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Transforming Powder Wound Dressing Relieves Pain and Manages Moisture Restoring Quality of Life

Purpose:

Painful wounds limit a patient's activities and interfere with quality of life. Transforming Powder Wound Dressing relieves pain while managing wound moisture, restoring quality of life for patients. This presentation demonstrates pain reduction in two patients who had wounds that limited their activity. Transforming Powder Dressing has a unique property in that it reduces or eliminates pain when applied to the wound.

Objectives:

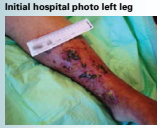
At the conclusion of this presentation the participant will be able to:
1. Realize that pain from wounds impacts on quality of life for patients with wounds.
2. Identify that nociceptive pain can be Procedural; related to dressings and their changes, Incident; related to movement with activity, and Background; related to factors related to wound etiology and local wound factors.
3. Identify a new novel Transforming Powder Dressing that has the ability to significantly impact on Procedural, Incident and Background pain and improve quality of life for wound patients.

Abstract:

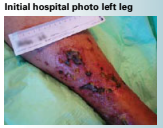
Pain has been categorized as Operative (debridement or surgically related), Procedural (related to dressing removal and application), Incident (related to movement, dressing slippage, etc.) and Background (persistent and underlying pain due to wound etiology). While Operative pain is managed by anesthetic agents and Procedural pain may be managed by both anesthetic agents and oral analgesics, Incident pain and Background pain are typically managed by oral analgesics either opioid or non-opioid. Co-analgesic medications are often added to manage Incident and Background pain. Patients tend to focus more on their Incident and Background pain as they experience this type of pain after they leave the clinic. Patients often understand that they will experience pain with surgical debridement and dressing change. Pain experienced in the clinic with debridement and dressing change can be addressed with topical anesthetics or other agents and techniques. When left on their own, Incident pain and Background pain are dealt with directly by the patient taking an oral medication. A new dressing material is available that has an exceptional unique property to reduce the pain commonly experienced by patients with wounds. Application of Transforming Powder Dressing not only reduces pain, but has a long wear time. Pain experienced with dressing change is less as the dressing lifts off easily. Oral opiates were not required in two patients with commonly painful wounds to manage pain with dressing change, during dressing wear or as Background pain treatment.

CASE 1

Initial hospital photo left leg



Initial hospital photo left leg



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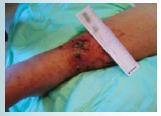
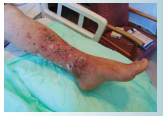
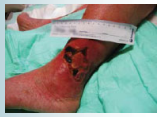


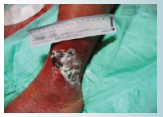
Transforming Powder Dressing applied



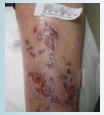
Left leg wound



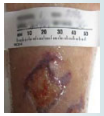
Left leg wound with powder



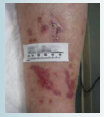
Outpatient wounds



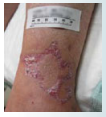
Outpatient wounds



Outpatient healed

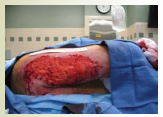


Outpatient healed

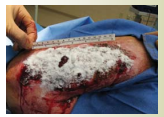


CASE 2

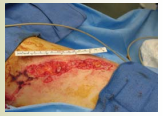
Arm wound



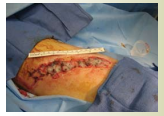
Arm wound



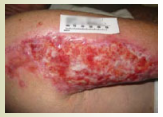
Thigh wound



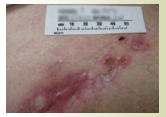
Thigh wound



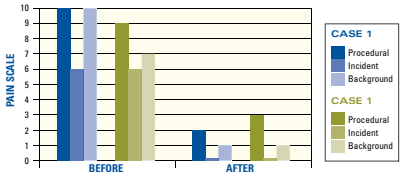
Arm wound healing



Thigh wound healed



Pain Reduction with Transforming Powder Dressing



Methods:

