rates, a smooth re-epithelialized surface and a low infection rate, in addition to the least amount of pain experienced and at a minimal cost [3]. More recently, a single-centre randomised control trial again showed superior results with a transparent, breathable film when compared to more modern dressings [4]. It is known however, that disadvantages to the transparent polyurethane film dressing includes post-operative leakage from under the dressing of the donor site wound, as well as fragility of this newly healed donor site [5]. Furthermore, some studies have shown that other dressings, such as Bovine collagen, perform better than transparent polyurethane film in achieving greater epithelialisation and less pain with dressing changes, but at much greater cost [6]. From the literature, re-epithelialization or the healing of

donor site wounds occurs on average on day 10 with a range of eight to 21 days [1] [4] [7]-[15]. Regarding VAS pain scores, a study published by Demirtas *et al*. (2010) dressed 100 consecutive patients' donor site wounds with a range of dressings and, where none of the dressings were reported to be ideal, the transparent polyurethane film dressing showed a mean (SD) VAS pain scale score of 2.8 (2.2), 2.1 (1.4) and 1.6 (1.2) on days four, seven and 14, respectively [12]. Although VAS scores were low, it was the second most painful dressing, but nevertheless one of the most cost-effective. A few years on, Lauchli's group in 2013 reported the basic transparent polyurethane film to be significantly less painful than other highly absorptive, modern dressings, like Calcium Alginate [16].

Complications are key factors in assessing quality of the final epithelialized donor site wound. Where more modern or complex dressings are often reported to be superior in guarding against secondary infection [15], these dressings are expensive and not readily available within the state sector South African hospitals.

Moreover, cost effectiveness is fundamental in our state sector hospitals functioning under limited resources. At our institution, the current standard of care dressing for split-thickness skin graft donor site wounds is a transparent polyurethane film which is adherent to the wound surface and reinforced by a crepe bandage. The frequency of dressing changes is arbitrary and driven mainly by the volume of drainage or the physical condition of the dressing. On the other hand, Drawtex® is a hydroconductive, non-adherent functional dressing which is locally manufactured by a South African company and is readily available in our state sector hospitals. It is a non-complex and relatively cheap dressing, at R29.18 ($2.46) for a 100 × 100 mm sheet (personal correspondence with Drawtex South Africa on January 31, 2018). It utilizes LevaFiber technology involving a combination of two types of cross-action structures that create the ability to move exudate from the wound bed through the dressing, reducing the amount of deleterious bacteria, cytokines and harmful matrix metalloproteases [17] [18]. To date, this locally manufactured hydroconductive dressing has not been compared prospectively to the current standard of care thin transparent polyurethane film dressing. Consequently, the question of whether the use of this hydroconductive dressing is a suitable alternative in the healing of split-thickness skin graft donor site wounds in our setting when compared to thin film remains unanswered.

We therefore aimed to investigate the efficacy of this non-adherent hydroconductive dressing as an alternative to the current standard dressing of care, specifically pertaining to healing time, quality of healing, pain and infection rates.

2. Materials and Methods

2.1. Ethical Considerations

The study protocol was approved by the Human Research Ethics Committee

(Medical) of the University of the Witwatersrand, South Africa (clearance certificate no. M130105). Signed informed consent was obtained, with an interpreter present, from all study participants prior to enrolment into the study.

2.2. Study Design, Setting and Participants

This was a prospective, within-patient controlled and multi-centre study that compared two wound dressings for the treatment of adult split-thickness skin graft donor site wounds. Study participants were recruited from two public hospitals in Johannesburg, South Africa: the Chris Hani Baragwanath Academic Hospital (CHBAH) situated in Soweto, which serves a lower-income population of approximately 2.5 million people, and the Helen Joseph Hospital (HJH) situated in Westdene, which serves a mixed socio-economic population of about 200,000 people.

2.3. Inclusion Criteria

- Both genders with an age 18 - 60 years at randomization.
- Presenting to either the Burns Unit at CHBAH or to the General Surgery unit at HJH and who required a split-thickness skin graft, which would result in 2 non-contiguous donor site wounds from the harvesting of split-thickness skin grafts.
- Donor site wound sizes of 50 - 250 cm^2. The total area of donor sites created will not exceed the size of defect that needs to be covered.
- Donor site depth 0.23 mm to 0.30 mm (0.010 - 0.012 inches). Both donor sites on a single patient will be harvested to the same depth.
- Signed informed consent.

