A Novel Pre-Grafting Wound Management Technique to Promote Granulation in Complex Painful Wounds

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BACKGROUND

Skin grafting (SG) is used to provide coverage in both acute and chronic wound settings. Preparation of the wound bed with development of granulation tissue is vital for graft success.[1] Traditional standard of care (SOC) wound management principles involve debriding the wound followed by negative pressure wound therapy (NPWT), bolstering or conventional dressing applications to accelerate wound healing prior to grafting.[2] Current SOC is limited in complex painful wounds. NPWT deployment and application is often difficult and painful.[3] Pain is also a significant issue often associated with repeated wound dressing changes.

METHODOLOGY & MATERIAL

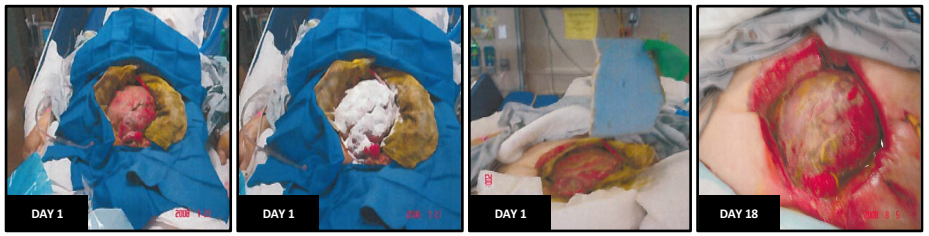
Three case studies incorporating treatment with Transforming Powder Dressing (TPD) to promote granulation in patients with complex wounds are reviewed. In each case, patients had extensive wounds with high levels of reported pain. Prior treatment in all cases failed to progress wounds to the stage to permit grafting. Cases reviewed include a large abdominal wound resultant of an automobile accident, complex wounds associated with uncontrolled chronic vasculitis, and an improvised explosive device (IED) accident. TPD was introduced to facilitate and promote granulation and allow grafting.

TPD is comprised primarily of biocompatible polymers. Upon hydration with saline, TPD granules aggregate to form a moist, oxygen-permeable matrix that protects the wound from contamination while helping to manage excess exudate through vapor transpiration. Once applied, TPD may be left in place for up to 30 days and additional powder may be added ("topped off") as needed without requiring primary dressing changes. Simple secondary dressings may be used in areas of high exudation or friction. TPD dries and flakes off as the wound heals.

RESULTS

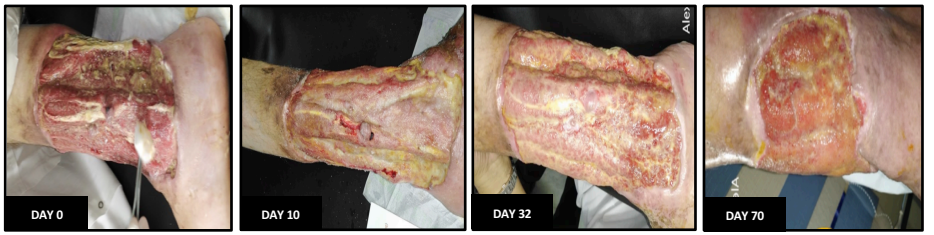
PATIENT 1: 40 y/o female with large complex abdominal wound resultant of car accident
Challenge: NPWT could not be placed due to risk of fistula
TPD Treatment: TPD applied to wound with foam for excess exudate absorption
Outcomes Post-TPD Treatment:

- Wound was ready for grafting by Day 18



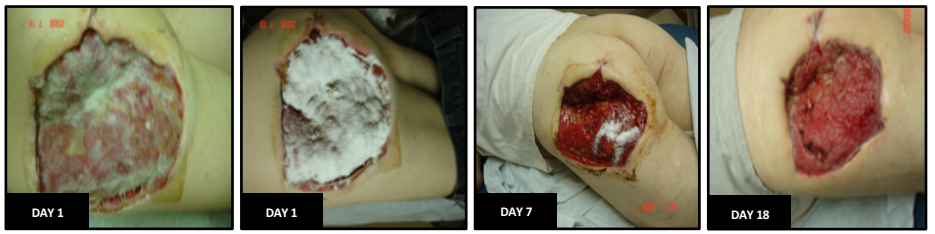
PATIENT 2: 42 y/o male with non-healing progressive venous ulcer, uncontrolled vasculitis, infection history, necrosis, exposed bone
Challenge: High pain score (9/10), failed SOC treatment
Treatment: TPD 2x/week in the first week and 1x/week after
Outcomes Post-TPD Treatment:

- Significant reduction in pain
- Granulation tissue covered bone and patient was grafted
- Avoided amputation



PATIENT 3: 40-year-old male with a 25cm x 25cm x 5cm IED blast wound due to consumer firework accident (M-80)
Challenge: NPWT was discontinued due to patient pain, porcine matrix failed to stimulate granulation
Treatment: TPD applied weekly
Outcomes Post-TPD Treatment:

- Wound depth reduced from 5cm to 2cm by day 7
- Wound was ready for grafting by day 18



CONCLUSION

A marked acceleration in granulation was observed in all three cases. Patients reported reduced pain and the frequency of dressing changes were also reduced relative to SOC. No adverse events were reported. Based on the clinical observations and outcomes, we conclude that TPD presents a safe and effective modality for preparing complex painful wounds for successful grafting.

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Steroids, Bioengineered Skin Substitute and Transforming Powder Dressing: Combination Therapy for Pyoderma Gangrenosum

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SAWC Fall 2022 Meeting, Las Vegas, NV | October 13-16

INTRODUCTION:

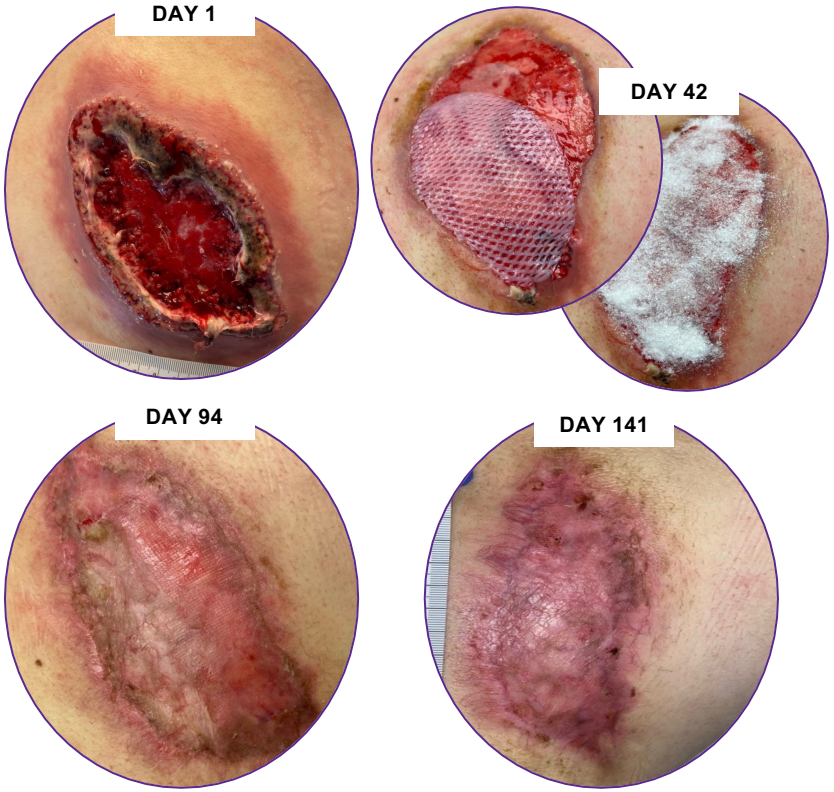
- Pyoderma Gangrenosum (PG) is neutrophilic dermatosis, often associated with malignancy and inflammatory/autoimmune conditions
- PG is characterized by pathergy-exaggerated response to or worsening of even a minor skin injury
- Treatment varies from systemic topical steroids to systemic immunosuppression
- Here we describe a case of PG treated with Prednisone, a bioengineered skin substitute (Apligraf) and transforming powder dressing (TPD*)

CASE DISCUSSION:

- 63-year-old male with a past medical history significant for Hepatitis B who presented to clinic for evaluation of a non-healing wound of the back which had been increasing in size following an excision of an epidermal inclusion cyst two months prior
- A biopsy was suggestive of PG

TREATMENT:

- Patient was started on a prednisone taper and local wound care with weekly application of bioengineered skin substitute and a transforming powder dressing



CONCLUSION:

- Wound has decreased in size from 88.3 cm^2 to 25.2 cm^2 (72%) and treatment is ongoing
- Since PG is diagnosed by exclusion of other possible ailments, the diagnosis of PG is often delayed or missed altogether
- Prompt recognition and initiation of treatment is essential

This case supports the use of bioengineered skin substitute and transforming powder dressing as adjuncts to systemic steroids in the treatment of Pyoderma Gangrenosum.

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- **Acknowledgements:** This case study was conducted independently by the authors and no compensation was paid to the authors. This poster was presented in collaboration with ULURU Inc. For application instructions and risks of this device refer to Altrazeal Instructions for Use.

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Graft Fixation and Wound Moisture Management with Transforming Powder Dressing*

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Introduction

Skin grafting is a fundamental method to repair skin defects and heal chronic wounds. Graft fixation and maintaining the wound environment is essential to the success of split or full thickness skin grafting. Skin grafts survive the first 24-48 hours as the result of serum imbibition. The graft is bathed in serum from the wound that supplies its nutrients via capillary action keeping the graft alive. Fixation methods prevent shear and slipping of the graft so as to hold it secure on the wound bed. Fixation allows the process of inosculation to occur as capillary buds in the wound bed align and grow into the vascular channels of the graft. Both of these processes are important for graft success and prevent graft loss.

Hypothesis

A new powder wound dressing technology can be utilized to "anchor" a meshed autograft or bio engineered skin substitute** in place on a wound without the use of fixation such as sutures or staples.

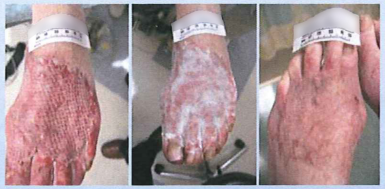
Materials and Methods

Transforming powder dressing was used to fix split thickness skin grafts and bio engineered skin substitutes. Skin grafts were harvested at 0.012 to.015 inch. The grafts were messed 1:1.5 and applied to the wound bed. Transforming powder was applied and aggregated fixing the grafts in place. Skin grafts were checked at weekly intervals until graft take was assured and documented.

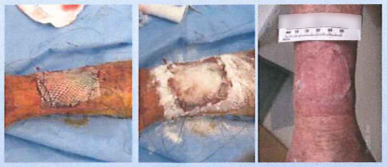
Bio engineered skin substitute was meshed 1.5:1 and applied to wounds. The graft was fixed with transforming powder dressing. Wounds were followed at weekly intervals. If necessary, Bioengineered skin substitutes can be re-applied at 2 week intervals.

The technique was tested on two cases involving autologous mesh grafts harvested as 0.015 inch thick split thickness grafts. One case was a debrided third degree burn on the dorsal left foot. The second case involved a surgical excision where the graft did utilize limited suture fixation. In both cases with autologous grafts, the transforming powder dressing was not changed after application.

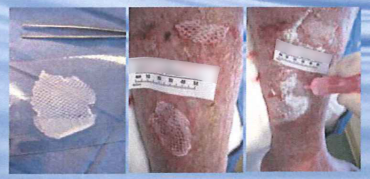
The technique was tested on two cases where living skin equivalent was meshed and applied directly to a debrided venous ulcer or DFU. In these cases, the powder dressing was left in place over the living skin equivalent for two weeks then the wound was cleaned and a new application of living skin equivalent was applied to the wound with another application of transforming powder dressing.



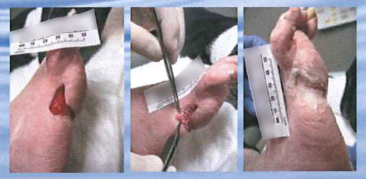
Case 1: Third degree burn debrided and treated with 0.0015 in ch split thickness skin graft meshed 1:1.5. Sutures and clips were not applied to this graft.



Case 2: Surgical excision site grafte with 0.015 inch autologous split thickness skin graft meshed 1:1.5. Sutures were used to anchor the edges of the graft.



Case 3: Venous Stasis Ulcer treated with Living Skin Equivalent fixed in place using Transforming Powder Dressing.



Case 4: Diabetic foot Ulcer treated with Living Skin Equivalent fixed in place with Transforming Powder Dressing. Patient was offloaded with a contact cast.

CONCLUSIONS

Transforming powder dressing can be employed as a method of graft fixation for both split thickness skin grafts and bioengineered skin substitutes. Whether applied in the operating room using split thickness skin grafts or in the clinic with bio engineered skin substitutes, the material remained in place with the grafts. The grafts were meshed and the powder material filled the spaces in the graft and securing it in place.

This method simplifies the use of bioengineered skin substitutes in the clinic setting and avoids problems with disturbing the grafts with dressing changes. Maintaining the moist wound environment without fluid build up is an important aspect of grafting and a material that optimizes the wound moisture while securing the graft in place can be beneficial. Graft take can be improved and optimize the effectiveness of these commonly used wound care products.

One other important finding from this study is that this technique of graft fixation can be used under compression wraps or in conjunction with contact casting.