A new Transforming Powder Dressing became available for use in our wound clinic and hospital. Transforming Powder Dressing was applied to the wounds and pain evaluated by the patients response to standard pain scoring measures. Patients were asked to rate their pain on a scale of 1-10. They compared their pain experienced before the use of Transforming Powder Dressing and during treatment with Transforming Powder Dressing. Assessment of Procedural pain (relative to application and removal of dressing), Incident pain (related to dressing slippage) and Background pain (underlying pain) was performed during patient interviews.

Case Studies:

Case 1: A 54 year old female undergoing chemotherapy for metastatic ovarian cancer had suffered with bilateral lower extremity edema from obstructed lymphatics. She had suffered significant edema for 5 months; initially developed blistering was hospitalized and had multiple deep marginated ulcerations of both lower extremities. The patient suffered pain from daily dressing changes, pain from movement of the dressings and Background Pain from her wounds. With a pain level rating of 10, she couldn't stand for the initial evaluation. Transforming Powder dressing was applied and the patient noted a marked decrease in background pain. She also reported a significant decrease in pain with dressing changes and did not experience pain from dressing movement. Prior to discharge to outpatient care, the patient was engaged in physical therapy and active.

Case 2: A 57 year old male undergoing chemotherapy and radiation therapy for metastatic intracranial melanoma fell against a steam radiator and suffered 3rd degree burn wounds to his right arm and right thigh. He had been treated as an outpatient with daily Silvadene dressing changes. Concern for failure of skin grafting during chemotherapy, the patient underwent tangential excision of dead burn eschar and was treated with Transforming Powder Dressing. He was followed weekly in the wound clinic and had his dressing reapplied at each visit.

Results:

When applied to the wounds both patients experienced a decrease in Procedural pain, Incident pain, and Background pain as reported to nursing staff on pain assessment scoring (Figure 1). As an inpatient, Patient 1 required IV narcotics to control her pain. With application of Transforming Powder Dressing, she was weaned to oral narcotics and subsequently required no pain medicine on discharge to outpatient care. She had a family member reapply the powder as needed and continued her care as an outpatient in the wound clinic. Patient 2 was using oral narcotics every 6 hours as allowed, after surgery but transitioned to non-narcotic analgesics when his wounds were covered with Transforming Powder Dressing. He reported some pain with dressing changes but did not require narcotic pain management for dressing changes. His Incident pain was nonexistent as the Transformed Powder stayed in place and he noted little Background pain throughout the week.

Conclusion:

Both patients experienced a reduction in their pain level when the powder dressing was applied to their wounds. The intimate contact with the wound surface and the ability to manage moisture may be an important aspect of this effect. The moisture content of the dressing material is very close to that of normal skin. Optimizing the wound environment and sealing the wound may also contribute to this observed effect. The wounds of patient 1 healed while she was managed as an outpatient. Her activity level was not limited by her wounds. She has become productive and active. Patient 2 succumbed to his disease but benefited from his dressing in that he did not suffer from the pain of daily dressing changes or the side effects of narcotic medications. His dressings were changed weekly or biweekly rather than daily which greatly reduced the episodes of pain may have experienced.

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Serendipity: Use of a Novel Transforming Powder Dressing to Treat Chronic Wounds Reduces Lower Extremity Wound Pain in Patients with Venous Wounds