2.4. Exclusion Criteria

- Donor sites located on Head, neck, or hands.
- Patients with necrotizing leucocytic vasculitis or pyoderma gangrenosa.
- Diagnosed underlying disease(s) (e.g. HIV/AIDS or cancer) known to interfere with the treatment.
- Patients with insulin dependent diabetes mellitus.
- Patients treated with systemic glucocorticosteroids, except patients taking occasional doses or doses less than 10 mg prednisolone/day or equivalent.
- Use of immunosuppressive agents, radiation or chemotherapy within the past 30 days.
- Known allergy/hypersensitivity to any of the components of the investigation products.
- Patients with physical and/or mental conditions that are not expected to comply with the investigation.
- Participation in other clinical investigation(s) within 1 month prior to and at the start of the investigation.
- Pregnancy.

2.5. Allocation of Donor Site Wound Dressings and Standard Surgical Technique

Allocation of donor site wound dressings were done at random, using a pre-determined random assignment of treatments to the two defined wound regions A and B. The randomisation scheme was designed using a computer-generated list (MS Excel). Initially the paired donor site wound regions would be labelled A and B by the surgeon, after which an envelope was opened that indicated which treatment to assign to region A and which to region B. Thus, one donor site wound randomly received the hydroconductive dressing Drawtex® (Beier Drawtex Healthcare (Pty) Ltd., Pinetown, KZN, South Africa) covered by thin film, whilst the other donor site wound received the thin film dressing only, Opsite® (Smith & Nephew (Pty) Ltd., Pinetown, KZN, South Africa).

The hydroconductive dressing was applied over and above a single layer of paraffin gauze that covered the wound surface, to prevent the dressing from adhering to the underlying epithelializing surface. The thin film dressing was applied immediately adjacent to the wound surface. Crepe bandage was used to re-enforce both dressings. The latter could be replaced as needed, whilst the hydroconductive dressing or thin film layer would remain in place, in accordance with the dressing schedule as set out in the study design. If the inner layer of the hydroconductive dressing or thin film dressing had to be removed and replaced, it was noted in the research record.

If infection was suspected at the donor site, based on clinical acumen, the dressing would be removed (and replaced with "like" dressing material), a broad-spectrum anti-microbial commenced and a pus swab taken to ensure correct antibiotic treatment according to the bacteriogram.

2.6. Data Collection

Data, including VAS pain scores, was collected at baseline, 24-hours, 48-hours and at 7-days after application of the study dressings. Final data was collected at three months. On post-operative days 5, 10 and 15, photographs of the donor site wounds were taken denoting the time to healing, *i.e.* >90% re-epithelialisation. The quality of healing at the time of dressing changes and at three months was determined by presence of scar hypertrophy, pruritus, erythema and/or induration.

To assess the pain intensity experienced on study days, investigators recorded the patients' VAS score for each donor site. The VAS score is a pain scale ranging from "no pain" (score of 0) to "unbearable pain" (score of 10).

If the patient became an outpatient, he or she would return to the outpatient clinic to be reassessed for wound healing. The covering wound dressing would be removed and replaced if the surgeon felt it to be surgically indicated. Again, such cases were noted as an adverse event.

2.7. Statistical Analysis

The STATISTICA suit of analysis software, Version 12.7 (Statsoft Inc., Oklaho-

ma USA), was used for all statistical analyses. Descriptive statistics was performed for each variable. Statistical analyses comparing the two dressings were carried out with the either the Wilcoxon matched pairs test for treatment comparisons on continuous and ordinal variables, or the McNemar Chi-square test for within-subject testing of equality of proportions. A p-value of <0.05 was considered significant.

3. Results

Between March 2015 and July 2016, 38 participants met the inclusion criteria of our study and gave written informed consent to participate. Eleven patients were excluded because of early loss to follow-up. Of the 27 participants included in the study, 20 had full data sets. The mean (SD) age was 34.8 (10.9) years and ranged between 18 - 61 years with a female (n = 7) to male (n = 20) ratio of 1:3. Even though the mean (SD) age of the males at 33.8 (9.7) years were slightly younger than the females at 37.6 (14.4) years, this did not reach statistical significance.