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** Apligraf ®-Organogenesis Inc.

A Randomized Clinical Study Comparing a Novel Transforming Powder Dressing to a Carboxymethylcellulose-Silver Dressing in Skin Graft Donor Sites

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Introduction

Donor site wounds are a necessary and painful byproduct of graft procedures used to regenerate large sections of damaged skin. The split thickness skin graft (STSG) is typically harvested from large sections of a patient's own skin using a microtome and has a thickness of 1-2 mm depending on the blade and surgical technique. The resulting donor site is usually painful and irritating to the patient but will typically heal in 10-30 days with moist wound healing techniques. The acute nature of the donor site makes it a good choice of wound for a pilot study to evaluate a dressing and compare pain and discomfort associated with a wound and treatment.

We report on the results of a single center, randomized, prospective clinical study comparing a novel Powder Wound Dressing (PWD)* to a carboxymethylcellulose dressing containing silver (CMC-Ag) when applied to patients having two split thickness skin graft donor sites. Results include an analysis of time to healing, pain, and patient comfort.

Objectives

- To evaluate the time-to-wound healing in skin graft donor sites with a new treatment PWD compared to standard of care treatment CMC-Ag
- To evaluate pain level, incidence of infection, and patient's satisfaction comparing the PWD to CMC-Ag.
- To compare tolerance of the two dressings.

Methodology

This study was designed as a single-center, prospective, randomized study in which each patient served as his/her own control. Each patient was to have at least two split-thickness donor sites identified prospectively as A or B. One skin donor site was dressed with PWD, the other with CMC-Ag in a randomized fashion. This study was performed in compliance with Good Clinical Practices including the archiving of essential documents. Prior to study initiation, the protocol was reviewed and approved by the Institutional Review Board (IRB) of UTSW Medical Center and the IRB of Parkland Health and Hospital System, Dallas, Texas.

Number of subjects (planned and analyzed)

40 patients were planned to be enrolled at one clinical trial site in the U.S. Enrollment into the study was closed after 20 patients were enrolled and 19 were treated with the study devices.

Major criteria for inclusion

1. Male or female patient between the ages of 3 and 85 (In order to maintain a broad representation of ages, no more than 50% of the patients enrolled in the study were to be between the ages of 3 and 16, inclusive.)
2. Patient in general good health
3. Patient with two independent skin donor sites of approximately the same dimensions.

Major Criteria for Exclusion

1. Male or female patient less than 3 years of age or more than 85 years of age
2. Acutely infected wounds
3. Wounds with surrounding cellulitis

Efficacy Assessments

Efficacy Analyses

Time to Healing

Mean days to healing were estimated using survival analysis methods. Matched-pairs t-test was used.

Pain Scores

Pain scores were averaged for each patient and each donor site side as follows: Day 2 to Day 5, Day 6 to Day 10, Day 11 to Day 15. Average pain scores at each of these 3 time points were compared between side using a mixed model repeated measures ANOVA analysis that accounted for the treatments being observed on the same patient.

Safety Assessments

Adverse Events

Throughout the course of the study, all adverse events were monitored and reported on an Adverse Event Case Report Form. When adverse events occurred, the main concern was the safety of the study subjects.

Procedure:

The NPD is a powder dressing that transforms from a powder into a moist wound dressing. This PWD is designed to provide high moisture vapor transpiration and does not typically require a secondary dressing. The CMC-Ag is a woven material containing 1.2% ionic silver. This dressing was applied to the surface of the wounds and anchored into place using staples.

The Investigator first identified the skin donor sites (A and B) for each patient and took baseline digital images and measurements immediately following surgery (Day 1). The investigator then applied the dressings provided by the Sponsor and labeled as A or B by the Sponsor in a random fashion. Typical meticulous wound care and adequate analgesic medical coverage were provided for the duration of the study. Patients were monitored daily as part of standard procedure while they were in the in-patient setting. If and when patients moved to the out-patient setting, they were to be monitored every-other-day at the study center. At each visit, the investigator determined whether each skin graft donor site had healed per standard care guidelines (i.e. >95% re-epithelization). Subjects were questioned about pain level, and adverse events were monitored. The last study visit was on Day 24 or on the day when both wounds had been assessed as "healed", whichever came first. If one or both of the graft donor sites were not healed on Day 24, a Follow-Up Visit (25-30 days post-surgery) was to be scheduled at the investigator's discretion. The medical staff recorded all dressing changes during the course of the study.

Results

Efficacy evaluation

Data Sets Analyzed

All 19 Subjects enrolled were included in the efficacy analysis.

Demographic and Other Baseline Characteristics

Demographic Characteristics

Table 01 summarizes Subject demographic information. Age ranged from 5 to 76 years and averaged 36.6. Only 4 subjects were female (21%) and 15 were male (79%).

Table 01 – Summary of Demographic Characteristics

Number of Subjects:	19 (100%)
Age (years)	
Mean (SD)	36.6 (16.7)
Median (Min–Max)	36.0 (5, 76)
Gender	
Male	15 (78.9%)
Female	4 (21.1%)

Source: Section 16.2.1

Donor Site Characteristics

Table 02 summarizes the donor sites characteristics. The mean (SD) size was 264 cm² (281.9) for PWD site and 229 (157.3) for CMC-Ag sites.

Table 02 – Summary of Donor Site Characteristics

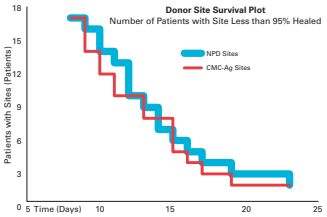
	PWD	CMC-Ag
Number of Subjects	19	19
Size (cm²)		
Mean (SD)	264 (281.9)	229 (157.3)
Median (Min-Max)	154 (36, 1008)	197 (64, 759)

Source: Section 16.2.3

Efficacy Results

Twenty Patients (15 male, 4 female) were enrolled into the study and 19 received study devices. Twelve subjects (63%) completed the study as planned, while 7 subjects (37%) prematurely discontinued due to adverse event (1 subject), subject's request (1 subject), protocol violation/non compliance (1 subject), lost to follow-up (3 subjects) and other reason (1 subject who became confused).

Time to Healing



Time to Healing

There was no significant difference in time-to-healing between the two treatment sides.

Table 03 – Mean Time to Healing (based on patients with healing day < 24 days)

	PWD	CMC-Ag	Difference (PWD minus CMC-Ag)	p-value a
N	17	17	17	
Means Estimate	14.2	13.16	1.1	0.16
(Standard Error)	(0.81)	(0.74)	(0.77)	
Minimum	10	9	-1	
Maximum	23	20	3	
95% Confidence Interval	12.5, 15.9	11.5, 14.6	-0.5, 2.8	

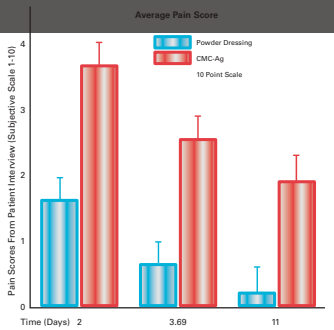
a p-value from matched-pair t-test.

