A Prospective, within-patient controlled study to compare the ability of the non-adherent Drawtex® Hydroconductive Dressing to an Opsite® Dressing (Standard of Care) on the healing of split-thickness skin graft donor sites.

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine

Johannesburg

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DECLARATION

I, Barend van den Bergh (student no. 669531), declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in Surgery at the University of the Witwatersrand, Johannesburg, South Africa. It has not been submitted before for any other degree or examination at any other University.

On this ___2nd____Day of ____February_____2018 in Johannesburg

DEDICATION

I dedicate this thesis to my parents: Hennie & Amór for their constant commitment to my success; a forging process that started at the inception of my thoughts.

PRESENTATIONS ARSING FROM THIS STUDY

This research article was presented at:

- The Department of Plastic- and Reconstructive Surgery, academic meeting in September 2017
- Accepted for oral presentation at the Association of Plastic and Reconstructive Surgery of South Africa (APRASSA), Annual Congress in Johannesburg from 15-17 September 2017
    - Winner: APRASSA award for best Registrar Clinical Paper
- Accepted for oral presentation at the Bert Myburgh Research Forum at University of the Witwatersrand, Department of Surgery on 29th November 2017
    - First Prize awarded

ABSTRACT

Background

Dressing of donor sites in split-thickness skin grafts can be traumatic for the patient. The associated pain and discomfort has impelled a myriad of publications in the quest for the ultimate dressing. The most advanced and expensive dressings have been studied and compared to the most basic of dressings, with little or no consensus and an unpersuasive level of evidence.

Objectives

We aimed to determine the efficacy of the locally manufactured non-adherent, hydroconductive Drawtex® dressing and compare it to the standard-of-care dressing in our setting, Opsite®, in the healing of split-thickness donor sites.

Methods

In this prospective, within-patient controlled and multi-center study, we included 27 adult participants, each with two split-thickness skin graft donor sites: one donor site wound was dressed with Drawtex® and the other one with Opsite®. The 54 donor site wounds were compared with regard to time to re-epithelialisation, perceived pain of the patient and quality of the healed wound.

Results

Comparing Drawtex®- and Opsite® dressings in the healing (defined as >90% of epithelialised surface) of donor site wounds, 22.2% of Drawtex® and 3.7% of Opsite® wounds were healed by day 5 ($p=0.00002$). On day ten and fifteen; 88.9% vs 85.2% and 100% vs 96.2%, of donor site wounds were healed for Drawtex® and Opsite® respectively. The hydroconductive dressing treated donor site wounds were significantly less painful than the Opsite®-treated donor sites wounds at 24-hours, 48-hours and 7-days post-operatively. Overall, there were less complications in the hydroconductive dressing group and the wound healing quality was superior to that of the Opsite®-treated group.

Conclusion

Drawtex® is a relatively cheap and readily available dressing made locally in South Africa. In this study we have demonstrated Drawtex® to be at least as safe, and potentially superior in wound healing, when compared to our current standard-of-care dressing, Opsite®.

ACKNOWLEDGEMENTS

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LIST OF ABBREVIATIONS

STSG	Split thickness skin graft
DSW	Donor site wound
VAS	Visual analogue score (pain)
KZN	KwaZulu-Natal
HJH	Helen Joseph Hospital
CHBAH	Chris Hani Baragwanath Academic Hospital
HIV	Human Immune deficiency virus
AIDS	Acquired immunodeficiency syndrome

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CHAPTER 1

INTRODUCTION

1.1 Background

Split-thickness skin graft (STSG) donor sites are partial-thickness wounds that heal 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 STSG donor site wound (DSW). The ideal dressing should be one that maintains a moist pH-balanced wound, manages exudates, limits infections, minimizes disturbance of the healing tissue beneath the dressing, reduces pain to the patient, and limits the number of dressing changes.

There is extensive literature available on the dressings and management of STSG DSWs. A wide variety of dressings, ranging from simple dressings, such as transparent polyurethane film, to more complex dressings like silver (Acticoat®)[1] or growth-factor impregnated dressings (rh-aFGF)[2] have been studied in the management of STSG DSWs, with lack of consensus from these studies. In a review article of 33 studies in 1998, the available empirical evidence regarding STSG 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-epithelialised surface and a low infection rate, in addition to the least amount of pain experienced and at a minimal cost.[3] It is known however, that disadvantages to the transparent polyurethane film dressing includes post-operative leakage from under the dressing of the DSW, as well as fragility of this newly healed donor site.[4] More recently, a single-centre randomised control trial again showed superior results with a transparent, breathable film, i.e. Mepitel film®, compared to more modern dressings.[5]

In contrast, some studies have shown that other dressings perform better than transparent polyurethane film: Bovine collagen in a comparison cohort study proved to achieve greater epithelialisation and less pain with dressing changes compared to a transparent polyurethane film[6], but at much greater cost. Most studies compare dressings to one another based on, but not limited to, the following criteria: days to epitheliazation, VAS pain scores and wound quality, factoring in the incidence of complications and cost effectiveness.

Regarding epithelialisation, it is evident from the literature that the healing of DSWs occurs on average on day 10 with a range of nine to 21 days.[1, 5, 7-14] This average however, was slightly earlier at 7.9 days for a Hydrofiber dressing.[15]

In a study in 2009, 100 consecutive patients' DSWs were dressed with a range of dressings including Aquacel Ag®, Bactigras®, Comfeel®, Adaptic® and Opsite®. Where none of the dressings were reported to be ideal, the Opsite® 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. Alhough VAS scores were low, it was the second most painful dressing, but nevertheless one of the most cost-effective.[12] In another study by Lauchli's group, basic transparent polyurethane film was contrastingly shown to be significantly less painful than other highly absorbtive, modern dressings, like Calcium Alginate.[16]

Complications are key factors in assessing quality of the final epithelialized DSW. From the literature, the ionic silver containing hydrofiber dressing, when compared to paraffin gauze, was also found to be superior in guarding against secondary infection[15], again these dressings are expensive and not readily available within the state sector South African hospitals.