3.1. Efficacy Assessment

3.1.1. Epithelialisation

Complete epithelialisation was defined as the day when >90% of the donor site wound surface had re-epithelialized. As seen in Figure 1, the percentage of patients with re-epithelialized donor site wounds was compared between the hydroconductive dressing and the thin film-treated groups on Day-5, -10 and -15. Significant differences were seen between these groups on Day-5 and -10

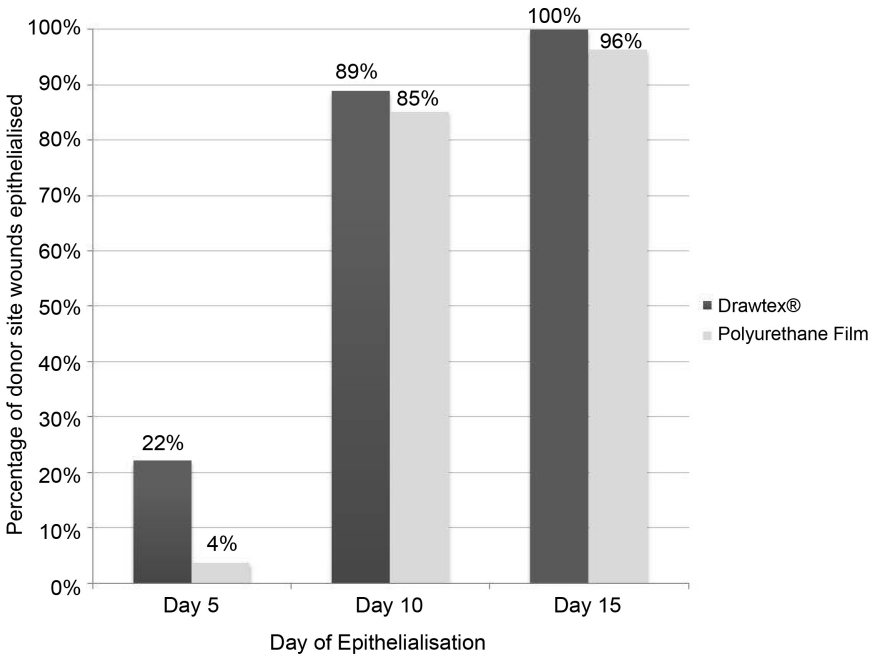

Figure 1. Day of epithelialisation of the donor site wounds with the Drawtex® vs transparent polyurethane film dressings.

(McNemar Chi-square test, both $p < 0.0001$). Almost a quarter (22%, n = 6) of donor site wounds in the hydroconductive dressing group had epithelialized by Day-5, compared to only 3.7% (n = 1) in the thin film group. Interestingly, the three hydroconductive dressing sites that had not yet epithelialized by Day-10, had already epithelialized in the corresponding paired thin film sites within these participants.

3.1.2. Pain

The VAS pain scale was applied to measure pain intensity at the donor sites at 24-hours, 48-hours and 7-days post-operatively. Table 1 shows a comparison of the frequencies of the pain scores between the hydroconductive dressing and thin film-treated donor sites, and these differences are visualized at 24-hours, 48-hours and 7-days in Figure 2(a)-(c), respectively.

3.2. Safety Assessment

The quality of healing of the donor site wounds was continuously assessed at dressing changes and at the time of final evaluation at three months. This was done by determining the presence or absence of the following adverse events: induration, pruritus, erythema and scar hypertrophy. Where 66.7% (n = 18) of patients reported the presence of an adverse event in the thin film-treated donor site wound, only 25.9% (n = 7) of patients reported an adverse event in the hydroconductive dressing group. Interestingly, for 61.1% of the participants with an adverse event in the thin film-treated donor site, no events are present in the hydroconductive dressing treated donor site. This finding reached statistical significance ($p = 0.003$). Furthermore, if an adverse event was present in the hydroconductive dressing treated donor site (n = 7), an adverse event was also present in the thin film-treated donor site. The frequency results for specific adverse events are displayed in Table 2.

With regard to infections, two patients had an infection, one in each of the hydroconductive dressing and thin film groups on day 15 and 5, respectively. Finally, only one donor site wound resulted in a full-thickness conversion and was from the thin film-treated group.