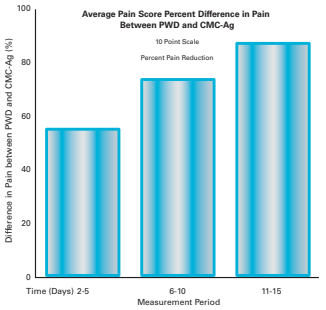
Pain Scores

Pain Scores

Pain scores showed significant differences at all time periods between the two dressings, with PWD eliciting lower pain scores than CMC-Ag. Between day 2 and day 5, the average pain score recorded was 3.69 on the CMC-Ag side versus 1.64 on the PWD side (p<0.0001). Similarly on days 6 to 10, the average pain score was 2.57 on the CMC-Ag side compared with 0.67 on the PWD side (p<0.0001).

Average Pain Score





Subject's Satisfaction Survey

Table 08 summarizes responses to the 3 subject satisfaction survey questions at the final visit. Questions were based on a 10-point scale with 1 being the worst score and 10 being the best score (except for pain).

When asked about comfort of the dressing at the edges, study subjects found PWD to be more comfortable than CMC-Ag (average score of 8.6 versus 5.9; p<0.001). Likewise, study subjects reported experiencing less pain when the dressing came in contact with clothes or bedding at the PWD side compared with the CMC-Ag side (average pain score of 2.1 versus 5.1; p<0.001).

There was no significant difference between the two dressings regarding how well the dressing remain in place after application as both dressings performed well on that measure (average score of 9.5 for PWD versus 8.6 for CMC-Ag).

Table 04 – Summary of Subject Satisfaction Survey Results

FINAL VISIT		PWD	CMC-Ag	p-value a
Number of Subjects with Responses:		17	17	
Q1 – On a scale of 0 to 10, with 0 being not at all and 10 being very secure, did the dressing remain in place after application?	Mean (SD)	9.5 (0.94)	8.6 (1.91)	0.06
	Median	10	10	
	(Min-Max)	7 to 10	5 to 10	
Q2 – On a scale of 0 to 10, with 0 being very uncomfortable and 10 being very comfortable, did you find the edges of the dressing to be comfortable?	Mean (SD)	8.6 (2.27)	5.9 (1.87)	<0.001
	Median	10	6	
	(Min-Max)	2 to 10	2 to 8	
Q3 – On a scale of 0 to 10, with 0 being no pain and 10 being the worse pain you have ever experienced, did you notice significant pain when the dressing came in contact with your clothing or bedding?	Mean (SD)	2.1 (2.5)	5.1 (2.22)	<0.001
	Median	1	5	
	(Min-Max)	0 to 10	2 to 9	

a p-value from matched-pair t-test

Discussion

Protocol Deviations

Timely Follow-up After Release of Subjects from In-patient Hospital Setting

[One main deviation from the protocol was that timely follow-up proved to be difficult after subjects were released from the hospital and asked to return for regular clinical check-up. A number of patients did not have twice-weekly follow-up. This impacted the precision with which the time to healing could be determined in this study. Both donor sites were impacted in the same manner by these protocol deviations.]

Randomization Deviation

It was noted that for 2 subjects (Subjects 01 and 08), the A versus B randomization sequence of the 2 donor sites was reversed. Per the randomization list, in both cases, PWD should have been applied to donor site B, but was applied to donor site A instead.

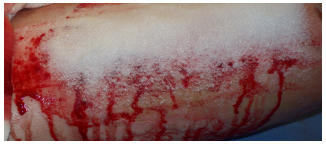
The clinical study personnel instituted a "second check" procedure to confirm site A and site B and which packet was to be applied to each. This deviation was not expected to impact either the safety of the subjects, or the validity of the data collected from these 2 subjects.

Donor Sites as Wound Healing Model

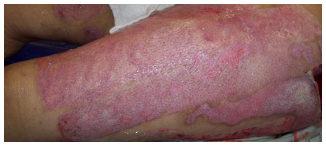
The use of donor sites as wounds in a healing model provides for a reproducible wound but also makes wound healing endpoint comparisons difficult for comparative treatments since the wound is partial thickness and acute. Thus the result of equivalent healing timepoints was not unexpected.

One major complaint among patients with donor sites is pain and comfort management, therefore, a dressing which reduces pain and increases patient comfort is an important finding for any donor site wound healing study.

An important extension of this study would be to determine if similar pain and comfort findings extend to wounds of a more chronic nature.



Initial Powder Dressing Application



Donor Site at Healing

Conclusions

In this clinical study it was demonstrated that for acute donor sites, a comparison of time to healing provides no statistically significant difference in the rate or percentage of donor sites closed between day 0 and day 23 (p=0.16) when covered by the NPD or the CMC-Ag.

For the mean pain scores of donor sites covered with the two dressings, the NPD showed a statistically significant difference of less pain at three different time periods (p<0.0001 at 2-5 days, p,0.001 at 6-10 days, and p=0.004 at 11-15 days).

For patient comfort, there was a statistically significant difference in comfort with the NPD having greater comfort (scale of 1-10 with 10 being more comfortable) (p<0.001).

Patients with donor sites can benefit in the areas of pain management and comfort if the NPD is used to treat the graft site over the CMC-Ag dressing.

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Acknowledgements

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*Altrazeal™ Transforming Powder Dressing

Comparison in Management of Large, Open Combat Wounds in Service Personnel Using Negative Pressure Wound Therapy as Standard of Care and a Novel Powder Dressing

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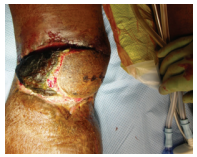
Home of Warrior Care
WALTER REED ARMY MEDICAL CENTER

Introduction

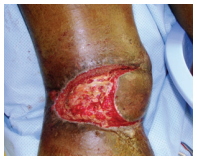
Combat trauma produces wound patterns that are seldom observed in civilian hospitals and require complicated surgery and post-operative care. The damage created by explosive devices depends on a number of factors, including the type of explosive, and the environment within which the detonation takes place. Injuries are dependent on the power of the explosion, the proximity of the casualty to the explosion and the environment (open or confined). When the energy of an explosion is directed towards tissue it creates a wound that is catastrophic to deep tissue and that will require surgical reconstruction until fully healed. In addition, this type of wound is universally accompanied by penetrating shrapnel which carries bacteria deep into the wound. Currently blast wounds in Uniformed Services Hospitals are managed uniformly with negative pressure wound therapy (NPWT), which is used to stabilize the wound, remove bacteria from tissue, and ultimately provide a well-vascularized granulation bed suitable for subsequent grafting.