At our institution the current standard of care dressing for STSG DSWs is Opsite® (Smith & Nephew (Pty) Ltd, Pinetown, KZN, South Africa), a transparent polyurethane film which is adherent to the wound surface and is re-inforced by a crepe bandage. The frequency with which the dressings are changed is arbitrary and dictated by the volume of drainage or the physical condition of the dressing. Drawtex® (Beier Drawtex Healthcare (Pty) Ltd. Pinetown, KZN, South Africa), 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 100x100 mm sheet (personal correspondence with Drawtex South Africa on 31st January 2018). It utilises Leva*fibre* 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 hydroconductive dressing have not been compared in a prospective study to the current standard of care: thin transparent polyurethane film dressing, Opsite®. Consequently, the question of whether the use of this hydroconductive dressing is superior

in the healing of STSG DSWs in our setting when compared to thin film remains unanswered. We therefore aimed to investigate the efficacy of this hydroconductive dressing compared to thin film in the healing of STSG DSWs, specifically pertaining to healing time, quality of healing, pain and infection rates.

1.2 **Objectives**

We aimed to investigate the efficacy of the non-adherent hydroconductive dressing, compared to thin film, the current standard dressing of care, in the healing of STSG DSWs:

The primary objectives of the study were:

1. To compare the length of time to complete healing (i.e. >90% re-epithelialisation).
2. To determine the quality of healing at the time of dressing changes and then at three months, as determined by presence of scar hypertrophy, pruritus, erythema and/or induration.

The secondary objectives of the study were:

1. To measure the patients' pain experienced using the Visual Analog Score (VAS) for Pain at 24-hours, 48-hours and 7-days post application.
2. To determine and compare the safety of the dressings with regard to the presence of infection and the conversion of the DSW to a full-thickness wound.

CHAPTER 2

METHODS

2.1 Study design, setting and participants

This was a prospective, within-patient controlled and multi-center study that compared two wound dressings for the treatment of adult STSG DSWs. 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. Eligible study participants were adult patients ≥18 years old who presented either to the Burns Unit at CHBAH or to the General Surgery unit at HJH and who required a STSG with two resultant non-contiguous DSWs.

Patients were excluded if they

1. Had any co-morbidities that are known to impede wound healing, such as HIV/AIDS, cancer or uncontrolled Diabetes Mellitus.
2. Were pregnant, or
3. Were on immune-suppresive- or systemic corticosteroid therapy.

2.2 Allocation of DSW dressings and standard surgical technique

Two non-contiguous DSWs of 50-250 cm^2 were created by the study's two investigative surgeons. The total area of the DSWs did not exceed the size of defect that needed to be covered. DSW depth was 0.23-0.30 mm (0.010-0.012 inches). Both DSWs on a single patient were harvested to the same depth.

Allocation of DSW 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 DSW regions would be labeled 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 DSW would randomly receive the hydroconductive dressing whilst the other DSW received the thin film dressing.

The hydroconductive dressing was applied over and above a single layer of paraffin gauze that covered the wound surface. The thin film dressing was applied immediately adjacent to the wound surface. Crepe bandage was used to re-enforce both dressings and blind the patient to the dressings. The latter could be replaced as needed, whilst the hydroconductive dressing or thin film layer would remain in place. If the inner layer of the hydroconductive dressing or thin film dressing had to be removed and replaced, it was to be noted as such in the research record.

If the clinician suspected infection 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 was taken to facilitate goal directed treatment for the specific organism.

2.3 **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 DSWs were taken denoting the time to healing, i.e. >90% re-epithelialisation. To assess the pain intensity experienced on the days of data collection, 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 surgeon would remove and replace the covering wound dressing if he felt that it was surgically indicated to do so. Again, such cases were noted as an adverse event.

2.4 **Ethical approval**

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.

2.5 **Statistical analyses**

The STATISTICA suit of analysis software, Version 12.7 (Statsoft Inc., Oklahoma USA) was used for all statistical analyses. Descriptive statistics was performed for each variable. Statistical analyses to compare the hydroconductive dressing- to the thin film-treatment groups were carried out with the following tests:

- Wilcoxon matched pairs test for treatment comparisons on continuous and ordinal variables.
- McNemar Chi-square test for within-subject testing of equality of proportions.

A p-value of <0.05 was considered significant.

CHAPTER 3

RESULTS

Between March 2015 and July 2016, 38 participants were identified that met the inclusion criteria of our study and gave written informed consent to participate. A total of 11 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, with the distribution showing a slight imbalance to the younger population group. The age range was 18-61 years with a female (n=7) to male (n=20) ratio of 1:2.86. 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 (Figure 3.1).