4. Discussion

We know from the literature that the dressing of donor site wounds, which in the case of a split-thickness skin graft includes the epidermis and varying amounts of dermis, is fraught with complications. In addition, it is often is a traumatic experience for the patient and may tax healthcare resources [19].

The aim of dressing the donor site wound is to enhance healing and to reduce the pain and discomfort experienced in the patient while the dressing is in place [19]. This should be achieved with as few as possible dressing changes, the latter of which reduces the risk of pulling migrating epidermal cells from the wound surface [19]. The quest for the panacea of all dressings is reflected in the diversity and number of publications in this regard. The most complex and expensive

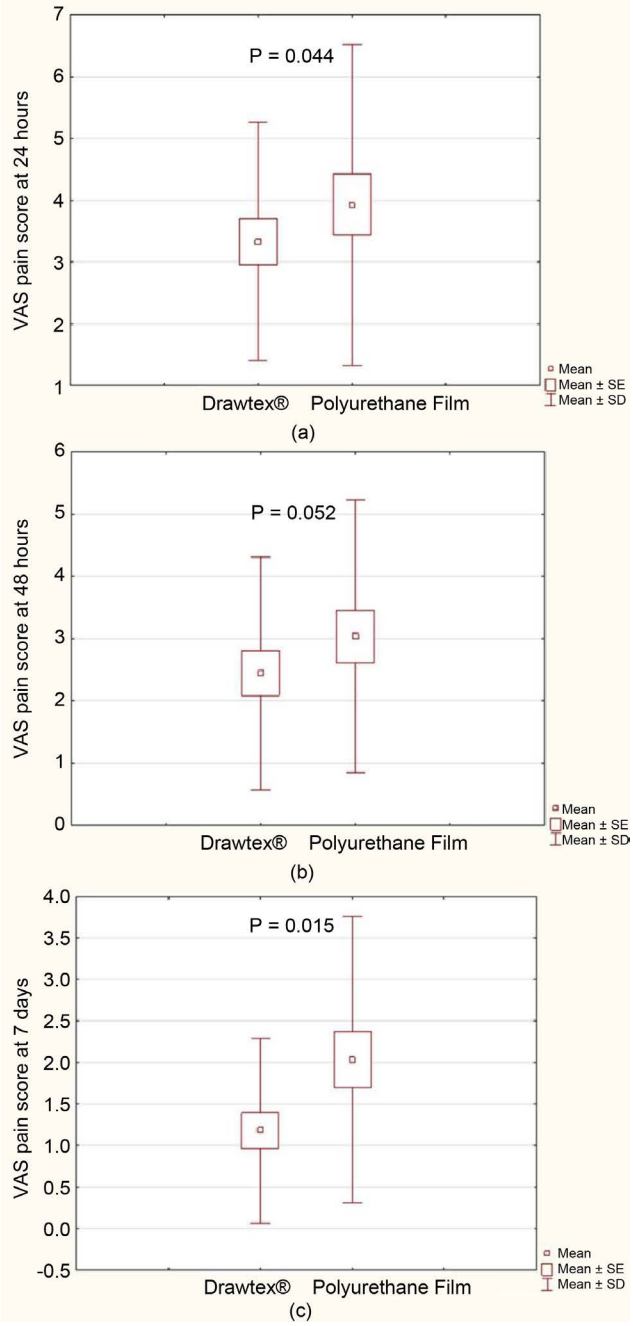

Figure 2. Box & whisker plots comparing the VAS pain scores from Drawtex® vs transparent polyurethane film dressing donor sites at 24-hours (a), 48-hours (b) and 7 days (c).

Table 1. Mean VAS for pain intensity at donor sites.

Time	Drawtex® VAS score Mean (SD)	Opsite® VAS score Mean (SD)	p-value*
24-hours	3.33 (1.92)	3.93 (2.59)	**0.044**
48-hours	2.44 (1.87)	3.03 (2.19)	0.052
7-days	1.19 (1.11)	2.04 (1.72)	**0.015**

*Wilcoxon matched pairs test. *Abbreviations*: SD, standard deviation; VAS, Visual Analog Scale.

Table 2. Frequency and day of adverse events.