This set of cases details the post-operative management of three combat trauma wounds where a combination of NPWT and a novel powder dressing are used to achieve closure.

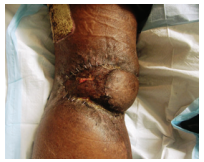
Saphenous artery fasciocutaneous flap coverage of a posterior popliteal wound with exposed nerve from a rocket-propelled grenade attack in Iraq.
Patient is a healthy 38 year old male with a concominant closed head injury.
Initial treatment was serial debridements with VAC coverage for ten days. The procedure was complicated by superficial skin necrosis which was managed by debridement and NPWT (4 days) followed by skin grafting covered with the powder dressing for 10 days.
Patient is now five months post-injury with a healed wound pending secondary nerve grafting.



Partial Flap loss
Pre-debridement



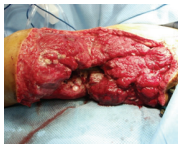
Post-debridement



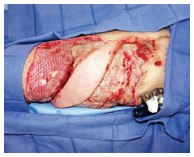
2 weeks post grafting

Latissimus dorsi myocutaneous free-tissue transfer with large skin grafts to the wound 2 weeks following injury.
Patient is a 26 year old male healthy medic who suffered an open fracture of his anterior knee/thigh with large soft tissue loss.
Initial pre-flap management was serial debridement and VAC dressings. Post-flap dressings were NPWT as a bolster over the recipient graft sites and the powder dressing to his skin-graft donor sites and the recipient site following removal of NPWT. The graft sites required two additional applications of the powder dressing until complete re-epithelialization occurred at 3 weeks following flap procedure.

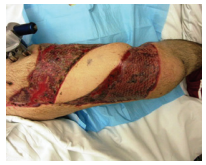
Patient is now 3 months post-op with a healed wound and ambulatory. He is also currently being treated by osseous distraction/lengthening of his femur fracture. Patient will require subsequent tendon grafting to improve knee extension power.



Initial Wound following debridement
NPWT, and external distractor

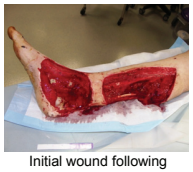


Flap inset with
Surrounding Skin Grafts

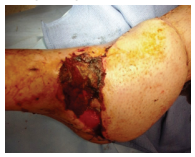


Three weeks post-op

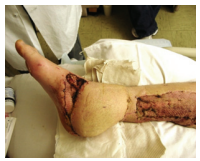
Anterolateral thigh free-tissue transfer and large skin grafting five months ago.
Patient is a 22 year old male healthy infantry soldier who suffered an IED blast injury to his lower leg and ankle with an open ankle fracture, exposed tendons and a segmental nerve deficit. The other injury was a traumatic below-knee amputation of the opposite leg.
Initial management was serial debridement, NPWTfor 10 days prior to free flap.
Post-op management was NPWT bolster over skin grafted areas with transition to powder dressing for two weeks (three applications required).
Patient is completely healed, ambulatory and awaiting nerve grafting



Initial wound following
debridement, and NPWT,



One week post free flap, powder
wound dressing in place



Three Weeks
Post Grafting

Discussion

Complicated trauma cases involve detailed assessment and planning prior to reconstructive surgery. The choice of techniques for post-operative management is critical and can often be overlooked after the surgical procedure is completed. For trauma cases involving reconstructive surgery with flaps or skin grafts, the conventional choice is NPWT or bolster dressing(s). These techniques are viable and functional options. A novel powder dressing was evaluated as a choice for covering and protecting a flap or mesh STSG after the application of NPWT. This technique was evaluated to determine if it was possible to transition from NPWT to the use of a unique powder dressing for closure. The data set is limited, however, the powder dressing does appear to cover and protect a wound during closure with dressing changes at intervals between 3 and 7 days.

Conclusions

It is possible to transition from NPWT to the use of a novel powder dressing in post operative care of combat trauma cases involving reconstructive surgery. Further studies as to the timing of the transition would benefit the development of best clinical practice for the use of this novel dressing.

2009 SAWC Meeting
Grapevine, Texas

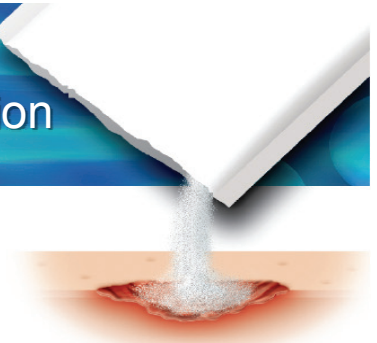
James Gleaves, MD, FACS

Kim Eldridge, RN, CNOR, RNFA, CFCN, WCC

Rush Hospital
Wound Care, Hyperbaric and Limb Salvage Center

Meridian, Mississippi

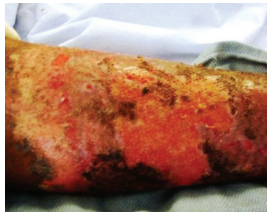
A New Treatment in Mesh Skin Graft Procedures Using A Novel Powder Dressing for Clipless, Sutureless Graft Fixation

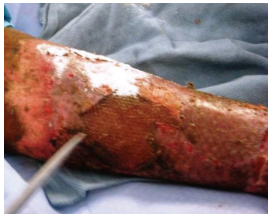


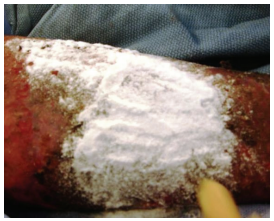
Objective
The objective of this presentation was to evaluate a technique for the fixation of a split thickness skin graft (STSG) using a novel powder dressing with different graft locations and different methods of external fixation including a sutureless, clipless graft.

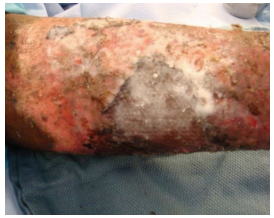
Patient History
72 year old male with history of hypertension, arthritis, urinary incontinence, heavy tobacco usage, deafness and low pain threshold.

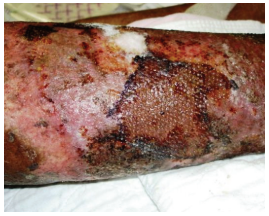
Wound History
Patient received burn to lower left leg. During ER visit, the burn was treated with silver sulfadiazine cream. Patient complained of severe pain; patient was prescribed hydrocodone pain reliever. Dressings were changed daily in Home Healthcare situation. Patient compliance and pain tolerance made dressing changes problematic. The burn showed no improvement for two weeks.