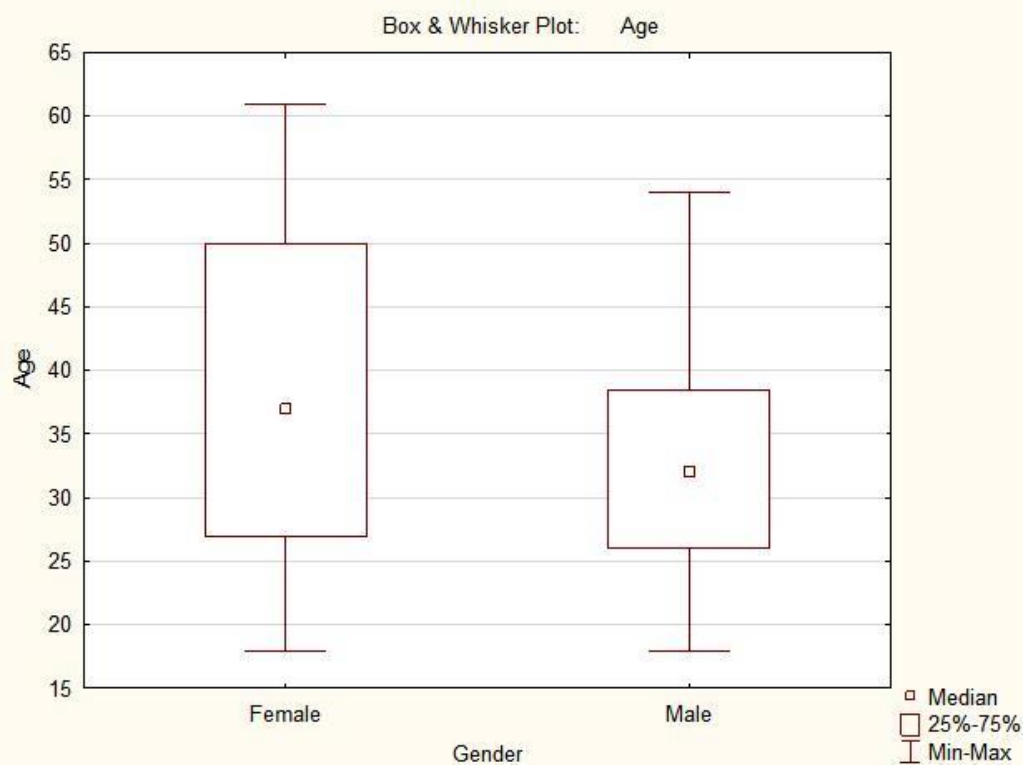

Figure 3.1. Box & Whisker plot of the study population age according to gender.

Efficacy assessment

Epithelialisation

Complete epithelialisation was defined as the day when >90% of the DSW surface had re-epithelialized. As seen in Figure 3.2, the percentage of patients with re-epithelialized DSWs was compared between the hydroconductive dressing and the thin film-treated groups on Day-5, -10 and -15. Almost a quarter (22.2%, n=6) of DSWs in the hydroconductive dressing group had epithelialized by Day-5, compared to only 3.7% (n=1) in the thin film group. This difference reached statistical significance with the McNemar Chi-square test, a within-subject test of equality of proportions (P=0.00002). Interestingly, the paired hydroconductive dressing donor site corresponding to this one epithelialized thin film donor site at Day-5 had not yet epithelialized. At Day-10, 88.9% of donor sites treated in the hydroconductive dressing group were epithelialized compared to 85.2% in the thin film group (McNemar Chi-square test, P<0.0001). Noteworthy yet again, the remaining three hydroconductive dressing donor sites that had not yet epithelialized by Day-10, had already epithelialized in the corresponding paired thin film donor sites within these participants. By Day-15, all DSWs in the hydroconductive dressing group had epithelialized and one patient's thin film DSW had not yet epithelialized.

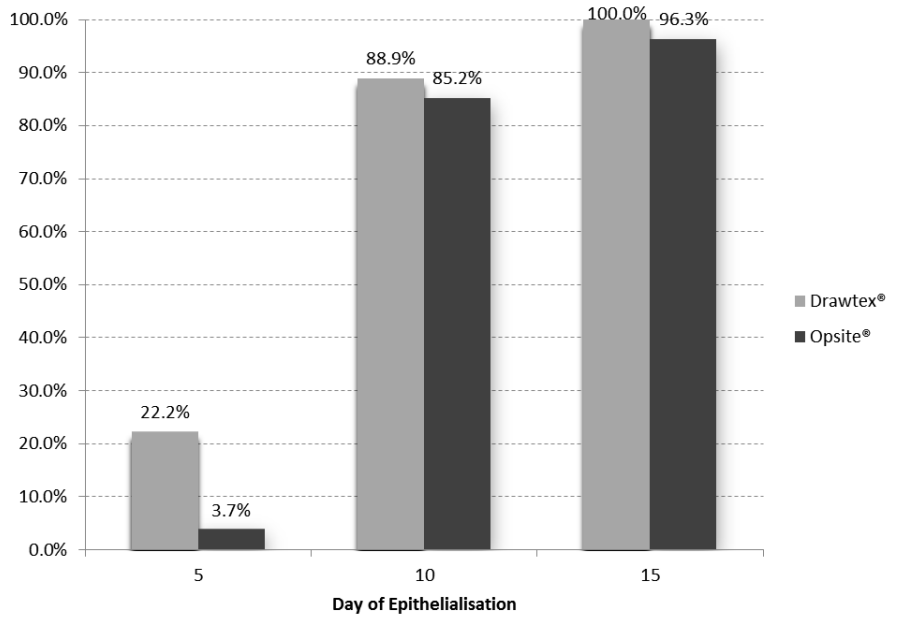

Figure 3.2. Day of epithelialisation of donor site wound dressing Drawtex® vs Opsite®

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 3.1 shows a comparison of the frequencies of the pain scores between the hydroconductive dressing and thin film-treated donor sites.

Table 3.1. Mean VAS for Pain intensity at donor sites

Time	Drawtex® Mean (SD)	Opsite® 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

Safety assessment

The quality of healing of the DSWs 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 DSW, only 25.9% (n=7) of patients reported an adverse event in the hydroconductive dressing group. From the bivariate distribution of the presence of adverse events for the two dressings shown in Figure 3.3, it is evident that for most of the participants (n=11, 61.1%) 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 with a P-value of 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 3.2 and Figure 3.4.

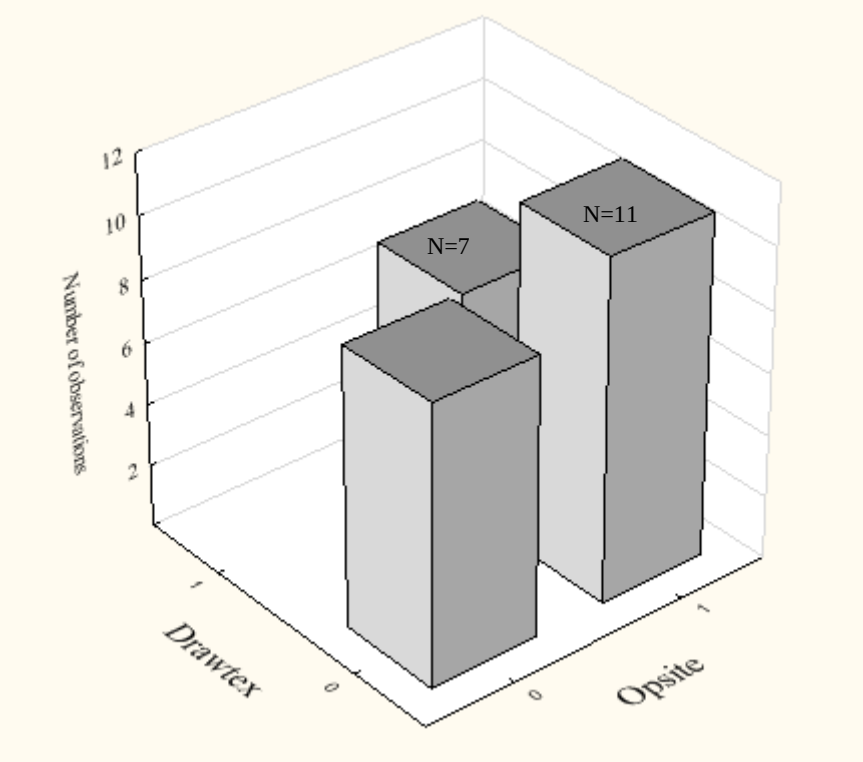

Figure 3.3. Bivariate distribution of all adverse events in the Drawtex® and Opsite® donor sites.