	Drawtex®		Opsite®	
Adverse event	Frequency	Day noted	Frequency	Day noted
Induration	3.7%	10	7.4%	12.5
Pruritus	7.4%	10	25.9%	7.1
Erythema	7.4%	17.7	33.33%	7.2
Scar hypertrophy	18.5%	90	40.75%	90

of dressings, as mentioned earlier, including Biobrane® [20] lipid-colloids [9] and even oxygen diffusion dressings [10] have been employed. Decreased infection rates [15] and exudation [20] have been shown from these studies, but the levels of evidence are insufficient to suggest a change in policy.

Recently, novel concepts like an autologous skin cell suspension has shown accelerated healing rates in donor site wounds [7], but fails to compare this to more conventional and readily available dressing approaches. Moreover, cost is a determining and mitigating factor, especially in the South African State Care setting: a resource constrained environment.

In this study we challenged the above mentioned complications of the transparent polyurethane film dressings, *i.e.* leakage, pain and fragile epithelialization [4], by assessing the efficacy of the hydroconductive dressing in a within-patient controlled model. The latter model excluded the potential bias that local and systemic conditions, age and gender could have on the process of wound healing. We photographed both of the within-patient donor site wounds at Day-5, Day-10 and Day-15 to assess for >90% epithelialisation. By Day-5, our study achieved significantly quicker rates of epithelialisation with the hydroconductive dressing when compared to thin film with 22% and 3.7% fully epithelialized, respectively ($p < 0.0001$). Furthermore, on Day-15 all hydroconductive dressing wounds were epithelialized compared to 96.3% of thin film wounds. Again from the literature, the average day of epithelialisation for thin film is on day 10 with a range of nine to 21 days [1] [5] [7]-[12]. In our hydroconductive dressing and thin film-treated groups, 88.9% and 85.2% of donor site wounds had fully re-epithelialized by day 10, respectively.

When assessing the pain experienced at the donor site wounds in our study population, the hydroconductive dressing had a mean VAS score of 3.33 at 24 hours compared to 3.93 for thin film ($p = 0.044$). This difference was even more significant by Day-7 ($p = 0.015$) with mean VAS scores of 1.19 and 2.04 for the hydroconductive dressing and thin film groups, respectively. Our pain scores for thin film were in keeping with the literature that showed a mean VAS score of 2.1 for thin film on Day-7 [12]. Furthermore, our hydroconductive dressing's pain scores were much lower compared to those reported in the literature for another hydrofiber dressing, *i.e.* with a mean VAS score of 3.12 on Day-7 [15].

The hydroconductive dressing proved to be at least as safe as the standard of care (thin film) in dressing the donor site wound, with only a quarter of patients

reporting an adverse event in the hydroconductive dressing group compared to more than two thirds of patients in the thin film group ($p = 0.003$). Notably, when adverse events were present in the hydroconductive dressing group, they were also present in the thin film group.

Our study is not without limitations. A full cost analyses based on the number of dressing changes and length of hospital stay would further substantiate the use of this locally manufactured dressing. Also, we did not address how the added paraffin gauze could influence the wound healing parameters. Nevertheless, this addition was essential as the test dressing could adhere to the raw wound surface and remove early epithelialization with subsequent dressing changes. Although patients were followed up until three months after the initial skin graft was done, as per the study design, the long term evaluation of these donor sites (at least a year) would provide even more valuable evidence with regards to the remodelling phase of wound healing; a future prospect.

The level of evidence from our study, in addition to the research methodology being a prospective and within-patient controlled design, suggests that we can at least review that the standard of care dressing in treating donor site wounds in our setting be replaced with the locally manufactured dressing Drawtex®. A larger, prospective, multi-centre trial could yield even more convincing evidence to suggest a change in practice.

5. Conclusion

In conclusion, our study shows that the hydroconductive dressing with Levafiber technology in treating donor site wounds has significantly quicker rates of epithelialisation by Day-5 post-operatively compared to the current standard dressing of care. Moreover, patients experienced the hydroconductive dressing wounds to be significantly less painful throughout the healing period when compared to the standard dressing of care. Importantly, the hydroconductive dressing matches the safety profile of the standard of care dressing, with a lower frequency of adverse events noted, when compared to thin film. Finally, the hydroconductive dressing treated group reported no incidences of infection or conversion to full thickness wounds.

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