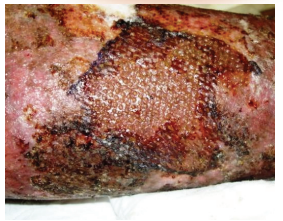

Burn Prior to STSG Procedure


Mesh STSG in Place


Powder Dressing Applied


Powder Dressing Hydrated and Transformed


Post Op Day 5, Dressing in place


Post Op Day 5, Dressing Removed, 100% Take

Introduction
The ability to cover and protect a STSG easily with few dressing changes while managing fluid and preventing infection represents a list of attributes that are a proverbial "gold standard" for a dressing over a mesh graft. The importance of proper wound bed preparation including sharps debridement and management of microbial contamination followed by good surgical technique in graft harvesting and placement can not be understated in terms of successful outcomes. However, following surgery the "take" of the graft on the underlying bed is impacted by the management of the fragile tissue and the interface between new tissue and the wound. In protecting the graft during take, two primary factors to consider are fluid and moisture management, and immobilization. Common techniques for managing both include bolstering with foam and other padded dressing materials, and negative pressure wound therapy systems. Both of these techniques manage fluid and provide necessary pressure but the graft is typically held in place with sutures or clips (staples) and each technique has complications associated with dressing changes or equipment.
One other factor that is rarely considered in STSG is the use of clips or sutures. Although nearly ubiquitous in graft placement, the employment of these fixation devices does require an initial surgical technique, and following healing, the fastening devices must be removed which can be time consuming for the woundcare professional, and cause discomfort for the patient. A technique of mesh STSG fixation without sutures or clips is an important potential alternative to conventional graft application and management.

Methods:
We report on a case of a sutureless, clipless mesh STSG where fluid management and holding the graft in place are both achieved through the use of a novel powder dressing applied once and then monitored through the graft take and subsequent healing.

Graft Procedure
Patient was referred to woundcare clinic and low tolerance for pain was a factor in decision to attempt a sutureless, clipless mesh graft. Previous use of staple fixtures resulted in intolerable pain for this patient. In the OR, a conventional STSG was harvested and meshed 1:3 then applied to the wound bed. The STSG was pressed gently into place and good contact was formed at all graft locations through careful placement. No clips or sutures were used to secure the graft to the tissue or surrounding skin.

Dressing Placement and Post-Operative Care
The powder dressing was applied liberally using a tongue blade to transfer the powder from a sterile cup over the STSG surface. The powder was initially applied approximately 2 mm thick and was white in appearance as shown in Figure 3 above. Previous experience with this novel dressing has shown that the material consistently adsorbs wound fluid and changes from a powder into a thin, translucent flexible covering on the wound and graft surface. Our experience has shown that this transformation can be accelerated by applying saline through a mist or by dripping it on the surface of the powder. Figure 4 shows the intact, moist dressing. For further protection of the dressing and graft, a fenestrated silicone wound contact layer ** was applied over the intact, transformed powder dressing and the leg was wrapped in gauze. No clips or sutures were used to hold the covering and no tieover bolster was employed.

The gauze and silicone contact layer could be removed as needed to observe the underlying dressing. In this case, observations of the graft held in place with the transformed powder dressing were made daily. At no point was there any wound fluid management issues with maceration and at the same time, the dressing maintained a moist layer on the graft itself. By day 5 the graft showed 100% take. Some areas covered by the transformed powder dressing remained intact while areas with epithelialized skin were uncovered as the dressing lost adhesion.

To date, the graft remains closed with improving cosmesis (3 weeks)

Results and Observations
It is important to understand that no dressing or post-operative care for a STSG can replace proper clinical treatment including establishing vascular flow and surgical debridement of non-viable tissue. Proper graft handling and placement is also critical. In most procedures, the use of clips or sutures is employed without a thought. Following the graft surgery, however, critical factors to improve success include holding the graft in place (bolstering) and managing exudate. In this evaluation we employed a novel powder dressing to a conventional mesh STSG, however, the dressing was used both to secure the graft in contact with the wound bed and to bolster and prevent movement or shear forces. In this single study, the dressing performed well. The mesh STSG showed no sign of movement, and moisture control provided by the dressings inherent physical properties prevented both excess fluid and drying. The material did not allow tissue to integrate into the material and the graft epithelialized smoothly beneath the dressing.

Conclusions
STSG will remain an important technique for the closure of wounds and this technique has been well refined to achieve positive results. Simple means of fixing the graft without sutures or clips have not been widely studied simply because materials did not exist to provide that type of fixation. Similarly, few major advances have been made in bolstering the graft site while managing fluid. We believe that this technique offers promise both for patients and clinicians in providing positive outcomes for the management of mesh STSGs.

This work was sponsored by ULURU, Inc.

* Altrazeal Transforming Powder Dressing
** Mepitel fenestrated silicone

Poster CS-114

A Procedure Using a Single Dressing Application for the Bolstering and Protection of a Meshed Skin Graft

2009 SAWC Meeting
Grapevine, Texas

Kim Eldridge, RN, CNOR, RNFA, CFCN, WCN

James Gleaves, MD, FACS

Rush Hospital
Wound Care, Hyperbaric and Limb Salvage Center

Meridian, Mississippi

Objective
The objective of this presentation is to demonstrate a new procedure for the immobilization and isolation of a meshed skin graft without dressing changes, bolstering or negative pressure wound therapy.

Introduction
Split thickness skin grafts (STSG)s are a common and very effective surgical technique to quickly provide reepithelialization for well prepared wound beds The survival or "take" of a graft is dependent on numerous factors, however, the most frequent causes of STSG failure are dislodging or shear, and accumulation of wound fluid between the graft and wound bed. The two primary methods of providing immobilization of grafts during the take period are the use of a tieover bolster or application of negative pressure wound therapy. Both of which are successful treatments but present some complications with either difficulty in observing the underlying graft or in terms of equipment and personnel resources.

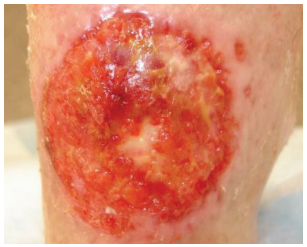
Methods
We present a treatment modality suitable for immobilizing, isolating and providing a moist wound healing environment for a meshed STSG. This treatment employs a novel powder dressing. When this powder dressing is applied to a mesh graft site, it transforms into a hydrating layer that adheres to the interstitial spaces between the graft. The material appears to fill in these spaces and behaves as a protective support bolster between the mesh graft and serves to anchor the mesh to the underlying wound bed. As new tissue begins to fill in the mesh spaces through contracture, the powder dressing sloughs off.