'0', no event; '1', event present.

Table 3.2. 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

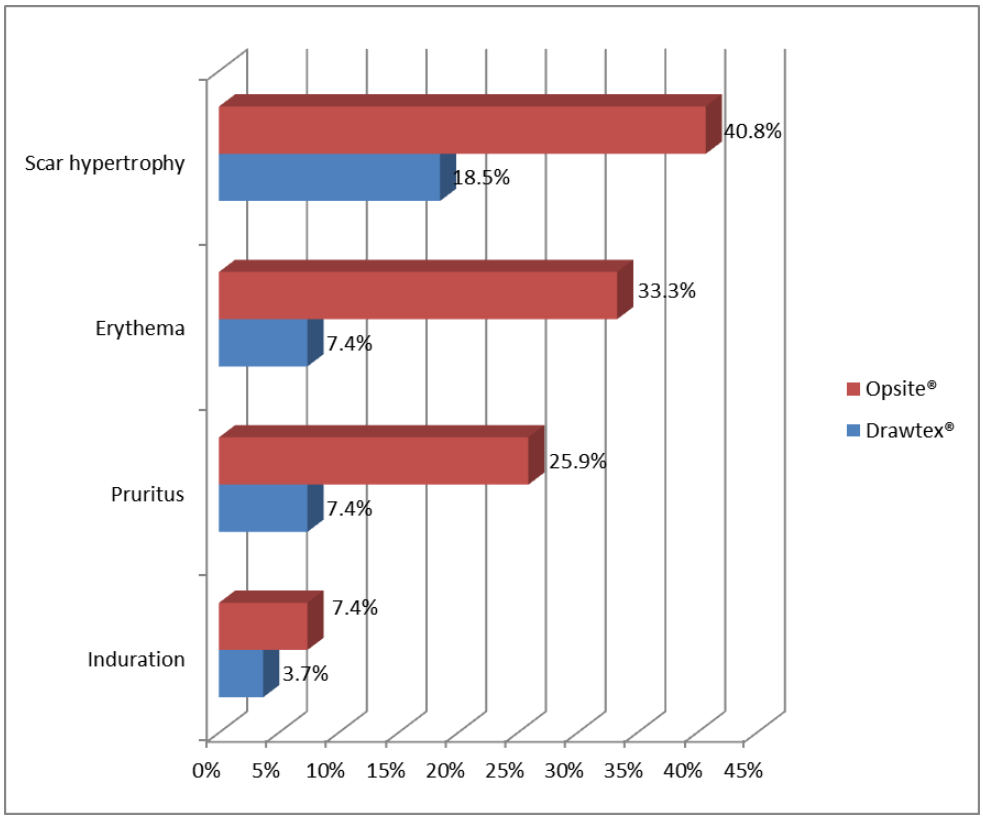

Figure 3.4. Frequency of adverse events noted in the Drawtex® and Opsite® donor sites.

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 DSW resulted in a full-thickness conversion and was from the thin film-treated group.

CHAPTER 4

DISCUSSION

We know from the literature that the dressing of DSWs, which in the case of a STSG 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 DSW 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.[20] 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 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 DSWs[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 epithelilisation[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 within-patient DSWs at Day-5, -10 and -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=0.00002). 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, 7-14] In our hydroconductive dressing and thin film-treated groups, 88.9% and 85.2% of DSWs had fully re-epithelialised by day 10.

When assessing the pain experienced at the DSWs 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 was in keeping with the literature that showed a mean VAS score for thin film on Day-7 of 2.1[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 DSW, with only a quarter of patients reporting an adverse event in the 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.

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 DSWs in our setting be replaced with the locally manufactured dressing Drawtex®. A larger, prospective, multi-center trial could yield even more convincing evidence to suggest a change in practice.

CHAPTER 5

CONCLUSION

Our study shows that the hydroconductive dressing with Levafibre technology in treating DSWs has significantly quicker rates of epithelialisation by Day-5 post-operatively compared to the current standard dressing of care. Moreover, patients experienced the 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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APPENDIX 1: Approved Protocol

A Prospective, internally-controlled study to compare the ability of the low adherent Drawtex Hydroconductive Dressing vs Opsite (Standard of Care) on the healing of Split Thickness Skin graft Donor Sites. MMED PROTOCOL

Supervisor: Professor J Goosen

2nd Supervisor: Mr Steve Moeng

External supervisor: Dr Robson

Principal investigator (author): Dr BH van den Bergh

Second investigator: Dr M Ndjo

Anticipated start date: January 2013

Anticipated end date: August 2013

Protocol approved: 24 April 2013
Supervisor added: Dr Deirdré Kruger

Introduction / background

Split-thickness skin graft donor sites are partial-thickness wounds that heal by the process of epithelialization. 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 these donor site wounds. The ideal dressing should be one that maintains a moist pH-balanced wound, maintains exudates, limits infections, minimizes disturbance of healing tissue beneath the dressing, reduces pain to the patient, and limits the number of dressing changes. The standard practice for donor site wounds depends on the depth of the wound and the co-morbidities that the patient possesses. At our institution the current standard of care is the use of Opsite (transparent film – adherent to wound surface) covered with a bulky gauze dressing. The frequency with which the dressings are changed is arbitrary and dictated by the volume of drainage or the physical condition of the dressing. Drawtex, a low adhernet Hydroconductive dressing, utilizes Leva*fibre* technology. *Levafibre* Technology is a combination of two types of cross- action structures that create the ability to move exudate from the wound bed through the dressing. Drawtex can decrease bacteria and deleterious cytokines from the wound. This reduces the risk of infection and maceration of the wound.