2010 SAWC Meeting
Orlando, FL

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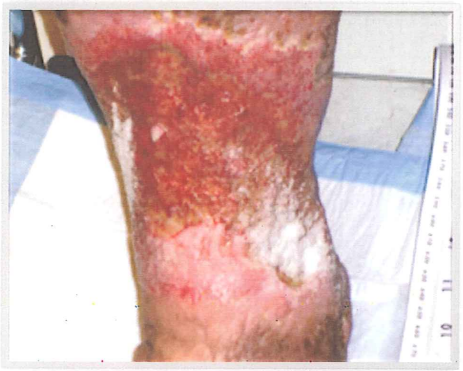
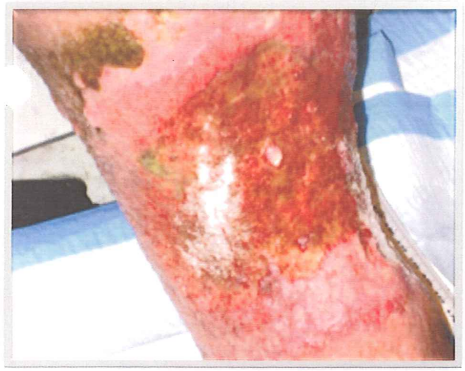
Clinical Problem: Wound pain is a significant issue for many patients with chronic wounds. 80% of patients with venous leg ulcers (VLUs) experience pain.[1] Its sequelae include fatigue, alterations in interpersonal relationships, sleep disturbances, and depression[2, 3].

Methods: Seven patients with VLUs were treated with a transforming powder dressing (TPD) * during an initial evaluation of this dressing's utility in wound management. All patients had failed previous attempts using various advanced dressings, bioengineered skin, or split thickness skin grafts. All had varying levels of non-adherence to the systemic plan of care – including inconsistency with compression garments/dressings, management of glucose, and routine, consistent dressing changes. Age of wounds varied from 3 to 27 years. All patients reported pain as an inhibiting factor with adherence with recommended regimen and wound sizes and had not decreased in several months.



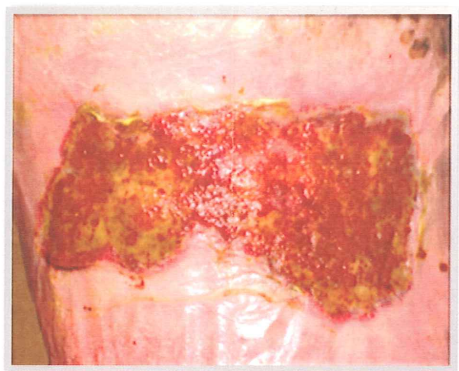
Initial Application of Transforming Powder Dressing



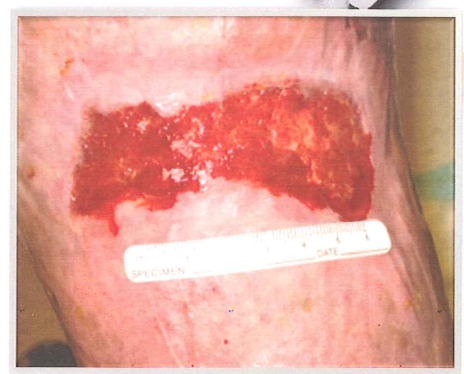
Initial Application of Transforming Powder Dressing

Presented Case: 62 year old male developed a right lower leg ulceration after post-phlebitic syndrome as a sequelae to a work accident. Co-morbidities include obesity, +MRSA, COPD, HTN, hyperlipidemia and Type 2 diabetes. Patient lives alone and refused home health services after receiving care from 5 different agencies. Patient has received a number of previous treatments for the last 27 years including STSGs, compression, NPWT, bioengineered skin, lymphedema, IV and oral antibiotics, pain management referral, and a variety of topical antimicrobial and non-antimicrobial dressings. Adherence to the treatment plan would vary but always would eventually fail. Pain associated with the wound itself, coupled with treatment pain often hindered compliance. The patient refused further surgical interventions to achieve wound closure. Pain levels were reported by the patient as 9-10 continuously.

At the time of application of the TPD followed by a nonadherent dressing to absorb drainage, the patient reported immediate reduction of wound pain to a level of 2. Within 2 weeks of continuous pain reduction, he agreed to light compression. He has steadily increased his compliance to the recommended treatment regimen and is now on full therapeutic compression levels but continues to refuse other modalities of care.