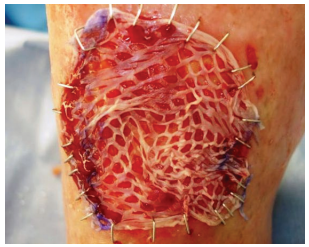
Patient History
81 year old female with history of diabetes, CHF, PAD, PVD

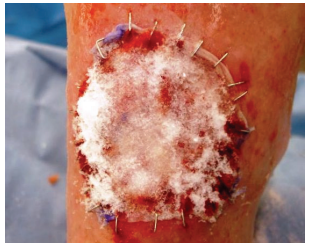
Wound History
Arterial ulcer on dorsal plantar of right foot. Wound was treated for several months prior to evaluation at Rush Hospital with little success. After evaluation of Vascular Status, she was found to have severe peripheral arterial disease and required vascular intervention.

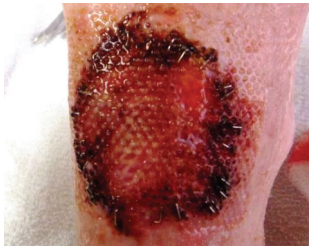
Wound Treatment
Vascular flow was established with angioplasty and stenting per vascular interventionist. This was performed with excellent results, then the patient was taken to the OR for sharp debridement and STSG. The STSG was harvested from the right thigh donor site, meshed 1:3 and then applied to the wound bed and anchored with staples.

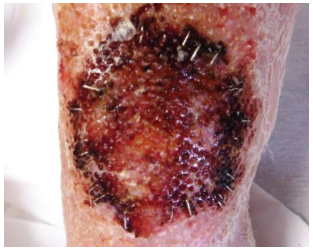
Powder Dressing Application and Follow-up
- The powder dressing was applied immediately post- op to a thickness of 1-2 mm
- A fenestrated wound contact layer** was applied over the graft site and covered with gauze
- The contact layer was changed at day 5 and 10.
- The powder dressing was removed at day 12 with greater than 90 % reepithelialization.

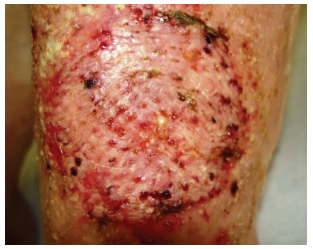

Ulcer Post Sharp Debridement

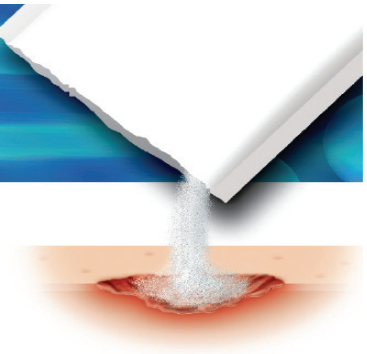

Mesh STSG in Place on Wound


Novel Powder Dressing on Wound


Day 5-No Dressing Changes


Day 10-No Dressing Changes


Day 12-Powder Dressing Removed



Results and Observations
The novel powder dressing described in this technique was initially evaluated as a covering for skin graft donor sites. Following evaluation in donor sites, the product was applied to a STSG with the hope that it could provide a convenient and comfortable treatment to protect a mesh graft during the period of "take" while the graft adheres to underlying tissue and reepithelializes across interstices.

The powder is applied with a procedure that is dramatically different from most films or pads using sprinkling rather than laying or stapling a pad in place. This application lends itself to covering the uneven surfaces of a mesh STSG. Additionally, the powder can be pressed into the spaces as it is applied over the surface. The resulting transformation from powder initially yields a white covering that gradually darkens in appearance with blood and wound fluid. The material does not resorb but does flatten somewhat over the graft surface and does not appear to allow shear forces to pull or dislodge the graft tissue as the mesh knits to the underlying wound. The chosen silicone mesh contact layer is easily removed from the powder dressing surface. Removal of the powder dressing if necessary can be accomplished by soaking the dressing in saline for several minutes after which pieces remaining on the wound can be peeled away without strong adhesion to the underlying tissue.

Conclusions
Results from this treatment were better than expected. The dressing provided a flexible, immobile surface that penetrated the gaps in the mesh graft and had strong adhesion to the underlying wound bed. The wound surface remained hydrated and the dressing did not dry or flake away from the moist tissue during the 12 day treatment. This technique appears to be a viable method of easily securing a STSG with a single dressing. The technique should be explored further to determine the best clinical practice and full benefits of this application.

This work was sponsored by ULURU, Inc.

* Altrazeal Transforming Powder Dressing
** Mepitel fenestrated silicone

Poster CS-022

2009 CSAWC
San Antonio, TExas

Gleaves, Jim, MD. Surgeon, Rush Hospital, Meridian, Mississisppi

Eldridge, Kim, RN, Rush Hospital, Merrdian, Mississippi

Treatment of a severe Fournier's necrotizing fasciitis involving the scrotum and volar penile skin associated with a malfunctioning penile prosthesis affixed in the erect position with a delicate split thickness skin graft anchored with a powder dressing

Objectives

Understand the significant complications following a Fournier's necrotizing fasciitis of a male perineum and its treatment with a meshed split thickness skin graft on the scrotum and volar surface of a penis which was incidentally associated with a damaged penile implant.

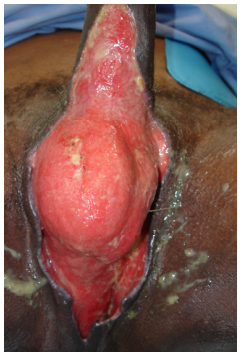
Be exposed to the delicate nature of graft suturing and affixation when attempting to apply a meshed split thickness skin graft in one setting to the penile and scrotal skin.

Introduction

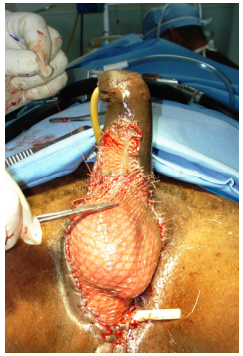
Simple geometry reveals that any one singular infintesimal point on the scrotal surfaces of two spheroidal masses can be assoiciated with only one plane. A spheroid surface has a multiplicity of planes throughout its surface extending to the periphery of the graft. It is very difficult to affix the graft without multiple sutures and/or clips throughout the grafts surface and not just at the periphery of the graft. This type of procedure typically requires multiple grafting procedures.