Dressings and management of Split thickness skin graft donor sites, have been studied with inconclusive results and lack of consensus. A wide variety of dressings, ranging from simple dressings for example Polyurethane film, to more complex dressings like silver (Acticoat®)[1]-, or growth-factor impregnated dressings (rh-aFGF)[2] have been studied in the management of donor sites (for split thickness skin grafting) . In smaller comparative studies, some of these dressings proved to be superior in acceptability, ease of use and efficacy, like Veloderm, compared to Algisite M® and Jaloskin® in 2006 [3]. Even mildly absorptive materials, like Xeroform® have been compared for instance to Jellonet®, but showed no benefit even in terms of cost effectiveness[4]. In 2009 bigger studies where a 100 patients were dressed with a range of dressings including Aquacel Ag®, Bactigras®, Comfeel® snd Opsite®, none of the tested materials were found to be ideal, but made some recommendations as to which dressings caused less pain than others [5]. One of the only prospective, randomised control studies from the Journal of Burn Care in 2011, a pilot study, again showed no significant

difference between materials tested with regards to healing time, infection rates and cosmetic outcome[6]. Bovine collagen in a comparison cohort study proved to achieve greater epithelialisation and less pain with dressing changes compared to a polyurethane film & Rayon® soaked in 0,9% Saline[7], An ionic silver-containing dressing also proved superior to paraffin gauze with regards to pain and time to complete epithelialisation[8].

In an article (1998, Journal for applied nursing res) integrating the available empirical evidence regarding STSG donor site dressings, a review of 33 studies was published: Transparent film was found to be the best dressing care with the fastest healing rates, a smooth reepithelialised surface and a low infection rate, with the least amount of pain and at minimal cost[9]. This is the standard of care for today. It is known however, that disadvantages to the polyurethane dressing were post operative leakage from under the dressing on the donor site, and fragility of this newly healed donor site[10]

The previously mentioned silver containing hydrofiber dressing in [8] *(compared to paraffin gauze)* was also found to be superior in guarding against secondary infection[11], but these dressings are expensive and not readily available in state sector.

A relatively cheap, non complex dressing, readily available in state sector, manufactured by a South African company have not yet been compared (in convincing studies with convincing research methodology) to the standard of care - polyurethane film, or Opsite®.

Taking this background into account, the following question arises:

Is there a better way of managing split thickness skin graft donor sites; using Drawtex (a hydroconductive dressing) compared to the current standard of care, in order to achieve quicker healing time, better quality of healing and less pain and chance of infection overall?

Aim & Objectives

In this prospective -internally controlled study- we aim to investigate the efficacy of low adherent Drawtex (a hydroconductive dressing) in the healing of Split thickness donor sites compared to Opsite®, the standard dressing of care.

Specifically, the ***primary objectives*** of the study are:

1. To compare the length of time to complete healing (>90% epithelialization)
2. To determine the quality of healing when the dressing separates and at three months after, based on the presence, or not, of scar hypertrophy, pruritis, erythema and induration.

The ***secondary objectives*** of the study are**:**

To measure the patient's pain experience using the VAS(pain) scores at 24 and 48 hours after application, and at 7 days

To determine and compare the safety of low adherent Drawtex using the following parameters:

- Presence of Infection
- Conversion of donor site to full-thickness wound

Hypothesis

Drawtex improves the quality of healing and reduces the time to complete healing, pain experienced and the likelihood of infection in the post-operative period when compared to the current standard of care.

Methods:

This is a study comparison of 2 wound dressings for treatment of adult split-thickness skin graft donor site wounds.

Study Design

This is a randomized, prospective, internally controlled study

After obtaining the split-thickness skin grafts at the size and depth stated in the inclusion criteria, initial hemostasis will be achieved with pressure. *Each of the wounds (paired) in the same patient* will be randomized to receive either low adherent Drawtex (over and above a single layer of paraffin gauze covering the wound suface) or Opsite immediately adjacent to the wound surface. The amount of skin harvested, will not exceed the amount needed to cover the defect. Drawtex can then be added to the Drawtex donor site as a cover dressing and held in place with a wrap of the surgeon's discretion. Standard burn gauze can be used as a

cover dressing to the Opsite treated donor site. The outer wrap and outer layer of dressings can be replaced as needed, but the low adherent Drawtex or Opsite layer will remain in place. If the inner layer of non-adherent Drawtex or Opsite must be removed and replaced, it will be necessary to note that on the research record. Post operative day five, day ten and day fifteen (or day of discharge), photographs of the donor sites will be taken denoting the time to healing (90% epithelialisation); If the patient becomes an outpatient, he or she will return to the outpatient clinic to be reassessed for wound healing. The clinician may on any moment decide to remove the covering wound dressing should he feel that it is surgically indicated to do so. It will be noted as an adverse event.

Study Population

Adult patients (18-60 years) presenting to the Trauma Unit at Charlotte Maxeke Johannesburg Academic Hospital and Leratong Hospital, that are predetermined to require a split-thickness skin graft with a resultant donor site wound and meet all study criteria will be enrolled in the study

Sample Size

The sample size will be approximately 20 patients. A review of literature has revealed an inadequate amount of existing research to determine a statistically powered sample size for this study. Therefore, Sample size selection was based on the feasibility of completing a small number of subjects in a pilot study to be used in the development of a larger study including sample size determination with power analysis.

Inclusion Criteria

- Patients with 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.
- Both genders with an age 18-60 years at randomization

- Signed informed consent

Exclusion Criteria

- Donor sites located on Head, neck , or hands
- Patients with necrotising 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 10mg prednisolon/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

Randomization

Allocation of treatment of wounds sites will be done at random, using a pre-determined random assignment of treatments to the 2 defined wound regions. Randomization scheme will be achieved using a computer-generated list (MS Excel). Wound regions will initially be labeled A and B by the physician, and then an envelope will be opened which will indicate which treatment to assign to A and which to B. One wound will be randomly assigned non-adherent Drawtex and the other wound will be assigned the Opsite standard of care dressing.