5 Months on Treatment Regimen of TPD with Compression



15 Months on Treatment Regimen

Results: All patients reported serendipitous and unexpected improvements in pain levels within 15 minutes of TPD application. As a result, this group of chronic wound patients increased compliance I to the recommended treatment plan – including compression, the mainstay of VLU treatment. All patients reduced oral pain medications and had slow, steady decreases in wound size and drainage.

Conclusion: The mechanism of sudden reduction of wound pain after dressing application may have several explanations including bacterial toxin binding, high moisture vapor transmission rate, or Substance P blockade. Regardless of the physiological mechanism, the reduction of pain in this group, this serendipitous finding and its subsequent impact of patient adherence and quality of life measures warrants further study

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2. Woo K, Sibbald RG. Chronic wound pain: a conceptual model. *Advances in Wound and Skin Care*. 2008; 21(4):175-188.
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4. Komegae KM. Pain in chronic leg ulcers. *JWOCN*. 2004; 31:275-83

* Altrazeal™ Transforming Dressing-ULURU, Inc.

Financial Disclosure: Costs associated with poster presentation were provided by ULURU, Inc.

IR-042

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

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Christiane M. Baud, PhD, Director Clinical Research, ULURU, Inc.

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

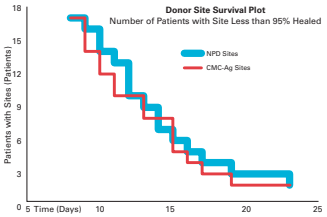
	PWD	CMC-Ag
Number of Subjects	19	19
Size (cm²)		
Mean (SD)	264 (281.9)	229 (157.3)
Median (Min-Max)	154 (36, 1008)	197 (64, 759)

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	

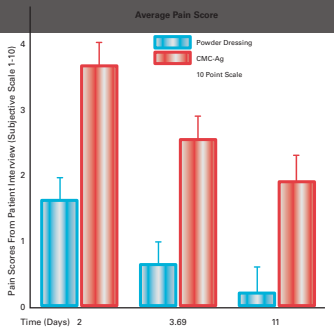
a p-value from matched-pair t-test.

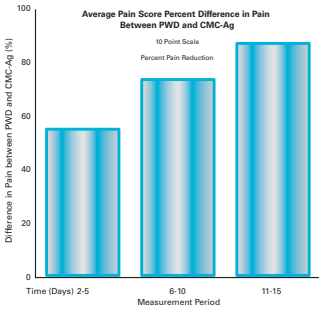
Pain Scores

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.

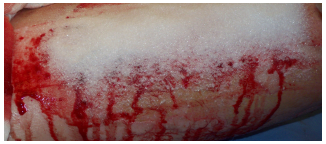
The clinical study personnel instituted a "second check" procedure to confirm site A and site B and which packet was to be applied to each. This deviation was not expected to impact either the safety of the subjects, or the validity of the data collected from these 2 subjects.

Donor Sites as Wound Healing Model

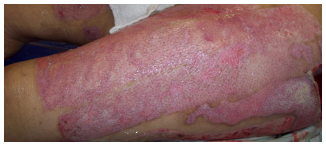
The use of donor sites as wounds in a healing model provides for a reproducible wound but also makes wound healing endpoint comparisons difficult for comparative treatments since the wound is partial thickness and acute. Thus the result of equivalent healing timepoints was not unexpected.

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.

References

1) Wiechula R, 2001 Post Harvest Management of Split Thickness Skin Graft Donor Sites. A Systematic Review No. 13, The Joanna Briggs Institute, Adelaide.
2) Fitzgerald RH, Bharara M, Mills JL, Armstrong DG. Use of a Nanoflex powder dressing for wound management following debridement for necrotising fasciitis in the diabetic foot. Int Wound J. 2009;6(2):133-139.

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*Altrazeal™ Transforming Powder Dressing