Methods

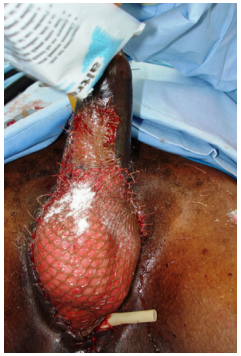
This case study presents the treatment of a 71 year old diabetic, African American male, who had a penile implant which became damaged and was malfunctioning with his penis in a permanent erect state ("bent" superiorly in the standard 90 degrees perpendicular to the patients body frame in a "functional position"). The damaged penile implant complicated the treatment after onset of the infection that had developed six days earlier, as Fournier's necrotizing fasciitis with severe systemic sepsis. This necrotizing faciitis involved the entire scrotum traveling along the volar surface of the penis toward the base of the glands. Immediate initial treatment included: broad spectrum antibiotics, treatment with hyperbarics prior to the urologist taking the patient to the operating room where under general anesthesia the entire scrotal skin was removed up to the base of and including that of the penis. He was treated for approximately two weeks with intravenous antibiotics, aggressive local care, and hyperbarics for two weeks prior to grafting. Grafting the scrotum is particularly difficult due to its shape and it usually requires multiple trips to the operating room to get adequate coverage due to the double spheroidal structure of the scrotum. The skin on the base of the penis is essentially perpendicular in relation to skin found on the scrotum. This tissue is quite delicate; pain and sensation can be extraordinarily excruciating and exceptionally miserable for the patient. One large graft (400 to 500 cm^2) was applied and this was meshed 3:1, sutured at the periphery where the scrotum had reached the base of the thighs and perineal area posteriorly and onto the penis using absorbable vicryl stitches; fewer than normal were used due to the Powder Wound Dressing* (PWD) fixation. No additional stitches were used in the bed of the graft nor in the area where an additional piece of graft was placed to cover the volar penile skin. The graft was covered with a PWD and aggregated with saline mist, which then affixed and anchored the graft to the underlying deep scrotal and penile wound surface. A light secondary dressing of 4x4's and net gynecology underwear was applied but no significant affixation to the secondary dressing was necessary. On one occasion in the following two weeks an additional dose of PWD was applied and aggregated again with saline.



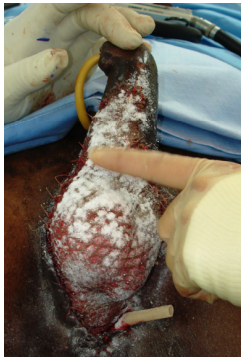
Gently Debrided Wound



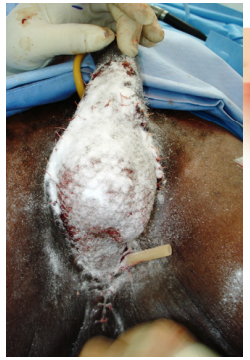
Application of Mesh Graft and Suturing



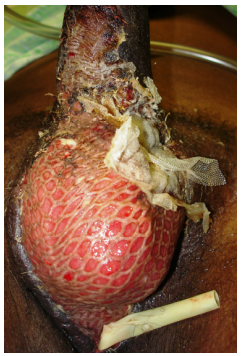
Graft in place with Application of Powder as Primary Graft Fixation



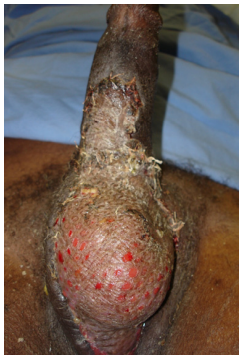
Gentle Spreading of Powder Dressing Over Graft and Tissue Surface



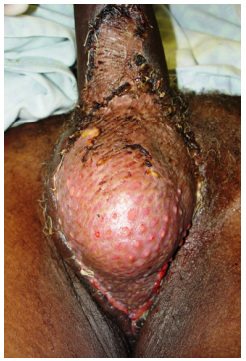
Powder Dressing in Place with Hydration and Aggregation Occurring



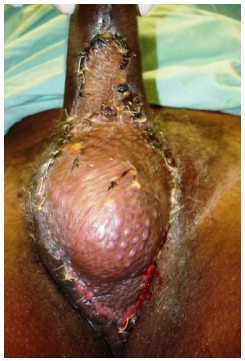
Day 5: Dressing Change. Powder Dressing has been removed from the scrotum. Some of the intact dressing and wound veil used to cover the primary dressing is visible on the dorsal skin of the penis.



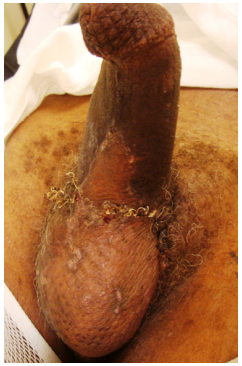
Day 12: Primary dressing left in place with tissue ingrowth visible at graft interstices.



Day 15: Graft in place with substantial ingrowth of new skin. Primary dressing no longer present.



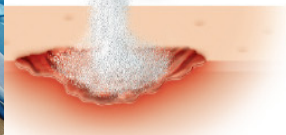
Day 19: Graft at nearly 100% take with new skin through all interstitial spaces.



6 Weeks Post Operative: Complete take of graft with excellent cosmesis.

Findings

The wound continued to show ongoing improvement following the grafting procedure. The skin graft began to turn obviously pink over its entire bed covering the scrotum and penis by the third day and it could be seen through the light layer of PWD as it was translucent. By the end of 14 days not only did the entire graft had a 100% take of all skin that was applied but the interstitial spaces between the webs were epithelialized. The graft remained anchored and "took" completely showing total epithelialization by the fourth week. It should be added that the PWD was also used on the donor site without a second dressing. The donor site was 24 cm x 8 cm. The donor site produced no pain post operation.



Conclusions

This case demonstrates that meshed STSG can be held in position and anchored to the bed with PWD that reconstitute themselves into a congealed "superstructure". Numerous areas on the graft that would have normally been sutured, were not sutured nor clipped at all, thusly decreasing pain. For the novel and unusual wound, dressing and treatment of the site following surgery requires delicate care and obviously in this case, minimal dressing changes and handling markedly improving the patients comfort. It also shows the scrotum which is a very difficult area to graft particularly when associated with a penile skin loss injury can be quite well handled with a PWD to help affix the graft to the wound bed. This is consistent with other studies where we have been successful in areas that are planar and flat or gently curved to be able to completely affix a skin graft without any other fixation including clips or sutures.
A secondary conclusion was that donor sites have very little to no pain when treated with the PWD.

The complications following a Fournier's necrotizing fasciitis of a male perineum and the treatment with a meshed STSG on the scrotum and volar surface of the penis associated with a damaged penile implant can be an exceptional challenge to both the patient and the surgeon.

This case study, reveals that delicate grafting of surfaces with complex geometry can be accomplished by fixation of a graft to a well perineum using a powder wound dressing. There was less pain as a minimal number of sutures were placed and dressing changes were minimized. There were no dressing changes for the donor site and powder wound dressing (PWD) was used as a the dressing, which also relieved pain in the donor site.

References

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Eldridge, K. E.; Gleaves, J. M. (2009) "A new treatment in Mesh Skin Graft Procedures Using a Novel Powder Dressing for Clipless, Sutureless, Skin Graft Fixation" Poster Presentation, Society for Advanced Woundcare Meeting, Grapevine, Texas.

*Altrazeal™ Transforming Powder Dressing