The same Practitioner will attempt to change the dressings; however, it may not be possible for all cases. All dressing changes or reinforcements will be recorded in the research record. Wound assessments will occur until full epithelization (at least 90% closed and no longer in need of a dressing. If the patient becomes an outpatient, he or she will return to the outpatient clinic to be reassessed for wound healing.

Outpatient visits will occur as required per standard of care. Study participation will not require more frequent visits to the outpatient clinic. The wound dressing changes and treatments provided at the outpatient clinic will be standard of care. A final evaluation of wound healing and scarring of each donor site will be made at three months.

Standard Surgical Practice

All patients will receive the standard pain management and wound preparation methods.

The tangential harvesting and splitting of donor skin:

- DAVIES GOLD SERIES DERMATOME, Duplex GD 103
- ZIMMER, Meshgraft II Tissue expansion system

Pain Management

The standard pain management regimen at this institution is:

Paracetamol 1g QID PO

Tramadol 100 mg BD PO/IV/IM if needed

Study Duration

	2013							
	JAN	FEB	MRC	APR	MAY	JUN	JUL	AUG
Literature review								
Preparing protocol								
Protocol assessment								
Ethics application								
Collecting data								
Data analysis								
Writing up thesis								
Submission								

Data Recording

Data will be collected at baseline, 24 hours after application of study dressings, and 48 hours after application of study dressings, at 7 days, and at the time of complete wound epithelialization. Final data will be collected at 3 months. Please see attached data collection sheet

Statistical analysis:

Analysis Plan

Data would be recorded in Excel and statistical comparisons made using STATISTICA, using non parametric tests. Univariate analyses will be used for distribution (ranges of values, frequency distribution), central tendency (mean, median, mode), and dispersion (range, standard deviation). If there are enough data to draw a conclusion, we will proceed with inferential statistics and stratification of groups according to age. Categorical data will be analysed using the Chi square test with Fisher correction for small numbers.

Benefits and risks

There is always the risk of one or more side effects developing in the course of treatment. For example, there may be a local irritation or even an allergic reaction to the treatment or the wound dressing. If this occurs, treatment with the non-adherent Drawtex dressing or Opsite will be discontinued.

The study staff will be looking for any such adverse side effects during the entire course of the study.

Another complication can be wound infection. If this occurs, the patient will be treated with an antibiotic. Pain is a common adverse effect of split-thickness skin graft donor sites and will be monitored. Conversion of the donor site to a full-thickness wound can occur in any donor site and if such an event happens, the wound will be treated as seen fit by the surgeon. There may be risks or side effects which are unknown at this time. The PI will perform a daily data review of any serious adverse events and conversions to full thickness.

Adverse Events

Definition of Adverse Events (AE)

Adverse events can be classified as either serious or non-serious. A serious adverse event is an occurrence of any of the following:

- Death
- Is life threatening
- Requires prolongation of hospitalization time
- Results in persistent or significant disability or incapacity

Common less serious adverse Events for Split-thickness Skin Graft Donor Sites

Low grade fever, wound pain, itching, inflammation, anxiety, agitation and disruption of dressing

Record All Adverse Events

- All adverse events that occur after the initial dressing application will be considered treatment emergent adverse events.
- Information on all AE's should be recorded on the source document
- At each contact with the subject the investigator must seek information on AEs by specific questioning, and as appropriate, by examination.
- Serious Adverse Events that are still ongoing at the end of the study must be followed to determine the final outcome**.**

The wound assessment for clinical evidence of infection is a study outcome and will be reported on the data collection form. It will not be considered an adverse event.

Benefits to Patients

We do not know if participation in this study will benefit the patient, however a favorable outcome as stated in the hypothesis, might decrease time to complete healing, decrease pain and decrease chances of infection, an overall decrease in length of stay in hospital.

Costs

The cost of a dermatome and mesher as described in 'Standard Surgical practice' have been undertaken by Beier Drawtex Healthcare, whom will also supply the Hydroconductive dressing material as described in the study design. The material used for the compared donor site, is the 'standard of care', as would be the case if the patient was not enrolled in the study, needing a split thickness skin graft for whichever reason. There are no financial conflicts of interest.

Ethical considerations and informed consent

In January 2013 , an application to the Human research ethics committee of Johannesburg was made to gain approval to conduct the study in the said hospitals. On 25 January 2013 approval was granted (M130105) subject to a small change, ensuring that donor sites won't exceed the surface area needed to cover the original defect. This change was incorporated in the study design and informed consent documents.

Consent process:

Adult patients that are admitted to the surgical service who require a split-thickness skin graft will be screened for study eligibility on a daily basis. Any patient that meets the study eligibility will be approached by one of the research team members. If a patient is eligible for enrollment, the study will be explained to the subject. All study discussion will be conducted privately. The study design (aims, methods, benefits and risks) will be discussed and the consent will be reviewed. The subjects will be informed that participation in the study is voluntary and that they may withdraw at any time; choosing against participation will not affect the care received for treatment. A copy of the consent will be left with the subject for review. A member of the research team will be available to answer any questions about the study. The research team will make case by case judgments on obtaining consent from the subject based upon their understanding of the research. If the study members feel that the individual providing consent does not understand the research, the patient will not be enrolled. The consenting research member will sign the ICF and a copy will be provided to the subject. Documentation of this process will be written in the patient's medical record with a copy of the signed informed consent. The subjects will be informed that they will be authorizing access of investigational staff to confidential medical records.

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APPENDIX 2: Datasheet

STUDY NUMBER	
PARTICIPATION NUMBER	
GENDER	Male / Female
AGE	
PRINCIPAL INVESTIGATOR	Dr Barend Van Den Bergh
SPONSOR	Beier Drawtex Healthcare
INVESTIGATORS	Dr Barend Van Den Bergh Sandra Oosthuizen
INSTITUTION	

PT NAME:
PATIENT ID NO :
DOA :
PT FILE NO:

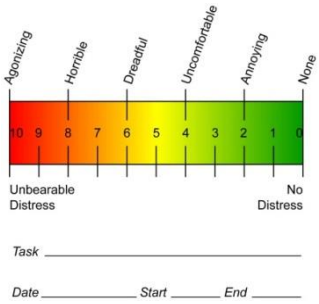
HOSPITAL STICKER

RANDOMIZATION

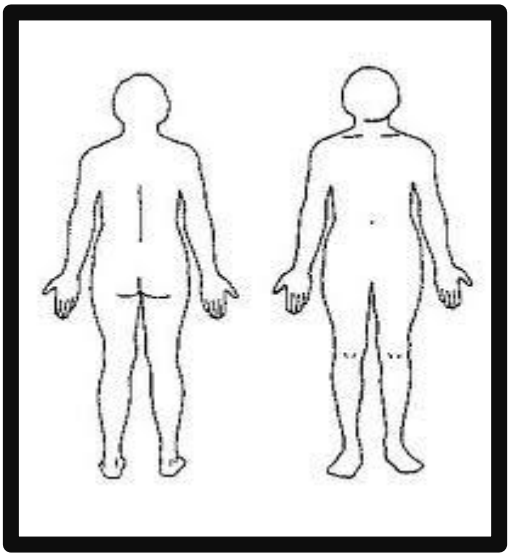
WOUND A	
WOUND B	

DATA COLLECTION

	Wound A	Adverse events	Wound B	Adverse events
24 Hours				
48 Hours				
7 Days				



WOUND LOCATION



WOUND ASSESSMENT

Day 5		**Signs of infection**		**Surrounding Erythema**		**Induration**		**Pruritis**		**Scar Hypertrophy**	
	Wound A	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present
	Wound B	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present
Day 10		**Signs of infection**		**Surrounding Erythema**		**Induration**		**Pruritis**		**Scar Hypertrophy**	
	Wound A	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present
	Wound B	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present
Day 15		**Signs of infection**		**Surrounding Erythema**		**Induration**		**Pruritis**		**Scar Hypertrophy**	
	Wound A	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present
	Wound B	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present
3 Months		**Signs of infection**		**Surrounding Erythema**		**Induration**		**Pruritis**		**Scar Hypertrophy**	
	Wound A	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present
	Wound B	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present

APPENDIX 3: Patient Participation and Informed Consent

Introduction

Good day my name is Dr Barend Van Den Bergh, I am a surgical registrar, in the Department of Surgery, Wits University and would like to invite you to consider participating in a research study, entitled - A Prospective, Internally controlled study to compare the ablility of a low adherent Drawtex Hydroconductive Dressing vs Opsite (Standard of care) on the healing of split thickness Skin graft donor sites.

1. Before agreeing to participate in the study, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, benefits, risks, discomforts and precautions as well the alternative procedures that are available to you, and your right to withdraw from the study at any time. This information leaflet is to help you decide if you would like to participate. You need to understand what is involved before you agree to take part in this study.
2. If you have any questions please do not hesitate to ask me.
3. You should not participate in the study unless you are satisfied about all the procedures involved.
4. You may not participate in another investigational medicine research study, nor take any other investigational medicine while participating in this study.
5. You should not have participated in an investigational study in the past 30 days
6. Please be open with me regarding your health history, since you may otherwise harm yourself by participating in the study.
7. If you decide to participate in this study you will be required to sign this document to confirm that you understand the study. You will be given a copy to keep.
8. If you have a personal Doctor you need to inform him of the possible participation in the study. I can also notify the Doctor in this regard.

PURPOSE OF THE STUDY:

- The surgery you are scheduled for is a split thickness skin graft. You have been injured and we need to place new skin onto the wound site. We do this by taking uninjured skin from another part of your body – called the donor site - and placing it onto the wounded area. We would take skin from two donor sites of the same size/ The one donor site we would cover with the usual dressing or bandage (standard of care Opsite) and the other site we would cover with the new dressing (Hydroconductive Dressing). This is a new dressing which has recently become available in the Hospitals.
- We will not take more skin, than what is needed to cover the area that needs skin replaced.
- We would compare the healing time, the amount of pain you experience, and the appearance (quality) of the two sites to determine whether healing is better using the new bandage; with photographs of the wounds, which makes it scientifically comparable.
- We would record personal data from your Hospital records (gender, reason and extent of injury, etc.) and follow up on the wound healing process.

LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS

- 20 participants will participate in this study.

- The participants will be between the ages 18 and 60
- The total amount of time required for your participation in this study will be a maximum of 3 months
- You will seen by myself and my team, 7 times during the study.

PROCEDURES

- If you agree to take part in this study, you will first be asked questions and examined to see if you qualify for this study.
- At each following visit you will undergo:
    - **Visit 1** – 24 hours after the surgery - tell us how much pain you have.
    - **Visit 2** – 48 hours after - tell us how much pain you have.
    - **Visit 3** – 5 days after- we will expose your donor sites, examine and photograph the wounds and ask you a few questions.
    - **Visit 4** – 7 days after - tell us how much pain you have.
    - **Visit 5** – 10 days after- we will expose your donor sites, to examine and photograph the wounds and ask you a few questions
    - **Visit 6** – 15 days after- we will expose your donor sites, to examine and photograph the wounds and ask you a few questions
    - **Visit 7** – 3 months after- we will examine and photograph the donor sites and ask you a few questions

WILL ANY OF THESE PROCEDURES RESULT IN DISCOMFORT?

- There is pain associated with all surgical procedures, you would receive the standard pain management regime of the institution which is Parcetamol 1gr 4 times per day PO, OR Tramadol 100mg bd po/ivi/imi if need be.
- Local irritation or even allergic reaction may occur, however the dressing has under gone trials and studies to prove biocompatibility and no know reactions have been reported. In the event of any of these symptoms occurring the dressings will be removed immediately and the use thereof discontinued.
- Wound infection may occur. If this occurs you will be treated with an antibiotic.
- Conversion to a full thickness wound may also occur, this will be managed by standard surgical procedures.

RISKS OF THE STUDY DRESSING

- No previous studies have been done on donor sites using Drawtex Hydroconductive dressings.

UNFORSEEN RISKS

- The study dressing is investigational and there may be other risks or side effects which are unforeseen or unknown. You should immediately contact me if any side effects occur throughout your participation in this study.

BENEFITS

- The potential benefit from your participation in this study may be that you would experience less pain and that your wounds would heal quicker, with no occurrence of infection.

- However, you may not benefit from this study.
- Your participation in this study will contribute to medical knowledge that may help other patients that, like you, may need skin grafts with donor sites.

ALTERNATIVE TREATMENT

- Alternative treatment: Opsite dressing of the wound, with a bulky gauze dressing over that, and this is the usual and standard of care for your wound.
- If you decide not to take part in this study you will still receive the best current care, from your usual doctor; this may or may not include the study dressing.

ARE THERE ANY WARNINGS OR RESTRICTIONS CONCERNING MY PARTICIPATION IN THIS STUDY?

- If you are pregnant, you may not take part in the study.
- You need to be between the age of 18-60.
- If you suffer from insulin dependent diabetes you may not take part in the study.
- If the doctor has diagnosed you with the following conditions you will not be able to be part of the study. Leucocytic Vasculitis or Pyoderma Gangrenosa.
- If you are taking any medicine like glycocorticosteriods, doctor will explain what these are.
- If you are using any immunosuppressant agents or have used in the last 30 days.
- If you have had cancer and have had any treatment like chemo or radiation therapy, in the last 30 days.
- If you are allergic to cotton, polyester, viscose you will not be able to take part in the study.

INTERACTIONS

- There are no known reactions and interactions to the study material.

RIGHTS AS A PARTICIPANT IN THIS STUDY

- Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason. Your withdrawal will not affect your access to other medical care.
- Discontinuation of study treatment.
  You must inform me if you wish to stop the study dressing

WITHDRAWAL

- Your withdrawal will not affect your access to other medical care.
- I retain the right to withdraw you from the study if it is considered to be in your best interest. If your participation is ended early, you may be asked to return for study-ending tests and procedures for your safety.
- If you did not give an accurate history or did not follow the guidelines of the study and the regulations of the study facility, you may be withdrawn from the study at any time.
  - **Pregnancy:** Because the safety during pregnancy of the dressing used in this study has not been established, you will be withdrawn from the study, should you become pregnant during your participation. All aspects of healthcare related to your pregnancy and infant will be your responsibility.

- Dr Barend Van Den Bergh will require access to your medical records and those of your child, from the time you became pregnant and for a minimum of 12 weeks after the baby is born.

EMERGENCY CARE AND HOSPITALIZATION

- If you seek emergency care or if hospitalisation (with regards to the donor site) is necessary from the date of enrolment of the trial and for the 3 months to completion of the trial, please tell the treating doctor that you are enrolled in this research study and I must be informed.

FINANCIAL ARRANGEMENTS

Maisha Medical has provided payment for

- Dressings
- Transport to and from place of residence at AA rates.
- Neither you nor your medical scheme will be expected to pay for any study dressings, study related visit or study procedures.

ETHICAL APPROVAL:

- This clinical study protocol has been submitted to the University of the Witwatersrand, **Human Research Ethics Committee (HREC)** and written approval has been granted by that committee.
- The study has been structured in accordance with the **Declaration of Helsinki** (last updated: October 2008), which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.
- This study has been sponsored by **Maisha Medical** as indicated above.

  I and the doctors treating you do not have any financial or personal interests with this organisation that may bias my actions.

ADDITIONAL INFORMATION

For the duration of the study, you will be under the care of Dr Barend Van Den Bergh If at any time between your visits, you feel that any of your symptoms are causing you any problems, or you have any questions during the study, please do not hesitate to contact me.
Other doctors from this department who are working on this study are:

- PROF J GOOSEN
- DR JONATHAN KOURIE

The 24-hour telephone number through which you can reach me or another authorised person, is 083 468 9962

- Please be aware that you need to follow all instructions given my myself or other doctors relating to your care at the Hospital and return for the follow-up visits.

CONFIDENTIALITY

- All information obtained during the course of this study, including hospital records, personal data and research data will be kept strictly confidential. Personal details would

recorded for the purpose of follow-up but such information would be kept separate from medical information by using a study number.

- Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.
- The final information would be reviewed by authorised representatives of ***Maisha Medical***.
- The information might also be inspected by the University of the Witwatersrand, Human Research Ethics Committee (HREC), and any other approved authorities.
- These records will be utilised by such authorities only in connection with carrying out their obligations relating to this clinical study.
- Any information uncovered regarding your test results or state of health as a result of your participation in this study will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this study but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission. The only exception to this rule will be cases of communicable diseases where a legal duty of notification of the Department of Health exists. In this case, you will be informed of my intent to disclose such information to the authorised state agency.

DO YOU HAVE ANY QUESTIONS REGARDING THE STUDY?
Yes/ No

1.
2.
3.
4.
5.

INFORMED CONSENT:

- I hereby confirm that I have been informed by the study doctor Dr Barend Van Den Bergh / Dr J Kourie about the nature, conduct, benefits and risks of clinical study:
    - Protocol Number:
    - Study Title:

- I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the clinical study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by **Maisha Medical** or on their behalf.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
-

1. PARTICIPANT:

Printed Name	**Signature / Mark or Thumbprint**	**Date**

2. STUDY DOCTOR

I, Dr Barend Van Den Bergh herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Printed Name	**Signature**	**Date and Time**

3.TRANSLATOR OR ANY OTHER PERSON EXPLAINING THE CONSENT
Designation:

Printed Name	**Signature**	**Date**

4. WITNESS

Printed Name	**Signature**	**Date**

APPENDIX 4: Ethics Clearance Certificate

M130105

R14/49 Dr BH van den Bergh

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130105

NAME: (Principal Investigator)	Dr BH van den Bergh
DEPARTMENT:	Department of Surgery CM Johannesburg Academic Hospital
PROJECT TITLE:	A Prospective, Internally-Controlled Study to Compare the Ability of the Low Adherent Drawtex Hydroconductive Dressing vs Opposite (Standard of Care) on the Healing of Split Thickness Skin Graft Donor Sites
DATE CONSIDERED:	25/01/2013
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof J Goosen
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 14/06/2013

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature

Date 17/6/2013

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES